



Center for *Clinical Standards & Quality/Quality, Safety & Oversight* Group

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DATE: *April 22, 2005*

TO: State Survey Agency Directors

FROM: Director
Quality, Safety and Oversight Group

SUBJECT: Interaction of the Emergency Medical Treatment and Labor Act (EMTALA) and the Born-Alive Infants Protection Act of 2002

***NOTE:** This memorandum is being reissued to remind hospitals of their obligation to comply with EMTALA as it relates to the Born-Alive Infant Protection Act. This is NOT new policy.*

Letter Summary

- The Born-Alive Infants Protection Act of 2002 (Pub. L. 107-207) adds to the United States Code a definition of the term “individual” to include every infant who is born alive, at any stage of development; it also adds a definition of the term “born alive.”
- The Emergency Medical Treatment and Labor Act (EMTALA) provides certain rights to “any individual” who comes to an emergency department and “any individual” who comes to a hospital. In particular, hospitals must provide an appropriate medical screening examination to any individual who comes to an emergency department, and either stabilizing treatment or an appropriate transfer for an individual who comes to a hospital and who is determined to have an emergency medical condition.
- **Attachment:** The attached Guidance provides direction to regional office and state survey agency personnel on how to apply EMTALA in investigations when the Born-Alive Infants Protection Act is potentially implicated.

The purpose of this memorandum is to provide guidance to regional office (RO) and state survey agency (SA) personnel regarding the enforcement of the Emergency Medical Treatment and Labor Act (EMTALA) during investigations of hospitals where the Born-Alive Infants Protection Act could be potentially implicated. It has recently come to the agency’s attention that there may be occasions where, in hospitals, an infant may be born alive within the meaning of the definition added to the U.S. Code by the Born-Alive Infants Protection Act, but where hospitals have failed to comply with the requirements of EMTALA.

Under the Born-Alive Infants Protection Act, such an infant is defined as an “individual.” Since EMTALA provides protection to “individual[s],” RO and SA personnel conducting EMTALA investigations need to be aware of the interaction of both statutes in order to appropriately comply with their obligations to conduct EMTALA surveys. This memorandum provides guidance on the interaction of the two statutes.

Background

Congress enacted EMTALA to ensure public access to emergency services, regardless of ability to pay. Section 1867 of the Social Security Act imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination (MSE) when an individual comes to the emergency department and a request is made for examination or treatment for a medical condition, including active labor, regardless of an individual’s ability to pay. In addition, when an individual comes to a hospital, and the hospital determines that the individual has an emergency medical condition, the hospital is required to provide either stabilizing treatment within its capabilities, or to effect an appropriate transfer. If a hospital is unable to stabilize an individual with an emergency medical condition within its capability, or if the individual requests, an appropriate transfer should be implemented.

To help promote consistent application of the regulations concerning the special responsibilities of Medicare-participating hospitals in emergency cases, the Centers for Medicare & Medicaid Services (CMS) has occasionally published regulations clarifying hospitals’ responsibilities and obligations under EMTALA. Most recently, in September of 2003, CMS published such regulations. Shortly after those regulations became effective, we issued revised Interpretive Guidelines to implement those regulations. We also amended our State Operations Manual to incorporate the new regulations. From time to time, we also issue guidance to surveyors to use when conducting an investigation and assessing a hospital’s compliance with EMTALA.

Effective Date: Immediately. Please orient surveyors and implement procedures to ensure that the information in this memorandum is operational within 60 days.

Training: This information should be distributed to all survey and certification staff, their managers, and the state/RO training coordinators.

/s/

Karen Tritz
Acting Director

cc: Survey and Certification Regional Office Management

Attachment

Attachment

GUIDANCE ON THE INTERACTION OF THE BORN-ALIVE INFANTS PROTECTION ACT AND EMTALA

Summary of the Born-Alive Infants Protection Act

The Born-Alive Infants Protection Act, Pub. L. 107-207, amended title 1 of the United States Code by defining the terms “person,” “human being,” “child,” and “individual.” In particular, the statute instructs that,

[i]n determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words “person”, “human being”, “child”, and “individual”, shall include every infant member of the species homo sapiens who is born alive at any stage of development.

1 U.S.C. § 8(a).

The statute goes on to define the term “born alive” with respect to the species homo sapiens, as any member of that species expelled or extracted

from his or her mother ... at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section or induced abortion.

1 U.S.C. § 8(b).

Summary of the Emergency Medical Treatment and Labor Act (EMTALA)

The EMTALA statute is codified at section 1867 of the Social Security Act, 42 U.S.C. § 1395dd. Hospitals and physicians generally have three obligations under EMTALA. The first is commonly referred to as the screening requirement, and applies to any individual who comes to the emergency department of a hospital and for whom a request is made for examination or treatment for a medical condition. Such an individual is entitled to have a medical screening examination to determine whether or not an emergency medical condition exists. The second is commonly referred to as the stabilization requirement, and applies to any individual who comes to the hospital and whom the hospital determines has an emergency medical condition. Such an individual is entitled to stabilizing treatment within the capability of the hospital. The third obligation flows from the second, and also applies to any individual in a hospital with an emergency medical condition. This obligation is sometimes known as the transfer requirement, and restricts the ability of the hospital to transfer that individual to another hospital unless the

individual is stabilized. If the individual is not stabilized, they may only be transferred if the individual requests the transfer or if the medical benefits of the transfer outweigh the risks.

In addition to the basic requirements of EMTALA, the statute contains “whistleblower” protection. In particular, section 1867(i) of the Act prohibits a hospital from taking adverse action against an employee because the employee reports a violation of the section. EMTALA is enforced by penalties that can be imposed against the hospital in an amount up to \$50,000 per violation (\$25,000 per violation in the case of a hospital with less than 100 beds); hospitals that violate EMTALA also put their Medicare provider agreements at risk. A physician that violates EMTALA is subject to a penalty of \$50,000 per violation and, if the violation is gross or flagrant, or repeated, to exclusion from the Medicare and Medicaid programs. In addition, EMTALA can be enforced by a private right of action brought in the U.S. District Courts by any individual harmed as a direct result of an EMTALA violation by a hospital. *Note: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 sets the civil monetary penalties annually for EMTALA enforcement actions.*

The 2003 regulations included some modifications and clarifications to hospitals’ responsibilities and obligations under EMTALA. For example, the regulations clarified the screening requirement and made clear that it applied to any individual who presented to an area of the hospital that met the definition of a “dedicated emergency department” and made a request for a medical screening examination. The regulation defined dedicated emergency department as the area of the hospital that met any one of three tests: that it is licensed by the state as an emergency department; that it held itself out to the public as providing emergency care; or that during the preceding calendar year, at least one-third of its outpatient visits were for the treatment of emergency medical conditions. The preamble to the regulation noted that it is possible that the labor and delivery department of a hospital could meet the definition of dedicated emergency department. (See 68 Fed. Reg. at 53229 (September 9, 2003)).

The regulation also clarified other circumstances in which the screening requirement may apply. For example, an individual who comes to certain locations on the hospital’s campus, but not to the dedicated emergency department, is entitled to the protection of EMTALA in certain circumstances. In particular, if the individual comes to the hospital and makes request for examination or treatment for an emergency medical condition, then the screening requirement will apply. If the individual does not make a verbal request, but a prudent layperson observer would conclude, based on the person’s appearance or behavior, that the person needed emergency examination or treatment, the screening requirement also applies.

In addition, the regulation also clarified the application of EMTALA with respect to inpatients. Prior to the issuance of the regulations, CMS had never made clear whether EMTALA applied to inpatients. With the new regulations, as codified at 42 C.F.R. § 489.24(d)(2), it is clear that EMTALA does not apply to inpatients, whether admitted after the individual has been admitted through the emergency department or whether the individual has been admitted for an elective procedure.

Notably, the regulations retained an earlier requirement that any individual (whether or not that individual is a Medicare beneficiary) who comes to the hospital and who is determined to have

an emergency medical condition is protected by both the stabilization requirement and the transfer requirement if the individual is not admitted. (See 42 C.F.R. § 489.24(d)(1)). The retention of this requirement meant that CMS continued to intend for hospitals to stabilize any individual (or to meet the applicable transfer requirements for any individual) who has not been admitted as an inpatient, but who is determined by the hospital to have an emergency medical condition. The preamble to the regulation also notes that it would be a violation of EMTALA to admit an individual to the hospital in a bad faith attempt to evade EMTALA obligations.

The preamble to the regulation also noted that even though EMTALA does not apply to inpatients, hospitals were still bound by the Medicare conditions of participation (CoPs) to provide appropriate care to inpatients (*42 CFR 482.1 through 482.58*). In particular, the preamble noted four CoPs that are potentially applicable when a hospital provides treatment for an admitted patient. For example, hospital governing bodies must ensure that the hospital medical staff has written policies and procedures for appraisal of inpatients who develop an acute medical condition while admitted. The preamble also notes the discharge planning CoP, which requires that hospitals have a discharge planning process that applies to all patients. Hospitals must also have an organized medical staff that is responsible to the hospital's governing body for the quality of medical care provided to patients. Finally, the hospital governing body must ensure that the hospital has an organization-wide quality assessment and performance improvement program to evaluate the provision of patient care. These CoPs are intended to protect patient health and safety, and to ensure that high quality medical care is provided to all patients. Failure to meet these CoPs could result in a finding of noncompliance at the condition level for the hospital and lead to termination of the hospital's Medicare provider agreement.

Interaction of the Born-Alive Infant Protection Act and EMTALA

With the definition of the terms "person" and "individual" codified at 1 U.S.C. § 8, it is clear that there may be some circumstances where EMTALA protections can attach to an infant who is born alive, as that term is defined in 1 U.S.C. § 8(b). For example, assume that a hospital's labor and delivery department meets the definition of a "dedicated emergency department" under the new regulations. If an infant were born alive (again, as that term is defined in 1 U.S.C. § 8(b)) in that dedicated emergency department, and a request were made on that infant's behalf for screening for a medical condition, (or if a prudent layperson would conclude, based on the infant's appearance or behavior, that the infant needed examination or treatment for an emergency medical condition and that a request would have been made for screening) the hospital and physician could be liable for violating EMTALA for failure to provide such a screening examination. This follows because the born-alive infant is a "person" and an "individual" under 1 U.S.C. § 8(a), and the screening requirement of EMTALA applies to "any individual" who comes to the emergency department.

Another example could occur were an infant to be born alive elsewhere on the hospital's campus (i.e., not in the hospital's dedicated emergency department) and a prudent layperson observer concluded, based on the born-alive infant's appearance or behavior, that the born-alive infant were suffering from an emergency medical condition. In such a circumstance, the hospital and its medical staff would be required to perform a medical screening examination on that born-alive infant to determine whether or not an emergency medical condition existed. If the hospital

or its medical staff determined that the born-alive infant were suffering from an emergency medical condition, there would then arise an obligation to admit the infant, or to comply with either the stabilization requirement or the transfer requirement, or risk a finding of an EMTALA violation. This follows because the born-alive infant is a “person” and an “individual,” as described above, and the stabilization and transfer requirements of EMTALA apply to “any individual” who comes to the hospital.

Finally, a third example could occur if the hospital were to admit a born-alive infant. As noted above, EMTALA does not apply to inpatients. Were an infant born alive and then admitted to the hospital, EMTALA would not apply to protect the infant in most circumstances. However, the CoPs described above clearly would apply to the infant once he or she was admitted to the hospital as an inpatient. If a hospital were to violate those CoPs, it would put at risk its Medicare provider agreement.

Conduct of Investigations

EMTALA is a complaint-driven statute. If you receive a complaint that suggests that a born-alive infant has been denied a screening examination, stabilizing treatment, or an appropriate transfer, you should treat that complaint as potentially triggering an EMTALA investigation of the hospital. Note that it is not necessary to determine that the hospital acted with an improper motive in any failure to provide a screening examination, stabilizing treatment, or an appropriate transfer in order to conclude that an EMTALA violation has occurred. The Supreme Court of the United States has held that a finding of improper motive is not required to conclude that an EMTALA violation has occurred.