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EMTALA: Dedicating an Emergency Department Near You

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EMTALA: Dedicating an Emergency Department Near You

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ABSTRACT: Congress enacted the Emergency Medical Treatment and Labor Act (EMTALA) in 1986 to prohibit patient dumping. Subsequent to its passage, however, issues concerning the application of EMTALA have vexed hospitals, patients, regulators, and courts. In an attempt to clarify these issues, the Centers for Medicare & Medicaid Services (CMS) recently promulgated new EMTALA regulations. This Article reviews the basic requirements of EMTALA and highlights the statutory definitions critical to its proper interpretation and application. The article then analyzes the impact of the new regulations, particularly in five major areas: where and when the statute applies, on-call physician requirements, hospital-owned ambulances, managed care, and bioterrorism. It concludes with a discussion of the implications of the new regulations for hospitals and their counsel.

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On September 9, 2003, the Centers for Medicare & Medicaid Services (CMS) issued its latest regulations¹ interpreting the Emergency Medical Treatment and Labor Act (EMTALA).² The regulations attempt to clarify issues that have vexed hospitals, patients, regulators, and courts for the eighteen years of the statute's history. This Article examines those regulations, beginning with an overview of EMTALA and its basic requirements. Although readers may be generally familiar with the statute, "[i]t is essential to revisit the statute continuously" to understand the scope of CMS's regulatory authority and enforcement and to put the regulations in context.³

The Article next turns to the regulations' clarifications and new interpretations of the statute, specifically addressing five major areas of EMTALA applicability: where and when the statute applies, on-call physician requirements, hospital-owned ambu-

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lances, managed care, and bioterrorism. Although a significant item in the new rule, this Article provides only a brief discussion of the physician on-call requirements, which are addressed in detail by a companion article in this issue.⁴ The present Article concludes with a discussion of the implications of the new regulations for hospitals and their counsel.

I. Background and Overview⁵

Congress passed EMTALA in 1986 as part of the Consolidated Omnibus Reconciliation Act of 1985.⁶ The statute prohibits the practice of “patient dumping,” which involves a hospital’s refusal to provide emergency screening and stabilization services for patients who seek emergency room care. This refusal typically results from the patient’s insurance status, inability to pay, or other grounds unrelated to the patient’s need for the services or the hospital’s ability to provide them.⁷

EMTALA was not the federal government’s first attempt to ensure access to emergency care for indigent patients and others.⁸ In 1946, Congress passed the Hill-Burton Act, which provided federal grants to states for the construction of hospitals and required those hospitals to provide services to all persons residing in the area, regardless of ability to pay.⁹ This requirement, known as the community service obligation, required Hill-Burton hospitals to maintain emergency rooms, provide emergency services without regard to a patient’s ability to pay, and accept Medicare and Medicaid payments.¹⁰ Despite these mandates, concern over patient dumping led Congress to address the issue again through EMTALA.¹¹

EMTALA imposes two primary requirements on hospitals that operate an emergency department and have a Medicare provider agreement. First, any person who “comes to” the hospital emergency department and requests examination or treatment for a medical condition, or for whom care is requested, is entitled to an “appropriate” medical screening exam.¹² Second, if the hospital determines that the person has an emergency medical condition, the hospital must either provide appropriate stabilization treatment or a medically appropriate transfer that meets certain standards identified in the statute and regulations.¹³ The interpretation and application of EMTALA turn on a number of key phrases. Thus, it is necessary to provide some definitions.

A. *Appropriate Medical Screening Examination*

The statute requires hospitals to provide an appropriate medical screening examination to any individual who comes to the emergency department requesting an examination or treatment for a medical condition, or on whose behalf such a request is made.¹⁴ This requirement applies whether or not the individual qualifies for Medicare or Medicaid.¹⁵ The statute does not define “appropriate medical screening examination,” but the courts and CMS interpret this language as requiring the application of uniform screening standards to determine whether a patient has an emergency medical condition.¹⁶ CMS issued the following interpretive guidance to state surveyors regarding the process and substance of a medical screening exam:

A medical screening examination 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 obligations under the Emergency Medical Treatment and Labor Act (EMTALA).

Depending on the patient’s presenting symptoms, the medical screening examination represents a spectrum ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or diagnostic tests and procedures.¹⁷

The appropriate medical screening exam obligation does not require the hospital to reach the correct diagnosis.¹⁸ Moreover, EMTALA does not create a federal cause of action for malpractice.¹⁹ Thus, patients who have been screened uniformly, albeit negligently, cannot rely on EMTALA for a cause of action. They must seek remedies available through state malpractice law.²⁰

The primary objective of the screening examination is to deter-

mine whether the patient has an “emergency medical condition.”²¹ As clarified in the new regulations, a hospital’s EMTALA obligations end if the hospital determines, through the use of nondiscriminatory examination procedures, that the individual does not have an emergency medical condition.²²

The statute defines “emergency medical condition” broadly. An emergency medical condition manifests 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” certain outcomes, including “serious jeopardy” to health, “serious impairment to bodily functions,” or “serious dysfunction of any bodily organ or part.”²³ In the case of pregnant women, in addition to the jeopardy, dysfunction and impairment standard applicable to both the woman and her “unborn child,” the statute establishes specific stabilization duties in any case in which a woman is having contractions, there is “inadequate time to effect a safe transfer,” or the “transfer may pose a threat to the health or safety” of the woman or her “unborn child.”²⁴

B. Necessary Stabilizing Treatment

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Thus, if the hospital provides an appropriate medical screening exam and the patient shows no sign of an emergency medical condition, the hospital satisfies its EMTALA obligation.²⁵ If the patient has an emergency medical condition, however, the hospital must provide the necessary stabilizing treatment or a medically appropriate transfer.²⁶ The statute defines “stabilized” with respect to an emergency medical condition such that “no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of an individual from a facility, or, with respect to [a pregnant woman, to] deliver.”²⁷ In addition, “to stabilize” under the statute means to provide such medical treatment of the condition as may be necessary to assure that a patient is stabilized.²⁸

C. Restrictions on Transfer

The law permits transfers of unstable patients with medical emergencies in relatively narrow situations. A hospital may not transfer an individual with an unstable emergency medical condition unless the patient requests the transfer in writing and a physician or other qualified medical person certifies in writing that the medical benefits of the transfer outweigh its risks.²⁹ The required transfer certification must include a summary of the risks and benefits upon which the certification is based.³⁰ In

addition, the transfer must be an “appropriate” one, which under EMTALA means that the transferring hospital (1) provides medical treatment within its capacity to minimize the risks to the individual’s health, or the health of an unborn child; (2) sends to the receiving facility the individual’s medical records related to the emergency medical condition; and (3) effects the transfer with qualified personnel and transportation equipment, including any necessary life support measures during the transfer.³¹ Further, the receiving facility must agree to accept the transfer and have available space and qualified personnel to treat the individual.³²

D. Enforcement of EMTALA

The Office of Inspector General (OIG), private plaintiffs, and a hospital that receives an inappropriate transfer can each take action to enforce EMTALA. A patient complaint, state survey, or report from a hospital that either received an inappropriate transfer or was refused an appropriate transfer can notify the OIG of a potential EMTALA violation. The OIG may then bring an administrative action against the hospital for the violation.³³

The penalties for EMTALA violations can be significant. The OIG can impose a civil monetary penalty of up to \$50,000 per violation for hospitals and physicians, exclude hospitals and physicians from the Medicare program, and require a hospital to publicly advertise a community outreach statement in major newspapers.³⁴ From 1995–2000, the OIG collected \$5.6 million in fines from 189 hospitals and nineteen physicians.³⁵ In addition, private plaintiffs can recover personal injury damages, subject to tort damage caps in some states.³⁶ Finally, a receiving hospital can bring a civil action to recover the financial loss created by an inappropriate transfer.³⁷

II. The New Regulations

On September 9, 2003, CMS issued a final rule clarifying hospital responsibilities under EMTALA.³⁸ The regulations grew out of a Regulatory Reform Task Force formed by Department of Health and Human Services (DHHS) Secretary Tommy Thompson. The Task Force was formed to review the agency’s regulations to determine how they affect the delivery of healthcare to Medicare and Medicaid beneficiaries and how they could be improved.³⁹ In its final report, based on testimony from physicians, hospital administrators, and others, the Task Force asserted, “what was designed as a straightforward guarantee of emergency care has

yielded a myriad of confusing regulations that in some cases have reduced access to care.⁴⁰ The Task Force recommended a number of clarifications, all of which DHHS addressed. Among the clarifications, the rule addresses where and when EMTALA applies, including the creation of the “dedicated emergency department” concept and EMTALA’s applicability to outpatients and inpatients; how the statute applies to physician “on call” requirements; managed care; hospital-owned ambulances; and bio-terrorism.

A. Where and When EMTALA Applies

Where and when EMTALA applies on a hospital campus has been the source of a significant amount of confusion and litigation. The recent regulations attempt to resolve these issues in several ways. First, the regulations categorize individuals depending on where they arrive on hospital property. An individual can come on to hospital property in one of three ways. The individual could: (1) come to the clearly-marked traditional emergency department, either on foot or via other transport, including air or ground ambulance; (2) come to the hospital itself, but not come through the traditional emergency department door; or (3) come to an off-hospital campus entity that operates under the hospital’s license and is considered provider-based for Medicare purposes, but is not physically in the same location as the host hospital.⁴¹ Second, the regulations classify individuals according to the type of services they seek, emergency or non-emergency. Third, the regulations categorize individuals according to whether they are existing patients of the hospital on an outpatient or inpatient basis.

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Each of these methods of classification will be discussed, but a general note is in order. The nomenclature is significant and requires a parsing of these methods of classification. This is necessary because the statute itself makes distinctions that have led to confusion in applying EMTALA depending on where an individual arrives at a hospital. The statute mandates that a hospital provide an appropriate medical screening exam to any individual who comes to the “emergency department” and requests examination or treatment for a “medical condition.”⁴² Note, however, that the stabilizing treatment requirement applies to any individual who comes to “a hospital,” as opposed to “the emergency department,” and has an “emergency medical condition,” as opposed to a “medical condition.”⁴³ Although these distinctions may appear to be nothing more than poor drafting or zealous language parsing, they have legal consequences. Thus, one’s EMTALA obligations, even under the new

regulations, differ across the methods of classification.

1. Individuals Who Come to a Dedicated Emergency Department

In the first scenario, an individual comes to what is commonly known as the emergency department and makes a request for examination and treatment of a medical condition, or such a request is made on the individual's behalf. In one of their most significant contributions, the new regulations expand the scope of what may be considered an emergency department by creating a new concept of a "dedicated emergency department," which goes beyond the traditional, clearly marked emergency department.⁴⁴

Under the new rule, EMTALA applies to a hospital or one of its components, such as a clinic, psychiatric unit, labor and delivery, or urgent care center, whether on or off the main hospital campus, if the entity qualifies as a "dedicated emergency department" in one of three ways: (1) the entity holds a state license as an emergency room or department; (2) the entity holds itself out to the public, through advertising or the use of signs, as a source of treatment for emergency conditions on an urgent basis without requiring a previously scheduled appointment; or (3) one-third of the entity's patient visits in the prior calendar year were for the treatment of an emergency medical condition without an appointment, based on a representative sample of patient visits.⁴⁵ If a hospital or one of its components satisfies any of the three prongs of this new test, EMTALA's protections apply and the hospital must provide an appropriate screening exam and either necessary stabilizing treatment or an appropriate transfer.

Although the dedicated emergency room concept generally provides more clarity to the question of where EMTALA applies, the objective test in the third prong may create additional difficulties in its interpretation and implementation. The other two prongs, state licensure and "holding out," also provide objective indicators of what constitutes an emergency department, but the one-third test is somewhat of a "catch-all" category for hospital components that do not satisfy the first two criteria.

CMS adopted the objective one-third test to provide "predictability and consistency" to the healthcare industry.⁴⁶ A commentator on the proposed regulations noted, however, that using an objective threshold "may lead to some cases in which the standard is exceeded or not met by a narrow margin."⁴⁷ CMS agreed,

but noted that such a result is “an unavoidable consequence of any objective standard.”⁴⁸ While this may be the case, it may have some troubling implications for patients. Potentially more significant than the situation in which a facility misses or exceeds the threshold by a narrow margin is the possibility that a hospital component may cycle in and out of being considered a “dedicated emergency department” from year to year depending on patient flow and the samples taken.

Contrary to the assertion by CMS that an objective standard “enables hospitals to know in advance whether they will be subjected to EMTALA,” the standard uses a retrospective review of patient records for the determination of whether a hospital component meets the test.⁴⁹ Thus, individuals seeking treatment and the hospital itself may not know with certainty from year to year which components of the facility meet the test. This potential variation is troubling because it provides no advance notice to individuals who visit hospital components that do not meet the other two criteria for a dedicated emergency department.

The new rule also applies a “prudent layperson” standard to the dedicated emergency department. In the absence of a request for examination or treatment of a medical condition by or on behalf of an individual who comes to the emergency department, a request will be considered to exist “if a prudent layperson observer would believe, based on the individual’s appearance or behavior, that the individual needs emergency examination or treatment.”⁵⁰

2. Urgent Care Centers

In response to the new dedicated emergency room concept in the proposed rule, a number of commentators asked for an exception for hospital “urgent care centers” or “acute care centers,” arguing that such centers are “capable of responding to an urgent need, but not an emergency medical condition.”⁵¹ CMS rejected these requests, noting that:

It would be very difficult for any individual in need of emergency care to distinguish between a hospital department that provides care for an “urgent need” and one that provides care for an “emergency medical condition” need. Indeed, to CMS, both terms seem to demonstrate a similar, if not exact, functionality.⁵²

Thus, urgent care centers can meet the definition of a dedicated emergency department, and would most likely do so under the

“held out to the public” prong of the test. In these situations, even though the urgent care center would have the EMTALA obligation to screen the individual for an emergency medical condition, such a center may not have the capacity to treat individuals who have a serious medical emergency. In those cases, the urgent care center may transfer the individual to a nearby hospital, whether or not the hospital is affiliated with the urgent care center.⁵³ Indeed, a hospital-affiliated urgent care center could be thirty miles or more away from the affiliated hospital. CMS noted that for such satellite centers, it is permissible to screen the individual and, if the condition is too serious to be treated on-site, to transfer the individual to a nearby, nonaffiliated hospital.⁵⁴ Otherwise, a “lengthy ambulance ride” to the center’s affiliated hospital may present an “unacceptable risk to the individual.”⁵⁵

A range of implications exist concerning EMTALA’s applicability to urgent care centers. Hospitals may act to avoid having such centers be deemed to be “held out to the public” in ways that would render them dedicated emergency departments under EMTALA. Such actions might include changing the name of the center to drop “urgent care” or changing the signage or hours of operation to make it less likely that the center would meet the “held out to the public” standard.

3. Individuals Who Come to a Dedicated Emergency Department for Non-Emergency Care

If an individual comes to a dedicated emergency department for what is clearly non-emergency care (e.g., suture removal), EMTALA still applies, but the screening examination can be less intensive than that required for an individual who requests screening or treatment for what may be an emergency medical condition.⁵⁶ In the preamble to the new rule, CMS notes:

We sometimes receive questions whether EMTALA’s requirements apply to situations in which an individual comes to a hospital’s dedicated emergency department, but no request is made on the individual’s behalf for emergency medical evaluation or treatment. In view of the specific language [of the statute] . . . we believe that a hospital must be seen as having an EMTALA obligation with respect to any individual who comes to the dedicated emergency department, if a request is made on the individual’s behalf for examination or treatment for a medical condition, *whether or not the treatment requested is explicitly for an emergency condition.*⁵⁷

The final rule reiterates that, while the medical screening exam requirement is constant, not all EMTALA screenings must be equally extensive.⁵⁸ According to CMS, the goal of the screening exam is to determine whether an emergency medical condition exists. As a result, “hospitals are not obligated to provide screening services beyond those needed to determine that there is no emergency medical condition.”⁵⁹ For example, one commentor on the proposed EMTALA rule expressed concern about

the scenario in which it is later determined that an individual who had presented to the dedicated emergency department for such medical treatment as suture removal . . . was, in fact, suffering from an emergency medical condition, and this emergency medical condition was not detected during this less extensive examination.⁶⁰

CMS responded that

We assume that qualified medical personnel or physicians will be performing the medical screening examination (however modified for the condition presented) to determine whether the individual is suffering an emergency medical condition. If it is later found that the individual *had* been suffering an emergency medical condition upon presentment to the dedicated emergency department but only asks for examination or treatment for the suture removal, or some lesser medical condition, and a complaint is filed for alleged dumping in [violation of EMTALA], the extent and quality of the screening . . . would be subject to review by State surveyors to permit a determination to be made as to whether there was an EMTALA violation. We note that if, upon investigation . . . it is found that an adequate medical screening had been performed, the hospital would not be found liable under EMTALA.⁶¹

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4. Individuals Who Come to a Hospital’s Main Campus but Not to a Dedicated Emergency Department

The impact of the statutory language distinctions is most evident in CMS’s approach to individuals who come to the hospital

property, but not to a dedicated emergency department, and request examination and treatment for a *medical condition*. In this scenario, EMTALA does not apply unless the individual is requesting examination and treatment for an *emergency medical condition* or a prudent layperson believes that, based on the individual's appearance or behavior, the individual needs examination and treatment for an emergency medical condition.⁶²

The new rule defines "hospital property" as

the entire main hospital campus . . . including the parking lot, sidewalk, and driveway, but excluding other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare, or restaurants, shops, or other nonmedical facilities.⁶³

Thus, this provision indicates that EMTALA does not apply to individuals who visit a hospital laboratory for blood tests, radiology for x-rays, or another hospital department that does not qualify as a dedicated emergency department for non-emergency services.

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B. Hospital Patients: Outpatient and Inpatient

1. Outpatients

Another significant change in the new regulations is the creation of a distinction between existing patients of the hospital and other individuals who come to the hospital. Prior to the regulations, it was unclear whether EMTALA applied to out-patients who came to an area of the hospital campus other than a dedicated emergency department for scheduled non-emergency services. Medicare defines an outpatient as "a person who has not been admitted as an inpatient but who is registered on the hospital . . . records as an outpatient and receives services (rather than supplies alone) directly from the hospital."⁶⁴

The new rule is clear that EMTALA does not apply to outpatients—even if during an outpatient encounter they are found to have an emergency medical condition and are transported to the hospital's dedicated emergency department.⁶⁵ Instead of EMTALA protection, the outpatient is protected by state malpractice law and Medicare conditions of participation.

2. Inpatients

Although CMS had proposed that EMTALA continue to apply to admitted emergency department patients until stabilized or transferred, the final rule backs away from this view and indicates that EMTALA does not apply to inpatients.⁶⁶ In reaching this view, CMS relied on a series of cases which held that a hospital's EMTALA obligations end once a patient is admitted for inpatient care.⁶⁷ CMS acknowledges that this means that an unstable emergency department patient loses EMTALA protection upon admission, although it notes that medical malpractice law and Medicare conditions of participation continue to protect the patient.⁶⁸

Anticipating potential negative responses to this interpretation, CMS notes that a hospital cannot admit a patient as a subterfuge to avoid EMTALA's requirements. That is, the hospital cannot admit the patient to end the EMTALA obligation and then immediately discharge the individual.⁶⁹ According to CMS, hospitals must admit individuals in "good faith with the intention of providing treatment," or EMTALA liability may attach.⁷⁰ It remains to be seen whether CMS's fears of subterfuge are well-founded, and how the agency will discover and handle these potential EMTALA violations.

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C. On-Call Physician Requirements⁷¹

Under Medicare provider requirements, hospitals must maintain a list of on-call physicians who are available to provide medical services necessary to treat an emergency medical condition after the initial examination.⁷² If a physician listed on the on-call roster does not appear after the hospital has called seeking assistance with an examination or treatment, the hospital and physician may be liable under EMTALA.⁷³

Neither the Medicare statute nor applicable regulations specify the exact level of on-call coverage required, such as the number of physicians who must be on-call or how many hours or days of the week coverage is required. The lack of specific and objective standards led to confusion among hospitals and physician groups about what level of call was required for compliance with Medicare and EMTALA.

CMS used the new regulations to dispel an industry belief that EMTALA required a "rule of three"—that if a hospital had three physicians in a particular specialty, the statute required twenty-four hour, seven-day-a-week on-call coverage for that specialty. In the new regulations, CMS clarifies that there is no "rule of

three,” and leaves hospitals discretion to determine the on-call roster that “best meets the needs of its patients” within the hospital’s capability.⁷⁴ CMS notes in the preamble to the regulations that physicians, including specialists and subspecialists, are not required to be on-call at all times.⁷⁵

The media and provider groups have raised concerns that this provision of the new regulations will allow hospitals to reduce the number of specialists who are on-call around the clock for emergency department patients, thereby exacerbating a shortage of on-call specialists.⁷⁶ For a number of reasons, this feared outcome may not materialize. First, for trauma centers, accreditation requirements mandate particular levels of on-call capability. Second, hospitals will want to provide sufficient on-call coverage to ensure that they meet the standard of care for purposes of risk management and malpractice liability. To do so, hospitals may use medical staff bylaws to require physicians to take call in order to receive or maintain hospital privileges.

D. Hospital-Owned Ambulances

The new rule clarifies that EMTALA applies to hospital-owned air or ground ambulances. An individual in a hospital-owned ambulance has “come to” the emergency department for purposes of the statute, whether or not the ambulance is on hospital property.⁷⁷ There are two exceptions to this rule. First, if the hospital-owned ambulance is operating under community-wide emergency medical service protocols that direct the ambulance to take the individual to a hospital other than the one that owns the ambulance, then the individual has “come to” the emergency department of the hospital to which the individual is transported.⁷⁸ Second, if the hospital-owned ambulance is under the medical command of a physician who is not employed or affiliated with the hospital that owns the ambulance, then the individual inside the ambulance has not “come to” the emergency department of the hospital that owns the ambulance.⁷⁹

If an individual is in a nonhospital-owned ambulance that has arrived at the hospital’s dedicated emergency department, then the individual has “come to” the hospital’s emergency department and EMTALA applies.⁸⁰ If, however, the nonhospital-owned ambulance is off hospital property, EMTALA does not apply because the individual has not “come to” the hospital.⁸¹ This is true even if the ambulance personnel contact the hospital and request permission to bring the individual to the hospital.⁸²

Although the preamble does not specifically address the Ninth

Circuit's decision in *Arrington v. Wong*,⁸³ CMS's comments appear to reject the decision. In *Arrington*, the Ninth Circuit interpreted DHHS regulations to apply EMTALA to individuals in nonhospital-owned ambulances en route to the hospital unless the hospital can demonstrate that it is on diversionary status.⁸⁴ A commentator on the proposed EMTALA rule asked CMS to incorporate language into the regulations that would reiterate that hospitals have no EMTALA obligation with respect to individuals "who are in ambulances that are neither hospital-owned and operated nor on hospital property."⁸⁵ CMS responded that "[w]e agree that this statement of policy is accurate, but believe the proposed regulatory language makes this clear. Therefore, we are not making revision in the final rule based on this comment."⁸⁶

E. Managed Care

The OIG published a special advisory bulletin on November 10, 1999,⁸⁷ that addressed a hospital's EMTALA obligation to managed care enrollees. The new EMTALA regulations formally codify this special advisory bulletin.⁸⁸

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EMTALA's screening and stabilization requirements do not differ if an individual is insured by a managed care organization. Indeed, EMTALA's requirements apply regardless of a patient's insurance status or ability to pay. Thus, prior authorization requirements in managed care contracts do not relieve a hospital of its EMTALA obligation. Furthermore, any delay in providing an examination to seek managed care approval can result in an EMTALA violation.⁸⁹

CMS clarifies in the new rule that a hospital can seek insurance information during routine admissions procedures as long as no delay in examination or treatment results from those procedures.⁹⁰ Authorization is a different matter. A hospital may not seek authorization from a managed care organization until after the required EMTALA screening exam.⁹¹ Once such an exam is complete, a hospital may seek managed care authorization concurrent with the provision of stabilizing treatment, as long as no delay in providing such treatment occurs.⁹²

F. Bioterrorism

The regulations add a provision regarding EMTALA's applicability during a bioterrorist attack or other public health emergency. Nothing in the regulations waives a hospital's underlying obligation to screen and provide stabilizing treatment during a public

health emergency, as defined by a presidential declaration of emergency and a public health emergency declaration by the Secretary of DHHS.⁹³ Relying upon the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,⁹⁴ however, the recent regulations do waive the *sanctions* for a violation of EMTALA. Sanctions are waived when the violation is the result of an inappropriate transfer of an unstable patient if the transfer arises out of circumstances during a public health emergency. For example, if a hospital transferred an individual inappropriately during a public health emergency because the hospital erroneously believed another facility could better treat the individual's condition, DHHS would not impose sanctions for the inappropriate transfer. The regulations do not waive sanctions for a hospital's failure to provide an appropriate screening examination.⁹⁵

III. Conclusion

EMTALA is the closest thing to universal access in the United States healthcare system. The statute imposes a legally enforceable duty of care on all Medicare-participating hospitals, entitling all individuals who seek care at hospital emergency departments to a nondiscriminatory examination and to either stabilizing treatment or a medically appropriate transfer if the individual has an emergency medical condition.⁹⁶ Although EMTALA operates as a condition of participation in the Medicare program, the law creates a hospital duty of care applicable to all individuals regardless of health insurance status or Medicare eligibility.⁹⁷ For these reasons, the importance of the statute cannot be overstated—and neither can the need for clear guidance to hospitals on how to comply with the law.

The interpretation and application of EMTALA in its first eighteen years has led to understandable confusion and frustration in the healthcare industry, and a significant number of law-review articles and judicial opinions that attempt to sort out the statute's implications. Noting that this confusion might get in the way of compliance with the statute and access to care, the DHHS Regulatory Reform Task Force recommended a number of clarifications to EMTALA, which DHHS addressed in the September 9, 2003, regulations.

In the five major areas of the new regulations discussed earlier, CMS has indeed attempted to clarify EMTALA's applicability, and the agency has succeeded in offering guidance that is clearer than what previously existed. What remains to be seen is whether and how these changes affect access to emergency care, and whether

any provision of the new rule leads hospitals to limit access points or capabilities to undertake the care required by EMTALA. For example, the rule is clear that EMTALA applies to urgent care centers. Will this provide an incentive to hospitals to limit their use of such centers or otherwise restrict their hours of operation? The rule is also clear that hospitals have flexibility with respect to on-call physician requirements. Will this exacerbate what is already described as an on-call shortage in certain specialties? Will hospitals that curtail on-call coverage face additional quality of care litigation or administrative enforcement actions? The rule is also clear that EMTALA does not apply once a patient is admitted to the hospital. Is CMS's concern over subterfuge in the admissions process warranted—and, if so, how widespread will the practice be?

Answering these and other questions will require carefully designed research studies that analyze emergency department usage and compare hospital approaches to compliance before and after the November 10, 2003, effective date of the regulations. Hospitals and their counsel, however, cannot wait for the results for such studies. Rather, hospitals must evaluate their operations in light of the new rule, paying particular attention to the following concerns.

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- Which areas of your hospital (on or off-campus) qualify as a “dedicated emergency department?”
- How will your hospital train medical and other staff on the new rule and hospital duties/individual rights that depend on where the individual presents and what type of service is requested?
- Does your hospital have clear guidance in place regarding what to do for an individual who may be experiencing a medical emergency in an area that does not qualify as a dedicated emergency department?
- Does your hospital have clear policies and procedures with respect to ambulances (hospital and non-hospital owned) and how your policies interact with community-wide protocols?

Endnotes

¹ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222 (Sept. 9, 2003).

² Emergency Medical Treatment and Active Labor Act, 42 U.S.C. §1395dd (2003).

³ Thomas R. Barker, et al., *AHLA Teleconference: EMTALA Update*, 37 J. HEALTH L.

- 7, 8 (2004) (hereinafter *AHLA Teleconference*).
- ⁴ See generally Erin M. McHugh, *The New EMTALA Regulations & The On-Call Physician Shortage: In Defense of the Regulations*, 37 J. HEALTH L. 55 (2004).
- ⁵ This background and overview is adapted from an earlier work in this journal. See Brian E. Kamoie, *EMTALA: Reaching Beyond the Emergency Room to Expand Hospital Liability*, 33 J. HEALTH L. 25 (2000). For additional details regarding the history of efforts to ensure emergency access, see RAND E. ROSENBLATT ET AL., *LAW AND THE AMERICAN HEALTH CARE SYSTEM* 36-93 (Foundation Press 1997).
- ⁶ Consolidated Omnibus Reconciliation Act of 1985, Pub. L. No. 99-272, § 9121, 100 Stat. 164-67 (1986) (codified at 42 U.S.C. § 1395dd (2003)). The statute is still sometimes referred to as “COBRA” or the “anti-dumping” law.
- ⁷ OFFICE OF THE INSPECTOR GENERAL, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *PATIENT DUMPING AFTER COBRA: ASSESSING THE INCIDENCE AND THE PERSPECTIVES OF HEALTH CARE PROFESSIONALS*, REP. NO. OAI-12-88-00830 (Dec. 1988).
- ⁸ Kamoie, *supra* note 5, at 26.
- ⁹ 42 U.S.C. § 291c(e) (2003). The statute also required hospitals to provide a reasonable volume of charity care. See *id.*
- ¹⁰ See 42 U.S.C. § 291c(e). See also the applicable regulations at 42 C.F.R. § 124.603 (2003).
- ¹¹ See H.R. REP. NO. 99-241, pt. 3, at 27 (1986), reprinted in 1986 U.S.C.C.A.N. 579, 605. Some commentators have argued that Congress passed the statute based on anecdotal evidence and the extent of patient dumping was unknown at the time of passage. See, e.g., David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 HEALTH MATRIX 29, 29-56 (1998); David A. Hyman, *Lies, Damned Lies and Narrative*, 73 IND. L.J. 797, 797-865 (1998); Richard A. Epstein, *Living Dangerously: A Defense of Mortal Peril*, 1998 U. ILL. L. REV. 909, 930-31 (1998).
- ¹² 42 U.S.C. § 1395dd(a) (2003).
- ¹³ *Id.* § 1395dd(b). Note that subsection (b) of the statute requiring stabilizing treatment applies to any individual who comes to “the hospital” as opposed to any individual who comes to “the emergency department” in subsection (a). The new regulations address this distinction. See *AHLA Teleconference*, *supra* note 3, at 13.
- ¹⁴ 42 U.S.C. § 1395dd(a).
- ¹⁵ *Id.*
- ¹⁶ Kamoie, *supra* note 5, at 27.
- ¹⁷ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *MEDICARE MEDICAID STATE OPERATIONS MANUAL*, APPENDIX V 19, Tag A406 (1998).
- ¹⁸ See *Williams v. Birkeness*, 34 F.3d 695, 697 (8th Cir. 1994).
- ¹⁹ See *Summers v. Baptist Med. Ctr. Arkadelphia*, 91 F.3d 1132, 1139 (8th Cir. 1996).
- ²⁰ Kamoie, *supra* note 5, at 28.
- ²¹ *Id.*
- ²² See Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222, 53,234 (Sept. 9, 2003) (codified at 42 C.F.R. § 489.24(a)(1)(ii) (2003)).
- ²³ 42 U.S.C. § 1395dd(e)(1) (2003).
- ²⁴ *Id.*
- ²⁵ See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *MEDICARE MEDICAID STATE OPERATIONS MANUAL*, APPENDIX V 19, Tag A406 (1998).
- ²⁶ 42 U.S.C. § 1395dd(b)(1)(A) (2003).
- ²⁷ *Id.* § 1395dd(e)(3)(B).
- ²⁸ *Id.* § 1395dd(e)(3)(A).
- ²⁹ *Id.* § 1395dd(c)(1).

- ³⁰ *Id.* § 1395dd(c)(1)(A)(ii).
- ³¹ 42 U.S.C. § 1395dd(c)(2) (2003).
- ³² *Id.*
- ³³ Medicare conditions of participation require a participating hospital to report potential violations of EMTALA to CMS or a state survey agency when the hospital receives what it believes to be an inappropriate transfer. *See* 42 C.F.R. § 489.20(m) (2003). Failure to make such a report can lead to termination of the hospital's Medicare provider agreement. *See id.* *See also* St. Anthony Hosp. v. United States Dep't Health & Human Servs., 309 F.3d 680, 711 (10th Cir. 2002) (upholding the imposition of a civil money penalty on a hospital that had specialized capabilities and refused to accept an appropriate transfer).
- ³⁴ 42 U.S.C. § 1395dd(d)(1) (2003).
- ³⁵ U.S. GENERAL ACCOUNTING OFFICE, EMERGENCY CARE: EMTALA IMPLEMENTATION AND ENFORCEMENT ISSUES 24 (2001), available at www.gao.gov/new.items/d01747.pdf (last accessed Dec. 28, 2003).
- ³⁶ 42 U.S.C. § 1395dd(d)(2)(A) (2003). *See* Power v. Arlington Hosp. Ass'n, 42 F.3d 851, 860 (4th Cir. 1994) (applying Virginia's \$1 million damages cap to EMTALA action); Barris v. County of Los Angeles, 972 P.2d 966, 973 (Cal. 1999) (applying the California Medical Injury Compensation Reform Act damages cap of \$250,000 to EMTALA action); *but cf.* Cooper v. Gulf Breeze Hosp., 839 F.Supp. 1538, 1543 (N.D. Fla. 1993), *aff'd without opinion*, 82 F.3d 429 (11th Cir. 1996) (holding that Florida's damages cap does not apply to EMTALA actions).
- ³⁷ 42 U.S.C. § 1395dd(d)(2)(B) (2003).
- ³⁸ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222 (Sept. 9, 2003).
- ³⁹ *See AHLA Teleconference, supra* note 3, at 7. *See generally* ADVISORY COMMITTEE ON REGULATORY REFORM, DEP'T OF HEALTH & HUMAN SERV., BRINGING COMMON SENSE TO HEALTH CARE REGULATION: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON REGULATORY REFORM (2002), available at www.regreform.hhs.gov/Finalreport.pdf (last accessed Dec. 28, 2003).
- ⁴⁰ *Id.* at 4.
- ⁴¹ *See AHLA Teleconference, supra* note 3, at 11–12.
- ⁴² *See* 42 U.S.C. § 1395dd(a) (2003).
- ⁴³ *Id.* § 1395dd(b)(1).
- ⁴⁴ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222, 53,262 (Sept. 9, 2003); 42 C.F.R. § 489.24(b)(4) (2003).
- ⁴⁵ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,230-31. The proposed regulations would have used the objective test on entities that, in the prior calendar year, had one-third of its visits for *evaluation* and treatment of emergency medical conditions. *See id.* at 53,231. CMS dropped the evaluation trigger on the basis of a commentor's suggestion that including evaluation would be overly inclusive because any outpatient ambulatory clinic might, as a general matter, evaluate patients for emergency conditions (and rule them out) without ever treating any emergency conditions. *See id.* Thus, CMS limited the one-third test to visits for *treatment* for emergency medical conditions. *See id.*
- ⁴⁶ *Id.* at 53,228.
- ⁴⁷ *Id.*
- ⁴⁸ *Id.*

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- ⁴⁹ *Id.* at 53,229.
- ⁵⁰ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,262; 42 C.F.R. § 489.24(b) (2003).
- ⁵¹ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,231.
- ⁵² *Id.*
- ⁵³ *See id.*
- ⁵⁴ *See id.*
- ⁵⁵ *Id.*
- ⁵⁶ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,263; 42 C.F.R. § 489.24(c) (2003).
- ⁵⁷ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,234 (emphasis added).
- ⁵⁸ *Id.* at 53,236.
- ⁵⁹ *Id.* at 53,234.
- ⁶⁰ *Id.* at 53,237.
- ⁶¹ *Id.*
- ⁶² *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,262; 42 C.F.R. § 489.24(b)(2) (2003).
- ⁶³ Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,263; 42 C.F.R. § 489.24(b).
- ⁶⁴ 42 C.F.R. § 410.2 (2003).
- ⁶⁵ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,240.
- ⁶⁶ *See id.* at 53,244.
- ⁶⁷ *See* Bryan v. Rectors and Visitors of the University of Virginia, 95 F.3d 349, 352 (4th Cir. 1996); Bryant v. Adventist Health Systems/West, 289 F.3d 1162, 1168 (9th Cir. 2002); Harry v. Marchant, 291 F.3d 767, 775 (11th Cir. 2002).
- ⁶⁸ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,244.
- ⁶⁹ *See id.* at 53,245.
- ⁷⁰ *Id.*
- ⁷¹ For an in-depth analysis of the on-call physician provisions of the new rule, see generally Erin M. McHugh, *The New EMTALA Regulations & The On-Call Physician Shortage: In Defense of the Regulations*, 37 J. HEALTH L. 61 (2004).
- ⁷² 42 U.S.C. § 1395cc(a)(I)(iii) (2003).
- ⁷³ *See id.* § 1395dd(d)(1)(C).
- ⁷⁴ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222, 53,251 (Sept. 9, 2003).
- ⁷⁵ *Id.* at 53,250.
- ⁷⁶ *See* Robert Pear, *Emergency Rooms Get Eased Rules on Patient Care*, NEW YORK TIMES (Sept. 3, 2003), at A1; Press Release, American College of Emergency Physicians, *New EMTALA Regulation Could Increase Shortage of On-Call Specialists in Emergency Departments* (Sept. 3, 2003), available at www.acep.org/1,33022,0.html (last visited Dec. 28, 2003).
- ⁷⁷ *See* Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency

Medical Conditions, 68 Fed. Reg. at 53,262-53,263; 42 C.F.R. § 489.24(b) (2003).

⁷⁸ See Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,263; 42 C.F.R. § 489.24(b)(3)(i).

⁷⁹ See *id.* § 489.24(b)(3)(ii).

⁸⁰ See *id.* § 489.24(b)(4).

⁸¹ See *id.* § 489.24(b)(4).

⁸² See *id.*

⁸³ *Arrington v. Wong*, 237 F.3d 1066 (9th Cir. 2001).

⁸⁴ See *id.* at 1072-73.

⁸⁵ See Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,257.

⁸⁶ *Id.*

⁸⁷ Office of the Inspector General, Dept. of Health and Human Services, Special Advisory Bulletin on the Patient Anti-Dumping Statute, 64 Fed. Reg. 61,353 (Nov. 10, 1999).

⁸⁸ See Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,224.

⁸⁹ See *id.* at 53,263-53,264; 42 C.F.R. § 489.24(d)(4) (2003).

⁹⁰ *Id.* at 53,264; 42 C.F.R. § 489.24(d)(4)(iv).

⁹¹ *Id.* § 489.24(d)(4)(ii).

⁹² See *id.* at 53,225-53,226, 53,264; 42 C.F.R. § 489.24(d)(4)(ii).

⁹³ See *id.* at 53,262; 42 C.F.R. § 489.24(a)(2).

⁹⁴ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 627 (codified in as amended in scattered sections of 42 U.S.C.).

⁹⁵ For a more detailed analysis of EMTALA's applicability during a public health emergency, see Sara Rosenbaum and Brian Kamoie, *Finding a Way Through the Hospital Door*, 31 J. L., MED. & ETHICS 590 (2003).

⁹⁶ See Medicare Program; Clarifying the Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. at 53,223.

⁹⁷ See *id.*

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