

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 489

[CMS-1350-ANPRM]

RIN 0938-AQ51

Medicare Program; Emergency Medical Treatment and Labor Act: Applicability to Hospital and Critical Access Hospital Inpatients and Hospitals with Specialized Capabilities

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

ACTION: Advance notice of proposed rulemaking with comment.

SUMMARY: This advance notice of proposed rulemaking announces the intention of CMS to solicit comment on the need to publish a proposed rule to address two policies related to the Emergency Medical Treatment and Labor Act (EMTALA). Specifically, this document serves as a request for comments regarding our need to revisit the policies articulated in the September 9, 2003 **Federal Register** (68 FR 53243) and the August 19, 2008 **Federal Register** (73 FR 48656) concerning the applicability of EMTALA to hospital inpatients and the responsibilities of hospitals with specialized capabilities, respectively.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1350-ANPRM. 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-ANPRM,
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-ANPRM,
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) 786-7195 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 FURTHER INFORMATION CONTACT:

Renate Dombrowski (410) 786-4645.

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. Overview

We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on the need to revisit through a notice of proposed rulemaking CMS' current policy on the applicability of the Emergency Medical Treatment and Labor Act (EMTALA). Specifically, this notice concerns the applicability of EMTALA to

individuals who are determined in the hospital's dedicated emergency department to have an emergency medical condition (EMC) who, prior to being stabilized, are subsequently admitted to the hospital as inpatients, and then need to be transferred to another hospital with specialized capabilities for stabilizing treatment.

II. 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 advance notice of proposed rulemaking, 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 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 all Medicare and Medicaid payments. In addition, section 1867(d) of the Act provides for the imposition of civil monetary penalties on a hospital and physician who negligently violate 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 hospital and request examination or treatment for a medical condition. The section 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 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 these 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

Although the focus of EMTALA routinely involves the treatment of individuals who present to a hospital's dedicated emergency department with a request for treatment of a medical condition, concerns have also arisen about the applicability of EMTALA to hospital inpatients. We have previously discussed the applicability of EMTALA to hospital inpatients in the May 9, 2002 Hospital Inpatient Prospective Payment System (IPPS) proposed rule (67 FR 31475) and the September 9, 2003 stand-alone final rule on EMTALA (68 FR 53243).

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 May 9, 2002 proposed rule, we proposed that EMTALA continue 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 believed the EMTALA requirements did 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 September 9, 2003 stand-alone final rule on EMTALA, we refined this position to state that a hospital's obligation under EMTALA ends either when the individual's EMC is stabilized or when that hospital, in good faith, admits an individual with an unstable EMC as an inpatient. That is, we stated that EMTALA does not apply to any inpatient, even one who was admitted through the dedicated emergency department, for whom the hospital had initially incurred an EMTALA obligation to stabilize, 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, 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: (1) review EMTALA regulations; (2) provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians; (3) solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and (4) 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, subcommittees established by the TAG developed recommendations, which were then discussed and voted on by members of the TAG. One of these recommendations, presented by the TAG during its September 2007 meeting calls 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 unstabilized 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.

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 IPPS proposed rule (73 FR 23669) two proposals that addressed the issue of hospital inpatients. First in the proposed rule, we stated that we believed 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, we stated, 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 proposed rule, we proposed 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 EMC so long as the hospital has the capacity to treat that individual regardless of whether that individual was ultimately an inpatient at the admitting hospital. We stated that we believed 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. And 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 an admitting 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 April 30, 2008 IPPS proposed rule, we proposed that when an individual originally covered by EMTALA is admitted as an inpatient at that hospital and continues to have an unstabilized EMC, a hospital with specialized capabilities has an EMTALA obligation to accept a transfer of that individual, assuming that the transfer of the individual is an appropriate transfer and that 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 April 30, 2008 IPPS proposed rule. The commenters stated that the proposed rule would "reopen" EMTALA for an admitting hospital by extending EMTALA's requirements for an "appropriate transfer" despite the fact that the admitting hospital's 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 capacity or 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 admitting 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 or not the individual being transferred had ever experienced a period of stability.

As a result, in the August 19, 2008 IPPS final rule we stated that, due to the many concerns that the commenters raised, we believe it is appropriate to finalize a policy to state that if an individual with an unstable emergency medical condition is admitted as an inpatient, the EMTALA obligation has ended, even if the individual's EMC remains unstabilized and the individual requires treatment only available at a hospital with specialized capabilities. Put another way, we determined that a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of an individual who had been admitted in good faith as an inpatient at the first hospital. We stated that we believed that finalizing the proposed policy might negatively impact patient care, due to an increase in inappropriate transfers, that could be detrimental to the physical and psychological health and well-being of patients. We further stated that we were concerned that finalizing the proposed rule could further burden the emergency system and could force hospitals providing emergency care to limit their services or care, thereby reducing access to emergency treatment. 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. And we generally agreed that hospitals with specialized capabilities would accept the transfer of an inpatient with an unstable EMC even if there was no legal requirement under EMTALA to do so. We also noted that the recommendation provided by the TAG to apply EMTALA to hospital inpatients was endorsed by the group on the narrowest of margins, and that the majority of hospital representatives serving on the TAG were opposed to the recommendation. And while we adopted a final rule that limits the EMTALA responsibilities of a hospital with specialized capabilities, we encouraged the public to make us aware if the interpretation of section 1867(g) of the Act as set forth in the rule resulted in harmful refusals by hospitals with specialized capabilities to accept the transfer of inpatients whose EMC remains unstabilized or any other unintended consequences.

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

There have been several court cases involving the applicability of EMTALA to hospital inpatients. For example, in Thorton 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), Bryant v. Adventist Health System/West, 289 F.3d 1162 (9th Cir. 2002), and Harry v. Marchant, 291 F.3d 767 (11th Cir. 2002).) In Lima-Rivera v. UHS of Puerto Rico Inc., (D.P.R. No. 04-1798, 2007), the U.S. District Court for the District of Puerto Rico rejected the claim that EMTALA does not apply to inpatients. Most recently in Moses v. Providence Hospital and Medical Centers Inc., 561 F.3d 573 (6th Cir. 2009), the court concluded 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.

III. Intention of this Notice

We are aware that there continues to be a range of opinions even at the Circuit Court level on the topic of EMTALA's application to inpatients. There also continues to be various opinions regarding whether EMTALA should apply to situations where a hospital seeks to transfer an individual, admitted as a hospital inpatient after seeking treatment for an EMC, to a hospital with specialized capabilities because the admitted inpatient continued to have an unstabilized EMC that required specialized treatment. Therefore, we are interested in receiving comments that address whether we should revisit the policies that were established in the September 9, 2003 final rule on EMTALA and the August 19, 2008 IPPS final rule, respectively.

We would find it particularly helpful if commenters could submit specific real world examples that demonstrate whether it would be beneficial to revisit the policies articulated in the September 9, 2003 final rule on EMTALA or the August 19, 2008 IPPS final rule. We also 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 are also 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. Specifically, we would be interested to know if commenters are 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.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. 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, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--
Hospital Insurance)

Dated: November 18, 2010

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 14, 2010

Kathleen Sebelius,

Secretary.

Department of Health and Human Services.

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