EMTALA Compliance and the Anti-Kickback and Stark Laws

HCCA 2009 Compliance Institute
Session 706

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Agenda

- EMTALA background and basics
- Developments in EMTALA enforcement
- Structuring call coverage without implicating fraud and abuse laws
- Q & A
What Is EMTALA?

- The Emergency Medical Treatment and Active Labor Act is a law enacted in 1986 to govern a hospital’s obligations to patients who come to the hospital seeking emergency medical care
  - EMTALA prohibits hospitals from treating emergency patients differently based on whether or not they have health insurance, Medicare, or Medicaid
  - EMTALA supplements state medical malpractice laws, but supersedes them if they are conflicting

Does EMTALA Apply To All Hospitals?

- EMTALA applies to hospitals that participate in Medicare through their provider agreements
- EMTALA applies to all emergency patients whether or not they are eligible for Medicare benefits
- EMTALA applies to a hospital’s dedicated emergency department and more
Core EMTALA Obligations

- EMTALA applies when
  - An individual comes to the emergency department, and
  - The individual requests an examination or treatment for a medical condition
- If EMTALA applies, then
  - The hospital must provide an appropriate medical screening examination
  - To determine if the individual is suffering from an emergency medical condition
  - If so, the hospital is obligated to provide stabilizing medical treatment or an appropriate transfer

What Is A Dedicated Emergency Department?

- Any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus that meets one of the following:
  1. Licensed by the state as an emergency department;
  2. Held out to the public as a place that provides care for emergency medical conditions on an urgent basis without an appointment; or
  3. Provided at least 1/3 of all outpatient visits for the treatment of emergency medical conditions on an urgent basis without an appointment
Emergency Department Examples

- Emergency rooms or departments
- Labor and delivery departments
- Psychiatric units providing emergency care without appointments more than 1/3 of the time
- On and off campus urgent care centers

What Does “Comes To” Mean?

- Coming to the emergency department means an individual
  - Presents to a hospital’s dedicated emergency department and requests care for a medical condition;
  - Is outside the dedicated emergency department but on hospital property within 250 yards of the main building and presents with an emergency medical condition;
  - Is in a hospital owned and operated ambulance for purposes of examination or treatment even if the ambulance is not on hospital property; or
  - Is in a nonhospital owned ambulance that has arrived on hospital property for examination and treatment

  - 42 USC § 1395dd(a); 42 CFR § 489.24(b); The EMTALA Answer Book § Q 1:10 (2008). Compare Morales v. Sociedad Espanola.
What Does EMTALA Require?

1. Medical screening examination; and
2. Necessary stabilizing treatment, or
3. Appropriate transfer

What Is A Medical Screening Examination?

- An MSE is the process required to reach with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist. If a hospital applies in a nondiscriminatory manner (i.e., a different level of care must not exist based on payment status, race, national origin) a screening process that is reasonably calculated to determine whether an emergency medical condition exists, it has met its MSC obligations under EMTALA.
- An appropriate MSE considers the same or similar screening to all patients complaining of or exhibiting the same symptoms or condition.
Does An Emergency Medical Condition Exist?

- An emergency medical condition means
  1. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:
     - Placing the health of the individual (or unborn child) in serious jeopardy,
     - Serious impairment to bodily functions, or
     - Serious dysfunction of any bodily organ or part; or
  2. With respect to a pregnant woman who is having contractions:
     - That there is inadequate time to effect a safe transfer to another hospital before delivery, or
     - That transfer may pose a threat to the health or safety of the woman or the unborn child
       - 42 USC § 1395dd(e)(1).

What Is Stabilizing Treatment?

- Necessary stabilizing treatment means an individual with an EMC must
  - Receive within the staff and facilities available at the hospital, further medical examination and treatment as may be required to stabilize the MSE, or
  - Receive an appropriate transfer

- Stabilization means that for an individual with an MSE
  - That no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or
  - With respect to an EMC for a pregnant woman, that the woman has delivered
    - 42 CFR § 489.24(b).
What Is An Appropriate Transfer?

- An appropriate transfer means
  1. The transferring hospital provides medical treatment within its capacity that minimizes the risks to an individual’s health and in the case of a woman in labor, the health of the unborn child;
  2. The receiving facility
     - Has available space and qualified personnel for the treatment of the individual; and
     - Has agreed to accept transfer of the individual and to provide appropriate medical treatment;
  3. The transferring facility sends medical records re: EMC; and
  4. The transfer is through qualified personnel and transportation equipment
     - 42 CFR § 489.24(e)(2).

EMTALA Obligations

- Under EMTALA, a hospital has met its stabilization requirements when
  - It determines that no EMC exists
  - The patient is stabilized
  - The patient is appropriately transferred, or
  - The patient is admitted to the hospital as an inpatient
EMTALA Enforcement

- Three-tier enforcement structure
  1. CMS Enforcement
  2. OIG Enforcement
      - Civil Monetary Penalties Law (CMPL) enforcement
      - Penalties
      - Priorities
      - Overview of recent settlements
  3. Private right of action

CMS Enforcement

- Staffing
  - Each CMS region has 1-5 people assigned to EMTALA with HQ staff of about 5 people
  
- Investigation initially performed by CMS
- Role of QIO
- Authority to terminate Medicare participation
- Corrective action plan
OIG Enforcement

- Case referrals from CMS
- Settlement terms
  - Description/Definition of Covered Conduct
  - No admission
  - Release limited to named respondent (hospital)
  - Reservation of claims
  - Binding on successors
  - Public disclosure (no confidentiality provision)
- Ability to pay and other factors considered in setting amount of penalty
- Compliance requirements

OIG Enforcement: Penalties

- Civil monetary penalties
  - Up to $25,000 per incident for hospitals with less than 100 beds
  - Up to $50,000 per incident for hospitals with 100 or more beds
  - Up to $50,000 for physician for negligent violations
- Exclusion against physician for gross, flagrant, or repeated violations
OIG Enforcement: Priorities

- Enforcement priorities include:
  - Trauma or acute emergency medical condition
  - Financial screening
  - With inappropriate transfer, birth or high risk event occurs prior to arrival at second hospital
  - Death or serious harm as result of violation
  - Other egregious violations

OIG Enforcement: Recent Settlements

- Baptist Hospital (Florida)
  - $22,500 Aug. 4, 2008
  - Allegation that suicidal patient not screened and left unsupervised in triage area; left and lacerated arm in adjacent parking lot

- Cape Fear Valley Medical Center
  - $42,500 June 30, 2008
  - Allegation that suicidal teenager released without appropriate screening exam; after release jumped out of moving car

- Rogers Memorial Hospital
  - $30,000 June 25, 2008
  - Allegation that hospital refused to accept 57-year old patient with depression; hospital stated it did not treat Medicaid patients in her age group

- Ephraim McDowell Reg. Medical Center
  - $25,000 May 7, 2008
  - Allegation that ER physician redirected ambulance arriving on hospital property with patient with EMC
OIG Enforcement Trends

Average Settlement Amount and Number of Settlements

- Number of Settlements
- Average Settlement Amount (thousands)

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OIG Enforcement Trends

Total OIG CMPL EMTALA Recoveries

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Private Civil Right of Action

- Individual who suffers harm may “obtain those damages available for personal injury under the law of the State in which the hospital is located and such equitable relief as appropriate”
- Facility that suffers financial loss as direct result of participating hospital’s violation may also recover for damages and equitable relief
- Claim can be filed in federal court

Litigation: Private Right of Action

- Morales v. Sociedad Espanola (1st Cir. April 18, 2008)
  - EMTALA covers patient in ambulance en route to hospital and hospital notified of patient’s arrival. Note: ambulance not hospital-owned and paramedics not hospital employees.
- Scruggs v. Danville Regional Medical Center (W.D. Va. Sept. 5, 2008)
  - Patient forced to wait 11 hours for examination may pursue inadequate screening claim
  - California cap on noneconomic damages does not apply to EMTALA claim
Litigation: Private Right of Action

  - Rejected claims that patient received disparate screening, not stabilized before transfer, and transfer did not meet condition for unstable transfer
- Fraticelli-Torres v. Hospital Hermanos (1st Cir. Nov. 13, 2008)
  - Failure to order thrombolytic treatment for patient who had suffered MI was not EMTALA violation
  - No private right of action against federal government

EMTALA And Physician Call

- Hospitals must have a list of physicians who are on-call “to provide treatment necessary to stabilize” ED patients
  - SSA § 1866(a).
- Prior to 10/1/08, CMS required physician call to be structured as “best meets the needs of the hospital’s patients”
- After 10/1/08, CMS requires physician call to be structured as “in accordance with the resources available to the hospital”
- Typically ED call is a requirement of medical staff membership
Paying For Call Coverage

- The most common structures for compensating physicians for call coverage
  - Per shift payments
  - Payment for after-hours and weekend call
  - Payments for uninsured patients
  - Employment

Per Shift (Per Diem) Stipends

- Physicians are paid a flat-fee per 24 hour on-call shift
- Payments not tied to actual patient services provided
  - Physician does not actually have to respond to a call or report to the hospital to receive payment
- Amount of per shift payment varies depending on
  - Physician specialty
  - Geographic location of hospital
  - Frequency each physician must take call
Payment For After-Hours And Weekend Call

- Call during weekdays is an uncompensated medical staff obligation
- For nights and/or weekends, physicians are paid a flat-fee per on-call shift
- Compensation is a fixed per-shift fee, not tied to actual patient services provided

Payment Subsidy For Treatment Of Uninsured Patients

- Physicians are paid a predetermined amount for each uninsured / underinsured patient actually seen during a scheduled on-call shift
- Compensation is usually determined based on percentage of Medicare rate paid for physician professional services
- Designed primarily to address financial burden of treating uninsured / underinsured patients
- Requires well written hospital policies
  - Policies for determining which patients qualify as “uninsured / underinsured” to merit payment
Legal And Compliance Implications

• Paying for call coverage potentially implicates
  • Stark Law
    • 42 U.S.C. § 1395nn.
  • Anti-Kickback Statute
    • 42 U.S.C. § 1320a-7b(b).
    • OIG, Advisory Opinion 07-10
  • IRS Regulation of Tax-Exempt Organizations
    • Internal Revenue Code §§ 501(c)(3), 4958.

Stark Issues When Paying For On-Call Coverage

• Stark Law prohibits referrals for DHS from physicians who have a financial relationship with the hospital, unless an exception applies
• Call payments create a compensation relation
• Personal services or employment exception can apply
  • Must meet all elements of an exception
Kickback Issues When Paying For On-Call Coverage

- Anti-kickback statute prohibits offering, paying or accepting remuneration to induce referrals of items or services
  - Intent-based statute; “one purpose” to influence referrals is sufficient
  - “Opportunity to bill” may be considered remuneration in some contexts
- Personal services or employment safe harbors may apply

Tax Issues When Paying For On-Call Coverage

- Applicable whenever nonprofit, 501(c)(3) hospital involved
  - Concerned with protection of charitable assets and transactions with “insiders” and “disqualified persons”
- Intermediate Sanctions – IRS Code § 4958
  - IRS can impose excise taxes on "disqualified persons" who engage in excess benefit transactions with 501(c)(3) public charities
Potential Compliance Pitfalls

- Documentation of need
  - Hospitals must have legitimate, unmet need for providing on-call coverage
  - Document by showing historical problems in physicians’ unwillingness to take call and, consequently, hospital’s inability to adequately care for its patients and community

- Establishing Fair Market Value
  - Payments must be FMV for services rendered
  - Process for determining compensation must be documented
  - Outside independent value suggested but not required

Potential Compliance Pitfalls

- Adequate contractual provisions
  - Exceptions and safe harbors require, signed written agreement, specify services covered, minimum one year term, compensation set in advance

- Administration of compensation plan
  - Compensation should be offered uniformly to all physicians in relevant specialty
  - Call obligations should be divided as evenly as possible
Potential Compliance Pitfalls

- Physician noncompliance with call obligations
  - Hospital should have process to hold physicians accountable for call services

- Long term implications
  - It is very difficult to end a practice of paying for call coverage, even if there is a change in community need

Q&A