

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 489

[CMS-1350-NC]

RIN 0938-AQ51

Medicare Program; Emergency Medical Treatment and Labor Act (EMTALA):

Applicability to Hospital Inpatients and Hospitals with Specialized Capabilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for comments.

SUMMARY: This request for comments addresses the applicability of the Emergency Medical Treatment and Labor Act (EMTALA) to hospital inpatients.

DATES: Comment Date: To be assured consideration, comments on the Applicability of EMTALA to Hospitals with Specialized Capabilities (section II.B. of this document) must be received at one of the addresses provided below, no later than 5 p.m. EST on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1350-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address

ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1350-NC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1350-NC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Renate Dombrowski, (410) 786-4645

Ankit Patel, (410)786-4537

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) were enacted as parts of the Emergency Medical Treatment and Labor Act (EMTALA). These statutory provisions impose specific obligations on certain Medicare-participating hospitals and critical access hospitals (CAHs). (Throughout this document, when we reference the obligation of a "hospital" under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital's "dedicated emergency department" (as defined at 42 CFR 489.24(b)) and request examination or treatment for a medical condition and apply to all of these individuals regardless of whether they are beneficiaries of any program under the Act.

EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99-272. Congress incorporated these antidumping provisions within the Social Security Act to ensure that any individual with an emergency medical condition (EMC), regardless of the individual's insurance coverage, is not denied essential lifesaving services. Under section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill its EMTALA obligations under these provisions may be subject to termination of its Medicare provider agreement which would result in the loss of Medicare and Medicaid payments. In addition, section 1867(d) of the Act provides for the imposition of civil monetary penalties on a hospital or physician who negligently violates a requirement of EMTALA under section 1867 of the Act.

Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the emergency department of a hospital and request examination or treatment for a medical condition. The statute further provides that, if a hospital finds that such an individual has an EMC, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility where stabilization can occur. The EMTALA statute also separately outlines the obligation of hospitals to receive appropriate transfers from other hospitals. Section 1867(g) of the Act states that "A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to

treat the individual." The regulations implementing section 1867 of the Act are found at 42 CFR 489.24. The regulations at 42 CFR 489.20(l), (m), (q), and (r) also refer to certain EMTALA requirements outlined in section 1866 of the Act. The Interpretive Guidelines concerning EMTALA are found at Appendix V of the CMS State Operations Manual: http://www.cms.gov/manuals/Downloads/som107ap_v_emerg.pdf.

A. Applicability of EMTALA to Hospital Inpatients

The focus of EMTALA routinely involves the treatment of individuals who "come to the emergency department," as we have defined that term at 42 CFR 489.24(b); that is, the individual is in a hospital-owned and operated ambulance or "has presented at a hospital's dedicated emergency department...and requests examination or treatment for a medical condition, or has such a request made on his or her behalf [or] [h]as presented on hospital property...other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf."

However, concerns have also arisen about the continuing applicability of EMTALA to hospital inpatients. We have previously discussed the applicability of EMTALA to hospital inpatients in the May 9, 2002 (67 FR 31475) Hospital Inpatient Prospective Payment System (IPPS) proposed rule entitled "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates" (hereinafter referred to as the FY 2003 IPPS proposed rule) and the September 9, 2003 (68 FR 53243) stand-alone final rule on EMTALA entitled "Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With

Emergency Medical Conditions" (hereinafter referred to as the 2003 EMTALA final rule). As we noted in these prior proposed and final rules, in 1999, the United States Supreme Court considered a case (*Roberts v. Galen of Virginia*, 525 U.S. 249 (1999)) that involved, in part, the question of whether EMTALA applies to hospital inpatients. In the context of that case, the United States Solicitor General advised the Court that HHS would develop a regulation clarifying its position on this issue. In the FY 2003 IPPS proposed rule, we proposed that EMTALA continues to apply to admitted individuals who are not stabilized (who presented under EMTALA), but that it would not otherwise apply to inpatients. We indicated that individuals whose conditions go in and out of apparent stability rapidly and frequently would not be considered "stabilized" and the hospital would continue to have an obligation to such individuals even after they are admitted. However, for all other inpatients we stated that EMTALA was intended to provide protection to individuals coming to a hospital to seek care for an EMC. Therefore, we stated that we believe the EMTALA requirements do not extend to stabilized inpatients even if they subsequently become unstable because those inpatients are protected by a number of Medicare conditions of participation (CoPs) as well as the hospital's other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

In the 2003 EMTALA final rule, we refined this position to state that a hospital's obligation under EMTALA ends either when the individual is stabilized or when that hospital, in good faith, admits an individual with an EMC as an inpatient in order to provide stabilizing treatment. That is, we stated that EMTALA does not apply to any

inpatient, even one who was admitted through the dedicated emergency department and for whom the hospital had initially incurred an EMTALA obligation to stabilize an EMC, and who remained unstabilized after admission as an inpatient. We noted that other patient safeguards protect all inpatients, including the hospital CoPs as well as State malpractice law. In addition, we noted that judicial interpretation of the matter and comments we received on the proposed rule helped shape the policy articulated in the final rule. However, we also stated in the rule that a hospital could not escape liability under EMTALA by admitting an individual with no intention of treating the individual and then inappropriately transferring or discharging that individual without having met the stabilization requirement.

B. EMTALA Technical Advisory Group Recommendation Regarding Responsibilities of Hospitals with Specialized Capabilities

Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, required the Secretary to establish a Technical Advisory Group (TAG) to advise the Secretary on issues related to the regulations and implementation of EMTALA. The EMTALA TAG's functions, as identified in the charter for the EMTALA TAG, were as follows:

- Review EMTALA regulations.
- Provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians.
- Solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations.
- Disseminate information concerning the application of these regulations to

hospitals, physicians, and the public.

The TAG met 7 times during its 30-month term, which ended on September 30, 2007. At its meetings, the TAG heard testimony from representatives of physician groups, hospital associations, and others regarding EMTALA issues and concerns. During each meeting, recommendations developed by subcommittees established by the TAG were discussed and voted on by members of the TAG. One of these recommendations, presented by the TAG to CMS during its September 2007 meeting, called for CMS to revise its regulations to address the situation of an individual who: (1) presents to a hospital that has a dedicated emergency department and is determined to have an EMC; (2) is admitted to the hospital as an inpatient for purposes of stabilizing the EMC; and (3) subsequently needs a transfer to a hospital with specialized capabilities to receive stabilizing treatment that cannot be provided by the referring hospital that originally admitted the individual. This recommendation can be found at the following website:

http://www.cms.gov/EMTALA/Downloads/EMTALA_Final_Report_Summary.pdf .

C. Applicability of EMTALA to Hospital Inpatients and Responsibilities of Hospitals with Specialized Capabilities

To further clarify our position on the applicability of EMTALA and the responsibilities of hospitals with specialized capabilities to accept appropriate transfers, the agency included as part of the April 30, 2008 Hospital IPPS proposed rule (73 FR 23669) entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules;

Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians" (hereinafter referred to as the FY 2009 IPPS proposed rule), two proposals that addressed the issue of hospital inpatients. First, we stated that we believe that the obligation of EMTALA does not end for all hospitals once an individual is admitted as an inpatient to the hospital where the individual first presented with a medical condition that was determined to be an EMC. Rather, once the individual is admitted, the admission only affects the EMTALA obligation of the hospital where the individual first presented (the admitting hospital). In the FY 2009 IPPS proposed rule (73 FR 23670), we stated that section 1867(g) of the Act (which refers to responsibilities of hospitals with specialized capabilities)

...requires a receiving hospital with specialized capabilities to accept a request to transfer an individual with an unstable emergency medical condition as long as the hospital has the capacity to treat that individual, regardless of whether the individual had been an inpatient at the admitting hospital.

We stated that we believe that permitting inpatient admission at the admitting hospital to end EMTALA obligations for another hospital would seemingly contradict the intent of section 1867(g) of the Act to ensure that hospitals with specialized capabilities provide medical treatment to individuals with EMCs in order to stabilize those conditions. We further noted that while a hospital inpatient is protected under Medicare CoPs and may also have additional protections under State law, the obligations of another hospital under the CoPs apply only to that hospital's patients, and there is no CoP that requires a hospital to accept the transfer of a patient from another facility. We proposed to interpret section 1867(g) of the Act as creating an obligation on hospitals with specialized capabilities to accept appropriate transfers of individuals for whom the

admitting hospital originally had an EMTALA obligation under section 1867 of the Act, if the hospital with specialized capabilities has the capacity to treat the individuals. Thus, in the FY 2009 IPPS proposed rule (73 FR 23670), we proposed to amend the regulations

...to add a provision to state that when an individual covered by EMTALA was admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the individual.

We received many comments opposing the proposal concerning hospitals with specialized capabilities included in the FY 2009 IPPS proposed rule. The commenters stated that the proposed rule would effectively "reopen" EMTALA for the admitting hospital by extending EMTALA's requirements for an "appropriate transfer" despite the fact that the admitting hospital's general EMTALA obligations ended, under regulation, when it admitted an individual as an inpatient. The commenters also stated that, because the original admitting hospital may claim that it lacks the capability to stabilize the individual's EMC, finalizing the proposed policy would result in an increase in patient dumping and inappropriate transfers, especially to teaching hospitals, tertiary care centers, and urban safety net hospitals. Commenters further asserted that finalizing CMS' policy as proposed would exacerbate confusion surrounding the determination of whether an individual is considered stable. That is, the hospital would be required to continuously monitor the individual to determine if at any point in the emergency department or even as an inpatient, the individual experienced a period of stability since such stability would end EMTALA obligations for all hospitals that might otherwise have obligations under the law. Under this scenario, the commenters asserted that the hospital

with specialized capabilities would be forced to accept the transfer of an individual, potentially increasing the number of inappropriate or unnecessary transfers, because that hospital would be unable, with complete certainty, to determine whether the individual being transferred had ever experienced a period of stability.

As a result, in the August 19, 2008 IPPS final rule (73 FR 48659) entitled, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals" (hereinafter referred to as the FY 2009 IPPS final rule) we stated that,

Due to the many concerns that the commenters raised which are noted above, we believe it is appropriate to finalize a policy to state that if an individual with an unstable emergency medical condition is admitted, the EMTALA obligation has ended for the admitting hospital and even if the individual's emergency medical condition remains unstabilized and the individual requires special services only available at another hospital, the hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual.

Put another way, we finalized a policy that a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of an individual who has been admitted in good faith as an inpatient at the first hospital. In the FY 2009 IPPS final rule (73 FR 48659), we stated that we believe that,

...finalizing the policy as proposed may negatively impact patient care, due to an increase in inappropriate transfers which could be detrimental to the physical and psychological health and well-being of patients [and we were] concerned that finalizing our proposed rule could further burden the emergency services system and may force hospitals providing emergency

care to limit their services or close, reducing access to emergency care.

In addition, we stated that we were concerned about the possible disparate treatment of inpatients under the proposed policy because an individual who presented to a hospital under EMTALA might have different transfer rights than an inpatient who was admitted for an elective procedure. In the FY 2009 IPPS final rule (73 FR 48659) we stated--

[W]e believe that, in the case where an individual is admitted and later found to be in need of specialized care not available at the admitting hospital, hospitals with specialized capabilities generally do accept the transfer, even in the absence of a legal requirement to do so.

Finally, while we adopted a final rule that limits the EMTALA responsibilities of a hospital with specialized capabilities (73 FR 48661), we

...encourage[d] the public to make CMS aware if this interpretation of section 1867(g) of the Act should result in harmful refusals by hospitals with specialized capabilities to accept the transfer of inpatients whose emergency medical condition remains unstabilized, or any other unintended consequences.

D. Litigation Related to the Applicability of EMTALA to Hospital Inpatients

We are aware that there continues to be a range of opinions, even at the Federal circuit court level, on the topic of EMTALA's application to inpatients. For example, in *Thornton v. Southwest Detroit Hospital*, 895 F.2d 1131, 1134 (6th Cir. 1990), the Sixth Circuit stated that, "once a patient is found to suffer from an [EMC] in the emergency room, she cannot be discharged until the condition is stabilized...." However, other courts have concluded that a hospital's obligations under EMTALA end at the time that a hospital admits an individual to the facility as an inpatient. (See *Bryan v. Rectors and Visitors of the University of Virginia*, 95 F.3d 349 (4th Cir. 1996) and *Bryant v. Adventist Health System/West*, 289 F.3d 1162 (9th Cir. 2002)). More recently, in *Moses v. Providence Hospital and Medical Centers Inc.*, 561 F.3d 573 (6th Cir. 2009), the Sixth

noted that the policy articulated in the 2003 EMTALA final rule that a hospital's obligation under EMTALA would end when that hospital, in good faith, admits an individual with an EMC as an inpatient was contrary to the plain language of the EMTALA statute. Rather, the court stated that a hospital's EMTALA obligations to an individual continue until that individual's EMC is stabilized regardless of the individual's status as an inpatient or outpatient.

E. Advance Notice of Proposed Rulemaking: Applicability of EMTALA to Hospital Inpatients and Hospitals with Specialized Capabilities

In 2010, United States Solicitor General advised the Supreme Court that HHS had committed to initiating a rulemaking process to reconsider the policy articulated in its current regulations, which state that a hospital's EMTALA obligations end upon the good faith admission as an inpatient of an individual with an EMC. In the December 23, 2010 **Federal Register** (75 FR 80762), we published an advance notice of proposed rulemaking (ANPRM) entitled "Medicare Program; Emergency Medical Treatment and Labor Act: Applicability to Hospital and Critical Access Hospital Inpatients and Hospitals With Specialized Capabilities" to solicit comments regarding whether we should revisit the policies established in the 2003 EMTALA final rule and the FY 2009 IPPS final rule. In addition, we sought real world examples that would inform our understanding of the current policy's impact on patients' access to care for an EMC. We noted that we would find it particularly helpful whether commenters could submit specific real-world examples that demonstrate if it would be beneficial to revisit these policies. We stated (75 FR 80765) that we--

...are interested in hearing whether commenters are aware of situations where an individual who presented under EMTALA with an unstable

EMC was admitted to the hospital where he or she first presented and was then transferred to another facility, even though the admitting hospital had the capacity and capability to treat that individual's EMC.

We further stated (75 FR 80765) that we were "...interested in receiving information regarding the accuracy of our statement in the August 19, 2008 IPPS final rule that a hospital with specialized capabilities would accept the transfer of an inpatient with an unstabilized EMC absent an EMTALA obligation." Lastly, we stated (75 FR 80765) that we were interested in learning whether commenters were "...aware of situations where an individual with an unstabilized EMC was admitted as an inpatient and continued to have an unstabilized EMC requiring the services of a hospital with specialized capabilities that refused to accept the transfer of the individual because current policy does not obligate hospitals with specialized capabilities to do so."

II. Provisions of the Request for Comments

A. Applicability of EMTALA to Hospital Inpatients

In the 2003 EMTALA final rule, we took the position that a hospital's obligation under EMTALA ends when that hospital, in good faith, admits an individual with an unstable emergency medical condition as an inpatient to that hospital. In that rule, we noted that other patient safeguards including the CoPs as well as State malpractice law protect inpatients. In response to our request for comments in the ANPRM as to whether we should revisit the policies that were established in the 2003 EMTALA final rule, very few commenters took the position that the admitting hospital should continue to have an EMTALA obligation after the individual is admitted as an inpatient. While some commenters advocated extending EMTALA to inpatients who do not experience a period of stability, the commenters did not provide any evidence that the existing policy has

resulted in patients being admitted and then subsequently discharged before they were stable, adversely affecting the clinical outcome of those patients. Most commenters expressed support for the current policy that EMTALA does not apply to any inpatient of a hospital, even a patient who was admitted through that hospital's dedicated emergency department and continues to be unstable. These commenters referred to our 2003 EMTALA final rule and concurred with our assessment that, under our existing policy, the numerous hospital CoPs that protect inpatients as well as inpatients' rights under State law afford individuals admitted to a hospital with sufficient protection. Moreover, commenters appreciated the clarity and predictability of a bright line policy. Commenters also noted that our current policy regarding inpatients is achieving Congress' intent by ensuring that every individual, regardless of their ability to pay for emergency services, should have access to hospital services provided in hospitals with emergency departments.

Therefore, in light of the comments we received regarding the extension of the EMTALA obligations for hospitals admitting an individual through their dedicated emergency departments, we are not proposing to change the current EMTALA requirements for these hospitals. That is, we are maintaining our current policy that, if an individual "comes to the [hospital's] emergency department," as we have defined that term in regulation, and the hospital provides an appropriate medical screening examination and determines that an EMC exists, and then admits the individual in good faith in order to stabilize the EMC, that hospital has satisfied its EMTALA obligation towards that patient. We continue to believe that this policy is a reasonable interpretation of the EMTALA statute and is supported by several Federal courts that have held that an

individual's EMTALA protections end upon admission as a hospital inpatient. For further explanation, we refer readers to the 2003 EMTALA final rule (68 FR 53244), in which we finalized the policy that a hospital's EMTALA obligations end upon admission.

B. Applicability of EMTALA to Hospitals with Specialized Capabilities

The second issue upon which the ANPRM solicited comment was, whether EMTALA should apply to situations where a hospital seeks to transfer an individual, who was admitted by that hospital as an inpatient after coming to the hospital's dedicated emergency department with an EMC, to a hospital with specialized capabilities because the admitted inpatient continues to have an unstabilized EMC that requires specialized treatment not available at the admitting hospital. Under current regulations, if an individual comes to the hospital's dedicated emergency department, is determined to have an EMC, is admitted as an inpatient, and continues to have an unstabilized EMC which requires the specialized capabilities of another hospital, the EMTALA obligation for the admitting hospital has ended and a hospital with specialized capabilities also does not have an EMTALA obligation towards that individual.

Although we received some comments that supported amending the current regulations to require hospitals with specialized capabilities to accept the appropriate transfer of an inpatient who had presented to the admitting hospital under EMTALA and requires specialized capabilities to stabilize his or her EMC not available at the admitting hospital, most comments supported making no change to the current policies regarding the applicability of EMTALA to hospitals with specialized capabilities.

Therefore, at this time, we are making no proposals with respect to our policies regarding the applicability of EMTALA to hospitals with specialized capabilities. However, we will continue to monitor whether it may be appropriate in the future to reconsider this issue. Thus, we are providing a 60-day comment period to allow the public to submit data or real world examples that are relevant to this issue.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble. If we proceed to issue a subsequent document on the issues raised therein, we will respond to those comments in the preamble to that document.

CMS-1350-NC

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774)

Dated: January 9, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: January 26, 2012

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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