Avoiding the EMTALA Financial Squeeze: Real World Lessons Learned

by Frank R. Ciesla, Esq. and Beth Christian, Esq.

It is Friday afternoon before a long holiday weekend. Your thoughts have turned to the well-earned relaxation you will enjoy over the next few days. The feeling quickly evaporates as you are handed a faxed letter from the Centers for Medicare and Medicaid Services ("CMS") advising you that your facility has been found out of compliance with the Medicare Conditions of Participation for Hospitals due to an alleged EMTALA violation. How you respond can affect not only your hospital's continuing viability as a Medicare provider, but also the amount of potential civil monetary penalties that may be imposed by the Office of Inspector General.

The preparation of a facility's response to a letter alleging the existence of an EMTALA violation should actually start months before the formal letter alleging a violation is received. Typically, the initiation of an EMTALA investigation begins when surveyors from the New Jersey Department of Health and Senior Services (acting as agents of the federal government) arrive at the facility to do an unannounced survey. 42 C.F.R. §488.10. The survey is generally initiated in one of two ways. Under federal regulations, a hospital is required to contact CMS or the state survey agency whenever it suspects it may have received an improperly transferred individual from another hospital. 42 C.F.R. §489.20(m). Alternatively, a patient or a patient's family member may file a complaint with the Department of Health and Senior Services. The survey is always unannounced.[1] The purpose of the survey is to determine whether a violation took place, whether the violation constitutes an immediate and serious threat to patient health and safety, to identify any patterns of violations at the facility, and to assess whether the facility has policies and procedures in place to address EMTALA. Id.

The survey will typically consist of a record review, interviews with staff, an evaluation of the emergency department (and possibly other) areas, an entrance conference and an exit conference. Interpretive Guidelines, 7-13, Part I, §III-§VII. The entrance conference is held with the CEO/President of the hospital (or his/her designee) when the surveyors arrive. Interpretive Guidelines, p. 7. At that time, the surveyors will ask the CEO to have the staff provide them with a variety of documents, including, but not limited to, emergency department logs, policies and procedures, meeting minutes, bylaws, credential files, staffing schedules, on-call lists, quality assurance and performance improvement minutes and materials, consent forms, and in-service training program records and schedules. Interpretive Guidelines, Part I, §III. The surveyors also select a sample of medical records for review that are identified by the surveyors during their review of the emergency department log. A sample of 20-50 records is typically selected. Interpretive Guidelines, Part I, §IV. Facility staff, such as nurses, the director of quality improvement, physicians, and admitting clerks will also be interviewed. Interpretive Guidelines, Part I, §VI.

Once the record reviews, interviews, and evaluation of the emergency department are completed, an exit conference will be conducted. Interpretive Guidelines, Part I, §VII. At that time, the surveyors will inform the hospital of the scope and consequences of a potential violation. While the surveyors will complete a Statement of Deficiencies (also known as a Form CMS 2567) while they are at the facility, they are not permitted to leave a copy with

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the hospital. Id. In addition, the surveyors are not permitted to tell the hospital whether or not a violation was identified, since it is the responsibility of CMS to make a final determination regarding the existence of a violation. Id.

While the survey process can be a stressful one, being as organized as possible under the circumstances will be helpful. It is important for staff members to work diligently to provide copies of any documentation requested by the surveyors. If a document which is requested by the surveyors cannot be produced while they are at the facility, the facility can be found to be in violation of EMTALA. It is also appropriate to have a member of the hospital's administration walk around the emergency department (and any other part of the facility) with the surveyors. Taking detailed notes during the exit conference and asking questions about the factual findings made by the surveyors is also crucial. To the extent the existence of any potential deficiencies is suggested by the surveyors, the hospital should immediately begin work on implementing a corrective action plan that will be responsive to the deficiencies identified. The more information that is collected by the hospital during the surveyor's tour of the facility and the exit conference, the easier it will be for the hospital to respond to a later CMS finding of an EMTALA violation.

Once the surveyors leave, it is important for the facility to assemble a working group which will be responsible for implementing any changes needed to address potential deficiencies identified by the state surveyors. The working group or committee should work regularly to ensure that deficiencies are addressed. Hospital legal counsel should be included as part of this process, since questions involving the EMTALA law and regulations and the CMS Interpretive Guidelines can often arise. In addition, documentation should be made of any corrective measures taken. For example, if the surveyors indicate that there are problems with proper completion of the EMTALA transfer certification form which is signed by the transferring physician, in-service training should be provided to emergency department staff (and possibly staff from other clinical departments as well), and records of each staff member's attendance should be maintained. Minutes of the meetings of the working group/committee (as well as all other committees addressing EMTALA issues) should be kept, and all documentation relating to corrective actions taken should be maintained in a central location. This will prove helpful if the facility receives a letter notifying it that CMS has found the existence of an alleged EMTALA violation.

If CMS determines that an alleged EMTALA violation exists, it can either place the facility on a 23 day termination track or a 90 day termination track. The 23 day termination track is reserved for situations where CMS has determined that the provider has exhibited a course of conduct which represents an immediate and serious threat to patient health and safety. Medicare State Operations Manual §3010 (hereinafter "State Operations Manual"). Under the processing for a 23 day termination, a facility typically will not get the letter announcing the proposed termination until five days into the termination period. State Operations Manual §3010B. In addition, during the time period between the receipt of the letter from CMS and the 23rd day, the hospital must submit a Plan of Correction to CMS and have the Plan of Correction accepted by CMS. Id. Because CMS needs time to review the Plan of Correction and respond to the facility, the Plan of Correction must be submitted to CMS several days before the effective date of termination in order to give CMS time to review it and get back to the facility with its findings following the review.

Because of these short time frames and the significant adverse financial impact that termination of a Medicare provider agreement can have upon a facility, it is crucial to submit a thorough response to CMS to document that the hospital has initiated corrective action with respect to all of the items listed in

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the Statement of Deficiencies. The hospital's working group (including hospital legal counsel) should be reassembled. The facility should review each and every allegation contained in the Statement of Deficiencies and ensure that it has documentation to establish that each deficiency has been addressed. The date of the corrective action taken (which must be after the date of the survey but can be before the date of the hospital's receipt of the Statement of Deficiencies) must be set forth in the hospital's Plan of Correction.

Under a 23 day termination track, the facility will often have less than a week to pull its response together. Therefore, sufficient resources should be dedicated to compiling the Plan of Correction response to ensure that any items identified in the Statement of Deficiencies which have not already been addressed by the hospital are attended to immediately. Hospital counsel experienced with drafting these types of responses should be assigned the task of working with the hospital's working group to prepare a complete and thorough response. An "evidence book" which can be assembled in the form of a three-ring binder with tabs, should be assembled. The evidence book should be organized with tabs that include the documentation being submitted in support of the hospital's response to an identified deficiency and corresponding to the ID prefix tags contained in the Statement of Deficiencies. Typing and photocopying resources should also be lined up for preparing the Plan of Correction. The working group should meet at regular daily intervals to insure that progress is being made towards completion of a response. Because the press often becomes aware of the existence of a potential EMTALA violation, it is important to make the hospital's communications staff aware of the identification of an alleged EMTALA violation so that press inquiries can be responded to appropriately.

Once the Statement of Deficiencies is submitted, CMS will review it to determine whether or not it is acceptable. If it is not acceptable, the facility will be notified prior to the 23rd day that compliance has not been achieved, and that they will be terminated from participation in the Medicare and Medicaid programs. 42 C.F.R. §488.456. While this sort of termination is rare, it is not unheard of. If CMS finds that the immediate threat to patient health and safety has been removed, or if an EMTALA violation is initially found which is not determined to be an immediate threat to patient health and safety, the facility will be placed on a 90 day termination track instead.

> ...the identification of an EMTALA violation can have a significant financial impact upon a hospital.

Medicare State Operations Manual §3012. The 90 day time period is somewhat deceptive, as the facility actually has less time to submit an acceptable Plan of Correction. Under the 90 day termination track protocol, the state agency must conduct a revisit to determine whether compliance or acceptable progress has been made. Only two revisits are permitted: one within 45 calendar days and one between the 46th and 90th calendar day. Id. Following the revisit surveys, CMS makes a final determination as to whether or not compliance has been achieved.

Even if a hospital submits an acceptable Plan of Correction to CMS and CMS rescinds its proposed termination of the hospital's provider agreement, the hospital's potential financial exposure from an alleged violation of EMTALA does not end. In many cases, a summary of an EMTALA violation will be referred to an independent physician reviewer who is affiliated with a Medicare Quality Improvement Organization (QIO). 42 C.F.R. §489.24(h). A physician review of the record will always be conducted prior to the proposed imposition of EMTALA civil monetary penalties by the HHS Office of Inspector General. Therefore, if a facility receives a letter from a QIO stating that it is in the process of reviewing the medical charts of patients who were the subject of an alleged EMTALA violation, the case is being referred to the Office of Inspector General for the potential imposition of civil monetary penalties.

The physician review is usually initiated by a review of the medical record by a physician with expertise in emergency medicine (or the specialty of the attending physician involved in a patient transfer that was potentially violative of EMTALA). Following the record review, the physician reviewer will send a letter to the facility setting forth his or her tentative findings regarding the nature and scope of the violation. The facility will then be given an opportunity to respond in writing or to request an informal hearing which can be conducted either by telephone or in person. 42 C.F.R. §489.24(h)(2). The facility must submit any additional information within 30 days of the QIO's letter or will be deemed to waive its rights to respond. Id.

The informal hearing is an opportunity to present the hospital's side of the story in a way that cannot always be obtained from a review of a paper record. Therefore, it is typically to the hospital's advantage to request an in-person

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hearing. The hospital should attend the hearing with witnesses who can discuss the case with the physician reviewer. It is advisable to attend the hearing accompanied by legal counsel. It is important to meet with counsel prior to the informal hearing so that each person who may be presenting testimony can be prepared for what to expect at the hearing and be prepared for the format and the type of questions that can be asked. The hearing is tape recorded, but no court reporter or judge is present.

Following the hearing, the matter will be referred by the QIO to the Office of Inspector General ("OIG"), U.S. Department of Health and Human Services. At that time, the OIG and the Office of Counsel to the Inspector General will review the case file and determine whether or not it is appropriate to impose civil monetary penalties. While the EMTALA statute and regulations provide for the imposition of a maximum civil monetary penalty of up to $50,000, the amount of the penalty is **per violation.** 42 C.F.R. §1003.103(e). Thus, a hospital that is found to have committed EMTALA violations with respect to multiple patients could have penalties imposed which are significantly higher. For example, on October 23, 2003, SouthPointe Hospital in Missouri agreed to pay $100,000 to resolve its liability for civil monetary penalties under EMTALA. The OIG alleged that the hospital failed to provide appropriate medical screening examinations and/or stabilizing treatment for several individuals who presented to its emergency department. See http://oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitemspd.html. On August 5, 2003, Griffin Memorial Hospital in Oklahoma agreed to pay $80,000 to resolve its liability for civil monetary penalties under EMTALA. The OIG alleged that the hospital failed to provide appropriate medical screening examinations to seven individuals who presented to its emergency department with psychiatric complaints. Id.

Counsel to the OIG will initiate the process of imposing a civil monetary penalty through the issuance of a letter to the hospital. The letter will state the amount of the civil monetary penalty which would be imposed and will offer the hospital the opportunity to request an administrative hearing to contest the imposition of the penalty.

The overwhelming majority of EMTALA civil monetary penalty cases are settled. Because the OIG will be represented by counsel in the course of any settlement discussions, it is important for the hospital to also be represented by counsel. Typically, the OIG will have an initial conversation with the hospital's counsel and discuss the possibility of settlement of the civil monetary penalty case, since the civil monetary penalty regulations provide for the OIG to increase or decrease the amount of the civil monetary penalty depending upon the existence of aggravating or mitigating factors set forth in the regulations. See 42 C.F.R. 1003-106. The existence of a prior EMTALA violation is considered to be an aggravating factor. Id. It is important for the hospital's counsel to be thoroughly familiar with the record when negotiating a civil monetary penalty with the OIG. The OIG's counsel is likely to mention the problematic parts of the record in arguing for a higher penalty. Therefore, any mitigating factors that can be identified by hospital counsel (including, but not limited to, the absence of prior violations of the hospital) can be helpful to convince the OIG attorney that a lower penalty amount is appropriate. If the parties are able to negotiate a settlement, the settlement will be formalized in a settlement agreement which is signed by both the OIG and hospital representatives. The OIG will generally post a brief summary of the settlement dollar amount and the alleged EMTALA violation at the OIG website: http://oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitemspd.html. If a settlement is not achieved, the hospital may request a hearing before an administrative law judge. 42 C.F.R. §1005.2.

As can be seen from the foregoing discussion, the identification of an EMTALA violation can have a significant financial impact upon a hospital. Knowledge of the appropriate way to respond to an alleged violation can minimize the adverse impact, both from a financial and a public relations perspective.

About the authors:

Frank R. Ciesla is an officer and shareholder in the law firm of Giordano, Halleran & Ciesla. He has been involved in the provision of legal services to hospitals and other health care providers for over 30 years. He has worked with hospitals on a wide variety of EMTALA-related issues.

Beth Christian is an officer and shareholder in the law firm of Giordano, Halleran & Ciesla. She has been involved in the provision of legal services to hospitals and other health care providers for more than 15 years and has worked with a number of hospitals in responding to findings of alleged EMTALA violations. Prior to joining Giordano, Halleran & Ciesla, she served as an Assistant Regional Counsel with the U.S. Department of Health and Human Services' regional office in New York City where she worked with HCFA (now CMS) on a variety of issues, including Medicare survey and certification issues.