

July 9, 2002

Thomas A. Scully
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 443-G
Washington, DC 20201

Dear Mr. Scully:

The undersigned medical organizations are pleased to submit the following comments to the proposed rule relating to the “Responsibilities of Medicare Participating Hospitals in Emergency Cases” under the Emergency Medical Treatment and Active Labor Act (EMTALA) dated May 9, 2002. The physician community is particularly pleased that Secretary Thompson's Advisory Committee on Regulatory Reform and the Administration has recognized the need to reform EMTALA. Past extensions of EMTALA requirements to settings other than the emergency department have increased the financial and legal liability of those caring for these patients and decreased the willingness of some physicians to provide on-call services. We believe the proposed rule is a substantial improvement over the current EMTALA regulations and represents a solid step in formulating a more workable EMTALA approach that takes into account the actual functioning of hospital emergency departments and emergency situations that occur on hospital grounds.

We greatly appreciate CMS clarifying through this proposed regulation that “(p)hysicians, including specialists and subspecialties, are not required to be on call at all times.” This clear statement of EMTALA policy indicates that hospitals should work with the physicians in their communities to “respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician’s control.”

In communities with limited numbers of specialists or subspecialists, requiring physicians to be on-call 24 hours a day/7 days a week is simply an unrealistic solution. Beyond the implausibility of the notion, this type of continuous on-call requirement serves as a significant disincentive for health professional shortage areas seeking to attract or retain physicians in their communities. Knowing that one would never have respite from being on-call would most likely warn away physicians from the areas where they are needed the most.

CMS should further strengthen the proposed rule by setting forth the meaning of “circumstances beyond the physician’s control.” For instance, we urge CMS to state that when physicians are performing surgery, they are unavailable for reasons that are “beyond the physician’s control.” This type of list need not be exhaustive, but should

provide illustrative examples to guide hospitals and physicians when they are faced with situations where physicians are unavailable and alternative arrangements are needed

One way to ensure that patients have access to appropriate emergency care is to state in the final rule that if a physician is unavailable for reasons “beyond his or her control” because he or she is performing surgery at another hospital, then the receiving hospital could transfer the patient to the hospital where the physician is located if another on-call physician were not available or it could implement a back-up plan. This would allow the physician to immediately care for the transferred patients as soon as he or she has finished operating. This solution is particularly important for areas with a shortage of physician specialists or subspecialists, as it would permit the physician to see the patient more quickly.

Limiting On-Call Coverage to Physician’s Scope of Practice.

On-call physicians should be expected to perform procedures or provide care for which they hold hospital privileges. If physicians are not comfortable performing more general procedures, they should modify their privileges to more narrowly reflect their subspecialty. The best interests of the patient may or may not be served by consulting with a subspecialist based on that physicians’ general specialty training. For example, an ophthalmologist subspecializing in vitreous and retinal surgery can be expected to have more information and expertise in general ophthalmology than an emergency physician or primary care physician. Yet a physician specializing in general surgery may not have the needed expertise to operate on an infant needing emergency care. In this later case, the physician would be privileged in only general surgery and not in pediatric surgery.

We believe that if the patient requires care that is beyond the physician’s particular expertise, the physician should be able to call another physician who can competently care for the patient. Medical staffs should work with hospitals to establish policies to ensure that patients receive an appropriately high level of care if it is available and relatively close in proximity to the receiving hospital. We also believe that a public-private sector workgroup similar to the workgroup described in H.R. 3391, the “Medicare Appeals, Regulatory, and Contracting Improvement Act of 2001” could effectively solve process concerns and other issues that emerge in this area.

Inpatient Admissions

We applaud the statement in the proposed rule,

EMTALA was not intended to apply to admitted inpatients who may become unstable subsequent to admission, but only to patients who initially come to the hospital’s emergency department with an emergency medical condition, and only until the condition has been stabilized.

This provision properly clarifies that EMTALA is intended to apply to emergency department admissions rather than to patients who have been admitted to the hospital as inpatients and later develop emergency conditions. Physicians and hospitals are still

required under Medicare conditions of participation to treat these patients. As this proposed rule indicates, it is simply that EMTALA would not apply in these instances.

However, as certain EMTALA requirements remain unclear in the proposed rule, CMS should draw a bright line as to inpatient status in issuing the final rule. In the proposed rule, CMS has stated,

In many cases, medical judgment will dictate that a patient be admitted to the hospital for further treatment on an inpatient basis because the patient's emergency medical condition has not yet been stabilized. In these cases, the hospital continues to be obligated under section 1867, irrespective of the inpatient admission.

First, this distinction could muddy the waters for physicians and hospitals who are not certain of the distinction between "stable for inpatient admission" and "inpatient admission for an emergency medical condition that has not yet been stabilized." EMTALA was enacted to prevent "patient dumping" so that hospitals could not refuse to treat patients arriving at the emergency room with an emergency condition. It is clear that hospitals are not attempting to evade patient treatment by admitting patients with unstable conditions as inpatients, as the patients are in fact, being treated as inpatients. As such, once patients are admitted as inpatients, as a bright line standard, the Medicare conditions of participation should govern physician and hospital care of patients rather than EMTALA.

Second, in Section 489.24(d)(2)(ii), found on page 31507, CMS states that if an unstable patient is brought to the emergency department and is then admitted as an inpatient before being stabilized and never becomes stabilized, this would be an EMTALA violation. In the everyday world, there are extremely ill, unstable individuals who present at the emergency department, are admitted in an unstable state, and subsequently die before ever being stabilized. Failure to move these patients to specialized intensive care units leaves the physician open to malpractice accusations. We urge CMS to modify the proposed rule to reflect this patient care reality and to ensure that EMTALA violations could not be alleged in these situations.

Applicability of EMTALA to Other Areas in the Hospital

In practical terms, patients with emergency medical conditions that arise when they are in the hospital lobby or in other non-emergency hospital locations most often cannot receive the same on-the-spot emergency screening services as a patient that arrives in the emergency department requesting treatment. In these non-emergency department locations, unless hospital personnel are readily available to provide medical treatment, the person with the potential emergency should be transported to the emergency room as quickly as possible. Medical personnel cannot be at all hospital locations to conduct screening and stabilization services. In fact, requiring emergency personnel or emergency department physicians to respond to potential emergency medical conditions at other hospital locations would significantly disrupt the workings of the emergency department and interrupt essential emergency room medical care as physicians and other

medical personnel were called away to other locations. We believe CMS should revise how medical staff are required to respond to potential medical emergencies at non-emergency department locations.

We also believe that Example 3 in this section is overly prescriptive. An emergency department would not normally send a team from the emergency department to retrieve a patient. The hospital should have full discretion to establish appropriate policies and procedures for transporting patients to the emergency department who present to other areas of the hospital. Although hospitals usually call “codes” for patients with certain conditions, hospitals typically arrange for immediate transport to the emergency department for individuals with emergency conditions that are not immediately life threatening.

Scheduled Emergency Surgery

We urge CMS to clarify that EMTALA would not apply to patients who are stable but who are scheduled for inpatient surgery for an emergency medical condition. These are patients who, for example, after seeing their physician for chest pain, need an angiogram or bypass surgery. The physician may schedule the surgery for that day as it clearly needs to occur as soon as possible. In these instances however, the patient has not presented to the emergency room and requested treatment. CMS should clearly establish in the final rule that the physician’s and the hospital’s conduct in scheduled emergency surgeries would be governed by the Medicare conditions of participation, rather than by EMTALA.

Likewise, the final rule should state that EMTALA would not apply when patients arrive on the orders of their physician, such as when a pregnant woman or a psychiatric patient arrives upon physician’s orders either for testing or because they are in need of immediate medical care. Often, when these patients are referred for testing or examination, they should be seen not by emergency department staff, but by medical staff in these departments who have already been contacted by the patient’s own physician.

Under the proposed rule, it is not clear that hospitals and physicians could ensure that their patients are getting the most appropriate care at the earliest possible juncture. Patients, upon their physicians’ orders, should be able to go directly to the departments that are providing the needed care, rather than having to be screened first at the emergency department. Although CMS notes tangentially that patients often arrive at these departments requesting medical treatment, it should acknowledge that these situations do not trigger EMTALA obligations.

As the EMTALA penalties are so substantial, we urge CMS to establish clear standards for situations where hospitals, physicians, and medical personnel can ensure that patients receive the appropriate care by the departments that are indicated, without having to stop at the emergency room because of a presumed EMTALA obligation.

Off-Campus Provider-Based Departments

First, we believe that the EMTALA standard which CMS has proposed to govern scheduled outpatient appointments may be unnecessarily confusing. The proposed rule states,

We are proposing that EMTALA would not apply to such an individual who then experiences what may be an emergency medical condition if the individual is an outpatient . . . *who has come to* the hospital outpatient department for the purpose of keeping a previously scheduled appointment. We would consider such an individual to be an outpatient if he or she has *begun an encounter* . . . with a health professional at the outpatient department. (*emphasis added*)

The proposed rule then states that EMTALA would not apply for patients who may have emergency medical conditions “after *the start* of an encounter with a health professional.”

CMS should clearly state that only hospital conditions of participation and not EMTALA would apply to patients with scheduled outpatient appointments or procedures. The language about starting the encounter makes it unclear whether EMTALA would apply to the situation where the patient were in the waiting room but had not yet seen the physician or health professional. We believe that CMS intended for EMTALA not to apply in situations where the patient has arrived for an appointment, even if they had not yet been assisted, and we urge clarification of this issue in the final rule.

Second, we urge CMS to clarify further in the final rule that EMTALA would not apply to services sought from off-campus provider-based departments that a physician has ordered such as x-ray or outpatient lab services. In these instances, although a patient has requested services and may believe that an emergency exists, EMTALA should not be triggered. We strongly believe that resources would be squandered if a facility were forced to create an EMTALA-compliant structure to process routine requests for services. We believe that EMTALA should not apply to patients arriving at outpatient locations under orders from their physician, regardless of whether an appointment has been scheduled in advance.

Additional Issues:

- CMS should clearly define the standards in the final rule under which a person is stable for purposes of EMTALA -- that the transfer would not result in the material deterioration of their condition. In addition, CMS should set forth the standards that would apply if a patient were not stable for the transfer that was occurring -- that the benefit outweighs the risk to the patient. These standards are unclear to the medical community and their clarification would aid greatly in a more straightforward understanding of EMTALA.

- CMS should clearly state that the movement of patients to on-campus entities that may not be physically attached (or owned by the hospital) to the main hospital building not constitute a “transfer” under EMTALA when such movement is for the purposes of performing EMTALA mandated screening and stabilization services (e.g., radiology or neurology services). In certain hospitals, these facilities are not located within the confines of the hospital campus, and movement to these locations should not trigger potential EMTALA liability.
- CMS should clarify that EMTALA obligations end once a patient’s condition has been stabilized (according to the EMTALA definition of stabilization) and that follow-up care, while it may be warranted by ethical considerations and other moral strictures, is not mandated by EMTALA.
- The proposed definition of emergency department is clear and does not need to be defined more specifically (significant portion of time or regular amount of time).
- The final rule should clearly state that when hospitals seek prior authorization for hospital services, they are also seeking prior authorization for physician services. Otherwise, third party payors may pay charges for hospital services and deny reimbursement for physicians who actually perform the needed procedures.
- The proposed rule does not address how an emergency physician should respond when a patient insists that the physician call the patient’s private physician and there is a delay in reaching the physician. In this case, if the patient still refuses treatment after the physician has explained that the private physician is unavailable, the EMTALA obligation should be discharged.
- We are concerned regarding the definition of labor in the EMTALA regulations. We are also concerned that the January 2002 Memorandum from the Director of the Survey and Certification Group has reverted to a prior CMS policy of requiring that only physicians certify that a patient is in false labor prior to the patient’s discharge. We urge CMS to reexamine this policy and its definition of labor within the EMTALA regulations.

Finally, we laud CMS’ efforts to conduct outreach to physician groups and to gather feedback during the past several months. We are particularly pleased with the recent CMS letters to its Regional Administrators relating to simultaneous call and to elective surgery during on-call periods. Physicians and hospitals need flexibility to permit physicians to perform elective surgery during on-call periods and is gratified that CMS has acknowledged this need. CMS’ clarification that simultaneous call is explicitly permitted will also serve to standardize Regional Administrators’ policies to accommodate what is truly a necessity in many locations. We urge CMS to include these clarifications in the final rule.

For your information, we have attached a recent letter from many of our medical organizations relating to this issue which was sent to Members of the HHS Advisory

Committee on Regulatory Reform. These are some of the most-pressing EMTALA issues for physicians, and we strongly urge CMS to address these issues in the final rule.

We would like to continue to offer our collective insight into how EMTALA has impacted physician and provider behaviors, and we would be happy to serve in any type of advisory capacity that would be helpful to CMS.

Sincerely,

American Academy of Child and Adolescent Psychiatry
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Gastroenterology
American College of Obstetricians and Gynecologists
American College of Osteopathic Surgeons
American College of Physicians-American Society of Internal Medicine
American College of Radiology
American College of Surgeons
American Geriatrics Society
American Medical Association
American Medical Group Association
American Psychiatric Association
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of General Surgeons
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Congress of Neurological Surgeons
Infectious Diseases Society of America
National Association for Medical Direction of Respiratory Care
National Medical Association
North American Society of Pacing and Electrophysiology