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Emergency Medical Treatment and Active Labor Act and Clinical Laboratory Improvement Amendments

Compliance Officers of hospitals and physician practices must understand the Emergency Medical Treatment and Active Labor Act (EMTALA). If the medical organization performs any type of laboratory tests on site, the Compliance Officer should also be familiar with Clinical Laboratory Improvement Amendments (CLIA) regulations. Compliance policies and procedures should be in place to ensure all regulations for EMTALA and CLIA are followed. Although hospitals are primarily held accountable for complying with EMTALA, physician practices must also be aware of these regulations if their providers work in the hospital setting (eg, emergency department).

Learning objectives for this chapter include:

- Identify EMTALA regulations and how they apply to healthcare providers.
- Review CLIA regulations and understand how they apply in healthcare practices and facilities.

Emergency Medical Treatment and Active Labor Act

EMTALA (42 USC 1395dd et seq) is a statute included in the Consolidated Omnibus Reconciliation Act of 1985 (COBRA). Congress enacted EMTALA in response to increasing concerns that hospitals were denying emergency care to indigent and uninsured patients, and “dumping” them to another facility for care (usually “charity” or county hospitals), or to no facility at all by discharging the patient after an inadequate medical exam. EMTALA is a non-discrimination statute.

Although EMTALA applies only to participating hospitals (those that accept payment from governmental entities), it applies to almost all hospitals and all patients. The one exception to this law is the Shriners’ Hospital for Crippled Children. EMTALA requires participating hospitals to adhere to three primary obligations regarding the treatment of any individual who comes to a participating hospital for emergency medical care: (https://www.ecfr.gov/cgi-bin/text-idx?SID=ad-ac92406bd2a5c3ca6c9a4017bd08ff&node=pt42.5.489&rgn=div5#se42.5.489_124)

Primary Obligations

- 1- Any individual who comes to the emergency department must be provided “an appropriate medical screening

examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether an emergency medical condition (EMC) exists.” In addition, the medical screening examination “must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations. EMTALA defines an emergency medical condition as “a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in – (i) placing the health of the individual in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ part.” EMTALA also defines an emergency medical condition to include a pregnant woman who is having contractions. Examination and treatment cannot be delayed to inquire about methods of payment or insurance coverage. Emergency departments must also post signs notifying patients and visitors of their right to a medical screening examination and treatment for emergency medical conditions.

- 2- If it is determined that an EMC exists, the hospital must provide treatment to stabilize the medical condition, or appropriately transfer the individual to another hospital. If the hospital admits the individual as an inpatient for further treatment, the hospital’s EMTALA obligation ends. Once an individual is admitted as an inpatient, state tort and medical malpractice law then govern the legal adequacy of that care. EMTALA is not a federal malpractice statute and is not meant to supplant available state malpractice and tort remedies.
- 3- The hospital must abide by restrictions on transferring unstable individuals. Patients may be transferred under EMTALA solely for medical necessity. Under EMTALA, a hospital can transfer an unstable patient only if the transfer is an appropriate transfer under the statute. An “appropriate transfer” involves numerous factors, including determining that the medical benefits of transfer outweigh the medical risks of transfer. The weighing of the risks and benefits of transfer must be certified in writing by a physician. A hospital must report to HHS, CMS, or the state’s survey agency anytime it has reason to believe that it may have received an individual who has been transferred in an unstable EMC from another hospital in violation of EMTALA.

A Medicare-participating hospital with specialized capabilities or facilities, such as a burn unit, neonatal intensive care unit, cardiac hospital, or orthopedic hospital, that exceed those of the transferring hospital cannot refuse to accept an appropriate transfer of a patient who requires the hospital's specialized capabilities, if the hospital has the capacity to treat the patient. Once an individual is admitted (to the original hospital) in good faith, a hospital with specialized capabilities does not have an EMTALA obligation to accept an inpatient transfer of that individual.

The statute contains significant penalties to prevent hospitals and physicians from disregarding their duties in treating all patients in a similar manner regardless of the ability to pay.

2003 Update to EMTALA

In 2003, a provision was added to clarify when/where EMTALA applies:

- A person who presents anywhere on the hospital campus and requests emergency services, or who appears to a reasonably prudent person to need medical attention, must be handled under EMTALA. Other presentations outside the emergency room do not invoke EMTALA.
- The 250-yard zone continues to apply when defining the "hospital campus." That sphere does not include non-medical businesses (shops and restaurants located close to the hospital), nor does it include physicians' offices or other medical entities that have a separate Medicare identity.
- EMTALA does not apply to any off-campus facility, regardless of its provider-based status, unless it independently qualifies as a dedicated emergency department.

CFR Section 489.24

Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- (1) It is licensed by the state in which it is located under applicable state law as an emergency room or emergency department;
- (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

- (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

The medical screening exam level depends on the patient's presenting symptoms and can range from a brief examination to a complex process involving many diagnostics and procedures. The hospital is expected to use the resources available, including on-call physicians, to screen and stabilize the patient. Additionally, there are obligations to report on-call physicians who don't respond to a page.

Hospitals and their physicians are obligated to provide any stabilizing treatment that's necessary for the patient to be discharged or transferred. Patients can refuse stabilizing treatment; hospitals and physicians should have a form to document a patient's refusal and should verify this by obtaining the patient's signature, if possible.

Transfers

If a provider cannot stabilize the patient, the patient can be admitted as an inpatient or transferred to another hospital. Patients can also request to be transferred. The transfer needs to be by a safe means, and a copy of the patient's medical records should be provided to the receiving hospital.

Several requirements must be met before transferring an unstable patient:

1. The consent of the receiving hospital must be obtained;
2. The patient's condition must be documented; and
3. The physician must attest (in writing) that the medical benefits expected at the receiving facility outweigh the risk of transfer. If the patient requests the transfer but the physician doesn't agree, that should be documented, and the patient should sign a request for transfer form. The patient's written acknowledgement of his refusal to consent to a physician-recommended transfer should also be documented.

Physician Liability

As stated above, EMTALA primarily affects hospitals, but in some situations, physicians may be subject to liability. First, there are those persons who are either employed by or working within the hospital who could violate the EMTALA provisions. The hospital is the entity that will bear the loss (fines/penalties), but the hospital could involve the person(s) who violated the statute in the government's claim or in a civil claim.

they are PAR physicians; when non-PAR physicians accept assignment for their low-income or other patients, their Medicare approved amounts are still only 95 percent of the approved amounts paid to PAR physicians for the same service. Non-PAR physicians would need to collect the full limiting charge amount roughly 35 percent of the time they provided a given service for the revenues from the service to equal those of PAR physicians for the same service. If they collect the full limiting charge for more than 35 percent of the services that they provide, their Medicare revenues will exceed those of PAR physicians.

Assignment acceptance for either PAR or non-PAR physicians also means that the MAC pays the physician the 80 percent Medicare payment. For unassigned claims, even though the physician is required to submit the claim to Medicare, the program pays the patient and the physician must then collect the entire amount for the service from the patient.

EXAMPLE: A SERVICE FOR WHICH MEDICARE FEE SCHEDULE AMOUNT IS \$100

Payment Arrangement	Total Payment Rate	Payment Amount from Medicare	Payment Amount from Patient
PAR physician	100% Medicare fee schedule = \$100	\$80 (80%) MAC direct to physician	\$20 (20%) paid by patient or supplemental insurance (eg, Medigap)
Non-PAR/assigned claim	95% Medicare fee schedule = \$95	\$76 (80%) MAC direct to physician	\$19 (20%) paid by patient or supplemental insurance (eg, Medigap)
Non-PAR/unassigned claim	Limiting charge/109.25% Medicare fee schedule = \$109.25	\$0	\$76 (80%) paid by MAC to patient+ \$19 (20%) paid by patient or supplemental insurance + \$14.25 balance bill paid by patient

15. Professional Courtesy Billing

Many physicians provide “professional courtesy” discounts to other physicians, as well as to those with whom they work or have a personal relationship (eg, office staff, hospital employees, and family members).

There is an exception under the Stark Law for professional courtesy, which is defined as “the provision of free or discounted healthcare items or services offered to a physician, immediate family member, or office staff.” The exception requires that:

- a. The professional courtesy is offered to all physicians on the entity’s bona fide medical staff or entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties;
- b. The healthcare items and services are of a type routinely provided by the entity;
- c. The entity’s professional courtesy policy is written and approved in advance by the board;
- d. The courtesy is not offered to a physician or immediate family member who is a federal healthcare program beneficiary, unless there is a good faith showing of financial need; and
- e. The arrangement does not violate the Anti-kick-back statute or any law or regulation governing billing or claims submission.

Many of the items listed above are already considered “not allowed” because of the Anti-kickback Statute, the prohibition in waiving copayments and deductibles of federal and private insurance plans, or the simple fact that most providers are not going to open their doors to all the physicians in their service area.

Professional courtesy does not apply to spouses and families of the office staff or other physicians in the service area, but only the physicians’ immediate family members and staff.

The only true professional courtesy is that given to immediate family members. In fact, a physician cannot bill for services or ordered services for his or her immediate family member, as shown below.

Medicare Carriers Manual [14-3-2332]

2332. CHARGES IMPOSED BY IMMEDIATE RELATIVES OF PATIENT OR MEMBERS OF HOUSEHOLD

A. General

Do not pay under Part A or Part B of Medicare for expenses, which constitute charges by immediate