

EMTALA Compliance and the Anti-Kickback and Stark Laws

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Agenda

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

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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

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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

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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

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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
 - 42 CFR § 489.24(b); Mark Moy, *The EMTALA Answer Book* § Q 1:11 (2008).

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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

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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*.

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What Does EMTALA Require?

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

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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.
 - State Operations Manual, App. V, Part I, Tag A406.
- An appropriate MSE considers the same or similar screening to all patients complaining of or exhibiting the same symptoms or condition.
 - 3 Kevin O'Malley, Federal Jury Practice & Instructions § 110.08 (4th ed. 1997).

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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).

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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).

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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).

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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

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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

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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

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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

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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

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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

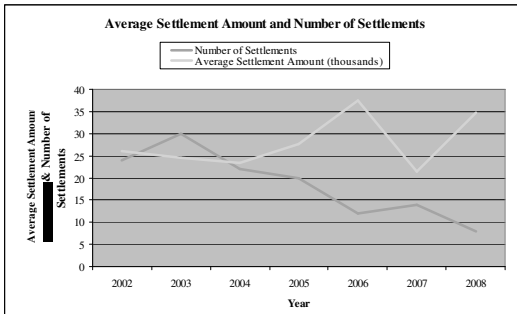
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OIG Enforcement: Recent Settlements

- 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

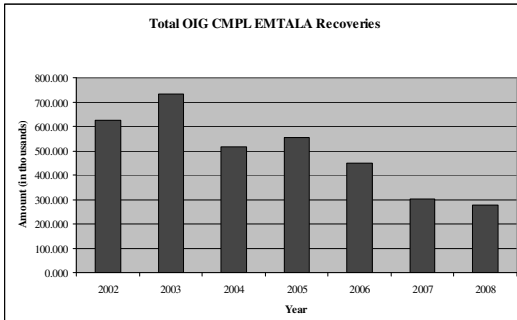
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OIG Enforcement Trends



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OIG Enforcement Trends



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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
 - 42 U.S.C. § 1395dd(d)(2).
- Claim can be filed in federal court

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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
- *Romar v. Fresno Community Hosp.* (E.D. Cal. Oct. 10, 2008)
 - California cap on noneconomic damages does not apply to EMTALA claim

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Litigation: Private Right of Action

- Smithson v. Tenet (E.D. La. Oct. 10, 2008)
 - 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
- Hoffman v. United States (E.D. Va. Jan. 7, 2009)
 - No private right of action against federal government

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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”
 - 42 C.F.R. § 489.24(j) (2007).
- After 10/1/08, CMS requires physician call to be structured as “in accordance with the resources available to the hospital”
 - 42 C.F.R. § 489.20(r) (2009).
- Typically ED call is a requirement of medical staff membership

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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

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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.

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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

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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

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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

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Q&A