REPORT NUMBER SIX

to the

Secretary

U.S. Department of Health and Human Services

From the

Emergency Medical Treatment and Labor Act

Technical Advisory Group

Hubert H. Humphrey Building

Washington, DC

May 3–4, 2007

EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)
TECHNICAL ADVISORY GROUP (TAG)
Minutes
May 3–4, 2007

Welcome, Call to Order, and Opening Remarks

Chair David Siegel, M.D., J.D., called the meeting to order on Thursday, May 3, and welcomed the members of the TAG and the audience. He announced that Brian Robinson had resigned from the TAG and that a new hospital representative is being sought. Dr. Siegel reiterated the group's functions, as identified in the charter, and outlined the agenda for the meeting. (See Appendix A for the meeting agenda).

Summary Reports of On-Call and Action Subcommittees

John Kusske, M.D., chair of the On-Call Subcommittee, and Julie Mathis Nelson, J.D., chair of the Action Subcommittee summarized the work of the subcommittees since the TAG's November meeting and identified the topics they wished the TAG to address at this meeting (Appendices 1 and 2).

Responsibilities of Level-I Trauma Centers

Amos Stoll M.D., F.A.C.S., of Broward General Medical Center said that receipt of patients at his hospital from as far away as Tallahassee is overwhelming the capacity of the specialist physicians to provide the required care (Appendix 3). In particular, he said, neighboring Palm Beach County has gone through a crisis in neurosurgery coverage, and patients are being transferred to Broward, often with very poor results.

David J. Ciesla, M.D., of the Washington (D.C.) Hospital Center said he is concerned about an increase in transfers to trauma centers of patients who do not need level-I trauma care (Appendix 4). Since 2001, there has been an 80-percent increase in transfers to trauma centers and a 20-percent decrease in the severity of injured among patients being transferred. Because the resources (including emergency, inpatient, and rehabilitation services) of trauma centers are finite, receipt of patients who do not need the full range of services threatens to overwhelm the ability of trauma centers to function.

Dr. Ciesla recommended that hospitals be encouraged to participate in state or regional trauma systems with guidelines on which patients to transfer and when to transfer. Typically this triage would be done by pre-hospital personnel, with a secondary triage for patients who are mis-triaged. Because hospitals have a duty to accept emergency patients, but community hospitals have no corresponding responsibility to accept them back, it is virtually impossible to repatriate patients back to the community hospital once they no longer need level-I trauma care.

Jeffrey Anglen, M.D., representing the Orthopaedic Trauma Association and the American Association of Orthopaedic Surgeons, said that the difficulty in providing on-call coverage by specialists is leading to unnecessary transfers, delays in care, and worse outcomes (Appendix 5). Many hospitals in central Indiana do not have orthopedic surgeons on call and have to transfer patients to trauma centers. There, patients may spend 3–4 days in the emergency department

(ED) before being discharged home because no bed is available. The Orthopaedic Trauma Association has developed a policy statement that recommends making EMTALA as clear and simple as possible, liability reform, disproportionate share payments for physicians similar to those provided to hospitals, call sharing systems, and repatriation of patients back to their communities.

Telehealth and Telemedicine

Robert Waters of the Center for Telehealth & E-Health Law (CTeL) said that legal and regulatory barriers continue to limit the application of telemedicine and requested that CMS endorse the use of technology to communicate with on-call physicians, including phone, fax, email, and transfer of digital images (Appendix 6). Marilyn Dahl, Director of the Division of Acute Care Services, said that changes are in the pipeline in response to the TAG's recommendation in November 2006 that HHS strike the current language in the Interpretive Guidelines on telehealth/telemedicine and replace it with language that clarifies that the treating physician may use a variety of methods to communicate with the on-call physician.

Ms. Nelson noted that although the TAG recommended CMS adopt a more permissive stance on using telehealth and CMS agreed to review the issue, providers still have questions about when and how telehealth can be used for communication under the current Interpretive Guidelines.

Recommendation

The TAG recommends that HHS reach out to providers to remind them that they can contact their Regional Offices for clarification of the Interpretive Guidelines or any other regulations regarding EMTALA, such as acceptable uses of telehealth for communication under the current Interpretive Guidelines.

Psychiatric Medical Emergency

Ann Pfeiffer, R.N., M.S., said that many hospitals struggle with compliance with EMTALA, particularly for psychiatric patients (Appendix 7). In many states, local laws dictate that patients be placed within the state mental health system in opposition to EMTALA requirements. She requested further guidance for surveyors.

Emergency Transport Service and Requirements for All Hospitals to Provide Basic Emergency Services

Ms. Dahl reported that the CMS Survey and Certification Group had released two memoranda to state survey agency directors. A memorandum issued April 27, 2007, follows up on the TAG's request for clarification of the July 2006 letter on emergency transport services (Appendix 8). It states that hospitals may not condition their acceptance of an EMTALA-related transfer upon the sending hospital's agreement to use a specific transport service designated by the receiving hospital. It also clarifies that the ED may ask the emergency medical service to stay and monitor a patient, but that the hospital must deal with the patient expeditiously. Some TAG members found the terms "immediately upon arrival" and "triage" as used in the letter problematic.

A memorandum dated April 26, 2007, clarifies that all hospitals, even those that don't have an ED, are required to appraise medical emergencies and provide initial treatment and referral when appropriate as a Medicare Condition of Participation (Appendix 9). It is not appropriate for them

to call 911 and use emergency medical service as a substitute for their own capability to assess a patient, initiate treatment, and refer.

Pandemic and All-Hazards Preparedness Act
George Morey of CMS reported that HHS is seeking comment on a revision to the EMTALA regulations (section 489.24(a)(2))to reflect changes made by the Pandemic and All-Hazards Preparedness Act involving waivers of sanctions during public health emergencies (Appendix 10). Also included in the notice of proposed rulemaking is a provision requiring hospitals to notify patients in writing whether a physician is available on the premises 24 hours a day, 7 days a week. The public comment period is open until June 12, 2007.

Update on EMTALA TAG Recommendations
Mr. Morey reported that of the 22 recommendations formally adopted by the TAG, CMS has revised its regulations or Interpretive Guidelines to adopt four so far:

- Adopted language in the 2006 Inpatient Prospective Payment System final rule making explicit that all Medicare participating providers with specialized capabilities are required to accept an appropriate transfer if they have the ability to treat the individual.

- Revised regulations to permit, in accordance with state law and hospital bylaws, a qualified nonphysician clinician to certify that a woman is experiencing false labor as part of the 2006 Inpatient Prospective Payment System final rule.

- Addressed two issues involving patients arriving at a hospital by emergency transport in Survey and Certification memoranda (discussed above).

Two recommendations made by the TAG—that hospitals with specialized capabilities not be required to maintain an ED and that physicians not be required to take emergency call—are consistent with current law, so no further action is expected. Fifteen items are still under consideration. Dr. Siegel expressed the TAG's appreciation for CMS's work on these items and the rapid action on regulatory issues.

On-Call Subcommittee Report

The On-Call Subcommittee presented a draft document, "Adequate and Appropriate Call Lists," describing a rationale and proposed recommendation for determining what is an adequate or appropriate call list (Appendix 11). The document recommends restoring language used in the Interpretive Guidelines prior to the 2003 change to EMTALA regulations which stated, "If a hospital offers a service to the public, this service should be available through the on-call coverage of the emergency department." In the 2003 revision, CMS stated it would consider all relevant factors in determining whether a call schedule is adequate; the unfortunate result has been greater ambiguity and uncertainty. The subcommittee concluded that establishing "safe harbors" as recommended by Alan Steinberg and Susan Lapenta of the law firm Horty, Springer, and Mattern would have similar results (Appendix 12). Because not all hospitals have EDs, members agreed the language should be modified to say "through on-call coverage of emergencies."

The subcommittee also recommended nonregulatory approaches, such as support for community call sharing arrangements and regionalization of emergency care, for maintaining adequate call schedules. The Emergency Medical Services Authority system in Oklahoma provides a successful model (Appendix 13). Members agreed that hospitals should be able to satisfy their on-call coverage through participation in a CMS-approved community call program.

The subcommittee presented a draft document, "Best Meets the Needs…," describing a rationale and proposed recommendation to eliminate the requirement that hospitals maintain an on-call list that "best meets the needs of the hospital's patients who are receiving services…" (Appendix 14). The subcommittee proposed changing the language in the Interpretive Guidelines at §489.24(j)(1), to ensure there is adequate medical staff participation in the planning of call schedules. Members agreed that the "best meets the needs" language should be replaced but that it was not the TAG's role to suggest the precise wording.

The TAG considered and approved the On-Call Subcommittee's recommendations as further refined during discussion.

Recommendation:

The TAG reiterates its previous recommendation that HHS move 42 C.F.R. 489.24(j)(1), the provision dealing with maintaining a list of on-call physicians, to 42 C.F.R. 489.20(r)(2), which relates to the Medicare provider agreement.

The TAG recommends HHS change 42 C.F.R. 489.20(r)(2) to read: "Each hospital must maintain an on-call list of physicians on its medical staff who are available to examine and stabilize the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians."

The TAG recommends HHS change the Interpretive Guidelines to state the following:

- If a hospital offers a service to the public, this service should be available for emergency care through on-call coverage.
- To satisfy the requirement for on-call coverage, at least annually, hospital and medical staff must develop a plan for on-call coverage that includes, at a minimum, evaluation of the following factors:
  - hospital capabilities/services provided (advertised/licensed)
  - community need for ED services as determined by ED visits
  - transfers out of hospital for emergency services
  - physician resources
  - past call plan performance
- The hospital must have a backup plan for patient care when it lacks capacity to provide services or on-call physician coverage is not available. The backup plan should consist of viable patient care options, such as the following:
  - telemedicine
  - other staff physicians

    - transfer agreements designed to ensure that the patient will receive care in a timely manner
    - regional or community coverage arrangements
- A hospital may satisfy its on-call coverage obligation by participation in an approved community/regional call coverage program (*CMS to determine appropriate approval process*).

EMTALA Education

The Action Subcommittee presented a draft document, "EMTALA Education Recommendations," that suggests ways of improving public information and professional education about EMTALA (Appendix 2). Ms. Nelson suggested eliminating the recommendation for patient education about use of social security numbers and citizenship documentation in order to receive payment for care rendered to undocumented patients. Members approved the recommendations, as amended.

Recommendation:

The TAG recommends that HHS take the following steps to improve understanding about EMTALA:

<u>More Comprehensive, Prominent, User-Friendly CMS EMTALA Website, including the following:</u>

- Statutes
- Regulations
- Interpretive guidance
- Current CMS/Office of the Inspector General (OIG) program memoranda/guidance letters
- EMTALA questions and answers
- Link to Medicare Conditions of Participation
- Enforcement statistics
- "Top 10" cited EMTALA deficiencies
- Special advisories of potential EMTALA violations
- Link to OIG website
- Topical cross-references
- EMTALA 101 "basics"
- Document downloads

<u>Standardized Regional Office/State Surveyor Education</u>

- Institute annual EMTALA surveyor education sessions (currently offered every 2 years).
- Establish a system to improve consistency in Regional Office EMTALA interpretations and enforcement (e.g., assign CMS central office person to monitor deficiency statements for consistency with CMS policy and consistency among jurisdictions and remedy concerns).
- Establish a system to monitor effectiveness of surveyor education.
- Establish a system to demonstrate surveyor competencies.

- Confirm prompt distribution of CMS EMTALA guidance, including EMTALA opinion letters and program memoranda, to Regional Offices and state agencies.

Provider Education

- Designate/approve specific CMS/OIG personnel to participate in provider education through various educational forums (e.g., American Health Lawyers Association, hospital/physician association meetings). Consider joint presentations by both agencies and establish a process to confirm consistency of information provided.
- Ensure a timely response to provider queries regarding EMTALA compliance and interpretation questions.
- Establish a timely process to address new obstacles to EMTALA compliance and remedy through regulatory or interpretive guidance change.
- Establish listservs or other mechanism so that interested parties can receive regular updates and information regarding EMTALA from CMS/OIG.
- Consider EMTALA training by quality improvement organizations (QIOs).

Patient Education

- Provide information about EMTALA rights and consequences (e.g., EMTALA requires hospitals to provide care irrespective of the patient's ability to pay; however, the hospital may still expect the patient to pay for services rendered). This information should be provided outside of the context of an ED visit.

Definitions of Capacity and Capability

Ms. Nelson presented the Action Subcommittee's draft recommendation and rationale for clarifying the distinction between capability and capacity (Appendix 2).

Enforcement

Ms. Dahl gave an overview and provided background materials on EMTALA enforcement for the TAG's information (Appendix 15). She described the process Regional Offices take in investigating complaints, the hospital's options for challenging a Regional Office's decision, and the types of enforcement actions CMS can take. In presenting statistical data, Ms. Dahl cautioned that the number of complaints should be taken into consideration when dramatic changes in the percentage of complaints are seen. Ms. Dahl was unsure about how much detail her office could provide about specific types of violations and said that breaking down the data into types of violations would yield "a very complicated report."

Ferdinand Richards III, M.D., chair of the American Health Quality Association's EMTALA Workgroup, testified on behalf of QIOs (Appendix 16). He offered several recommendations to improve the consistency, transparency, and efficiency of EMTALA enforcement efforts nationally. The TAG discussed recommendations put forth by the Action Subcommittee in light of Ms. Dahl's and Dr. Richards' comments.

Recommendations

The TAG recommends that HHS establish an appeals process for hospitals/providers before making a termination decision.

a. Hospitals should be allowed to request QIO review for medical issues prior to termination.
b. Hospitals should be allowed to request an appeal from the CMS Regional Office on factual, policy, and legal issues before submission of a plan of correction or a decision to terminate. For example:
   i. If the Regional Office believes a violation has occurred, a hospital is first given a draft statement of deficiencies, after which it has 10 days to provide CMS with any objections or additional information. CMS would have 10 days to consider the additional information and issue a final statement of deficiencies that responds to it. An expedited appeals process should be in place for hospitals to be placed on a 23-day termination track.
   ii. Region VI process (to be submitted by TAG member Dodjie Guioa).

The TAG recommends that HHS establish intermediate sanctions, such as an opportunity to correct with follow-up inspection or a system of warnings, for less serious EMTALA violations. Hospitals with technical violations (e.g., signage, log books) should receive lower sanctions.

The TAG recommends that HHS establish a method for consistent data collection of all EMTALA violations and central evaluation of the information, in a format determined by CMS to improve consistency of enforcement across the regions and that can serve as a resource for providers.

Framework Subcommittee Papers

Charlotte Yeh, M.D., chair of the Framework Subcommittee, reiterated that students from the Harvard University School of Public Health and the Johns Hopkins University School of Public Health helped research and write papers on four subject matter areas that were beyond the scope of the TAG but affect compliance with EMTALA. For each of the four areas, *Reimbursement*, *Liability*, *Capacity*, and *Disparities in Care*, Dr. Yeh instructed the writers to focus on the issue from the perspective of EMTALA compliance, to be as objective as possible, and to provide evidence to support assertions and opinions.The *Capacity* area was broken down into two topics, *Workforce Capacity* and *Inpatient Hospital Capacity*, and a separate paper was prepared for each topic. In addition to the students who worked on the papers, Dr. Yeh thanked Megan Cosgrove for her help in coordinating the subcommittee's efforts. Dr. Yeh welcomed comments that would help fine-tune the papers but said substantial revisions could not be undertaken. Comments should be emailed to Dr. Yeh as soon as possible.

Reimbursement

Carly Cammarata gave an overview of the *Reimbursement* paper and acknowledged the assistance of Harvard University student Christine Parkins in revising it. TAG member Warren Jones, M.D., suggested adding a recommendation that CMS extend the upper payment limits for treating Medicare and Medicaid patients. TAG member James Nepola, M.D., asked that a recommendation be added to increase the payment to physicians for treating patients who fall under the EMTALA regulations.

Liability
Shannon Mills gave an overview of the *Liability* paper, noting that perceptions surrounding professional liability insurance were changing rapidly. Dr. Yeh emphasized that the paper will reflect the dissonant views on the effect that taking call in the ED has on professional liability.

Capacity
Carrie Williams Bullock presented an overview of the *Workforce* paper. TAG member Cesar Aristeiguieta, M.D., suggested the paper note that the health care industry has been very inaccurate in its predictions on the supply of physicians. TAG members David Tuggle, M.D., and Rory Scott Jaffe, M.D., suggested adding a recommendation about training surgeons to act as surgical hospitalists as one component of addressing workforce shortages. Dr. Siegel asked that the document reference legislative efforts to address the health care workforce shortage.

Cara Demmerle outlined the issues dealt with in the *Inpatient Hospital Capacity* paper. Ms. Nelson noted that hospital throughput is a response to overcrowding in the ED, and lack of efficient throughput is not the cause of overcrowding. TAG member Mark Pearlmutter, M.D., said the effect of hospital throughput on capacity is a subject of debate. He suggested the writer contact the Heller School at Brandeis University and the Center for Studying Health System Change for more data on oversupply of beds in some markets and asked that the definition of boarding be clarified in the paper. Dr. Jones suggested adding text on how state policies on certificates of need affect inpatient bed capacity.

Disparities
Edward Garcia and Maik Schutze described the challenge of addressing the complex issue of disparities because of the lack of data on disparate care in the ED. Mr. Garcia noted that the paper seeks to go beyond access and income to address disparities in care according to gender, race, citizenship status, and disease. Ms. Nelson asked that the writers strengthen the argument substantiating disparate care in the ED. Dr. Jones said that, despite the lack of specific studies, it is reasonable to extrapolate from evidence of disparities seen across the health care system. Dr. Pearlmutter said the ED may be the "canary in the coal mine" that signals the problem of disparate care in the system. Dr. Yeh said the paper would incorporate information received during this meeting on patient transfers for nonmedical reasons.

Action Item
The TAG Chair will write a letter of commendation to the Harvard University School of Public Health and the Johns Hopkins University School of Public Health acknowledging the student writers' efforts and recognizing their assistance in addressing health care problems in the United States.

Duty to Accept Transfers
Ms. Nelson presented for comment the Action Subcommittee's revised draft document "Duties of Hospitals with Specialized Capabilities to Accept Patient Transfers" that outlines the responsibilities of both transferring and receiving hospitals in cases of a transfer under EMTALA regulations (Appendix 2; note that language in italics has not been finalized by the Action Subcommittee). She asked the TAG to consider two issues in particular: 1) Transfers by a hospital that usually has the capability to provide the needed care but lacks the capability at the

moment the patient arrives and 2) whether a receiving hospital can request that the sending hospital readmit a transferred patient after the emergency condition is addressed and a long hospital stay is anticipated (i.e., repatriation). Dr. Kusske said the first issue ties in with the question of whether the presence of a specialty physician on the on-call list alone constitutes capability, which the TAG agreed should not be true, and Sandra Sands, J.D., of the OIG emphasized that CMS had never interpreted the statute in that manner.

Discussion covered such issues as whether a hospital should be required to accept a transfer if doing so would require the hospital to go into "surge" mode, when transfer to a more distant hospital is appropriate in situations in which closer hospitals may be capable of receiving a transferred patient, hospitals' duty to maintain a list of on-call physicians for the ED, and appropriate and acceptable discussions between hospitals and physicians about potential transfers. Diane Godfrey of Florida Hospital described Florida's efforts to address the lack of physicians on call for certain specialties, such as neurosurgery. The TAG agreed with the concepts presented in the document "Duties of Hospitals with Specialized Capabilities to Accept Patient Transfers" with specific revisions.

Action Item
The Action Subcommittee will make the following specific revisions to the document "Duties of Hospitals with Specialized Capabilities to Accept Patient Transfers," further revise the document as needed, and present a final proposal at the next TAG meeting.

Duties of Transferring Hospital
Item 2. Revise the phrase "unless doing so would cause harm to the patient or undue delay in the patient's care" to "unless doing so would cause harm to the patient in the best judgment of the physician."

Item 4. Revise to "The transfer must be an appropriate transfer, i.e., the transferring hospital lacks the capacity or capability to stabilize the patient's unstable emergency medical condition (EMC) or to perform a complete medical screening examination (MSE)."

Item 6. Revert to the language used in the current Interpretive Guidelines, but specify that "capabilities" refers to capability to treat the specific patient in question (not a general expansion of capabilities).

Item 7. Add the statement, "In determining the appropriateness of the transfer, surveyors will take into account the distance, hospital availability, and patient's needs."

Duties of Receiving Hospital
Item 4. Revert to the language used in the current Interpretive Guidelines, but specify that "capabilities" refers to capability to treat the specific patient in question (not a general expansion of capabilities).

Item 8. Clarify that this duty does not exclude the duty to maintain a list of on-call physicians.

Public Comments
Ms. Nelson summarized public comments received that may not have been addressed by the TAG or one of its subcommittees. In several cases, the TAG felt the issues raised had been discussed or otherwise resolved.

Action Items
The TAG requests that the Action Subcommittee continue to address the meaning of the term "stable," particularly the distinction between stabilizing an EMC and resolving it.

At the next meeting, the TAG will discuss the recommendation that a hospital's governing body has the authority to approve qualified medical personnel and that the authority to do so can appear in any hospital communication, not just hospital bylaws, rules, or regulations.

The OIG will evaluate the current regulations to determine whether and at what point patients can be advised that a hospital is not a participating provider under the patient's health plan.

The TAG requests that the Action Subcommittee consider the EMTALA regulations guiding the responsibility of the ED staff to intervene with police officers who want to remove a patient from the ED.

The TAG requests that the On-Call Subcommittee consider recommending that specialty hospitals be required to maintain a list of on-call physicians.

Psychiatric Issues
The following recommendations are under consideration by the Action Subcommittee.

Definition of Psychiatric Emergency Medical Conditions
The TAG should consider recommending that CMS remove the current separate guidance on psychiatric EMCs so that the remaining rules would apply equally to EMCs of either psychiatric or medical origin.

The TAG should consider recommending that CMS generate specific examples or vignettes to shed more light on aspects of psychiatric EMCs that are causing confusion.

Definition of an Appropriate Medical Screening Examination
The TAG should consider recommending that CMS describe that an MSE should attempt to determine whether an individual is gravely disabled, suicidal, or homicidal. Gravely disabled implies a danger to oneself due to extremely poor judgment or inability to care for oneself. If a patient is felt to be gravely disabled, suicidal, or homicidal, this does not necessarily mean that the patient has an EMC. The TAG supports the use of community protocols, community services, and other supportive resources (e.g., police custody, nursing home settings) to ensure appropriate disposition of the patient.

The TAG should consider recommending that CMS explore educational tools, training options, and further education of ED physicians and other clinical staff in general acute care hospitals without psychiatric services about the proper psychiatric medical screening, discharge, and transfer of patients with behavioral health conditions.

Designation of Qualified Medical Personnel

The TAG should consider recommending that CMS add the following statement to the Interpretive Guidelines: "Hospitals shall be allowed to utilize contracted agencies or services to assist with psychiatric MSEs. Hospitals shall ensure that such agencies/services are properly credentialed in accordance with hospital and medical staff bylaws."

Definition of Stabilization

The TAG should consider recommending that CMS add language to the Interpretive Guidelines that distinguishes between providing chemical and/or physical restraint treatment to stabilize a patient and providing such treatment to minimize risk to the patient during transfer (i.e., to effect a safe transfer). Accordingly, the administration of chemical and/or physical restraints to a psychiatric patient with an EMC may provide a temporary safe environment by minimizing risk, but it does not necessarily equal stabilization. The patient might still be deemed to have an unstable EMC. The TAG should consider recommending that CMS provide examples of stabilization and safe transfers with regard to psychiatric patients.

Written Testimony

The TAG reviewed the Institute of Medicine Committee for the Future of Emergency Care in the U.S. Health System's statement by Harvey V. Fineberg, M.D., Ph.D., and Megan McHugh, M.P.P. (Appendix 17).

Administrative Items

Dr. Siegel noted that the TAG's charter expires October 1, 2007, and the TAG would have one more meeting, probably in September. The TAG's recommendations to the Secretary and the Framework Subcommittee's papers will be finalized and approved by the TAG at the last meeting. Dr. Siegel and the CMS staff will work together after the last meeting to develop a final report for the Secretary.

Recommendation

The TAG recommends the Secretary extend the charter of the TAG for 1 year to allow the TAG to continue its work.

Adjournment

Dr. Siegel adjourned the meeting at 4:20 P.M. on Friday, May 4, 2007. Collected recommendations and approved motions of the TAG are listed in Appendix B.

EMTALA TAG Members Present at the May 3–4, 2007, Meeting

EMTALA Technical Advisory Group Members

David Siegel M.D., J.D., *Chair*
Emergency and Internal Medicine Physician
Senior Physician Consultant and Clinical Coordinator
Florida Medical Quality Assurance (Quality Improvement Organization)
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Orthopedic Trauma Surgeon
Health Policy Committee, Chairman
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Liz Richter, Director
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Sandra Sands, J.D., Senior Attorney
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Public Witnesses
Jeffrey O. Anglen, M.D.
Orthopaedic Trauma Association
American Association of Orthopaedic Surgeons

David J. Ciesla, M.D.
Washington (D.C.) Hospital Center

Diane Godfrey
Florida Hospital

Ann Pfeiffer, R.N., M.S.
Nelson Mullin

Ferdinand Richards III, M.D.
Chair, EMTALA Workgroup
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Amos Stoll, M.D.
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Robert J. Waters
Gardner Carton & Douglas

Rapporteur
Dana Trevas
Magnificent Publications, Inc.

APPENDICES

Appendix A: Meeting Agenda
Appendix B: Recommendations and Action Items from the May 3–4, 2007, meeting

The following documents were presented at the EMTALA TAG meeting on May 3–4, 2007, and are appended here for the record:

Appendix 1: Minutes and supporting documents of the On-Call Subcommittee
Appendix 2: Minutes and supporting documents of the Action Subcommittee
Appendix 3: Testimony of Amos Stoll, M.D., F.A.C.S., Broward General Medical Center
Appendix 4: Testimony of David J. Ciesla, M.D., Washington (D.C.) Hospital Center, on EMTALA and Tertiary Referral
Appendix 5: Testimony of Jeffrey O. Anglen, M.D., on behalf of the Orthopaedic Trauma Association and the American Association of Orthopaedic Surgeons
Appendix 6: Testimony on Behalf of the Center for Telehealth & E-Health Law
Appendix 7: Letter from Ann Pfeiffer, R.N., M.S., of Nelson Mullin to TAG Chair David Siegel, M.D., J.D.
Appendix 8: CMS Memoranda to State Survey Agencies dated April 27, 2007
Appendix 9: CMS Memoranda to State Survey Agencies dated April 26, 2007
Appendix 10: Excerpts from Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates
Appendix 11: Draft: Proposed Recommendation and Rationale from the EMTALA TAG On-Call Subcommittee: Adequate and Appropriate Call Lists
Appendix 12: Letter from Alan Steinberg and Susan Lapenta of Horty, Springer, and Mattern, Attorneys
Appendix 13: Communitywide On-Call System, Dr. John Sacra
Appendix 14: Draft: Proposed Recommendation and Rationale from the EMTALA TAG On-Call Subcommittee: Best Meets the Needs…
Appendix 15: EMTALA Enforcement
Appendix 16: Testimony of Ferdinand Richards III, M.D., Chair, EMTALA Workgroup, American Health Quality Association
Appendix 13: Institute of Medicine Committee for the Future of Emergency Care in the U.S. Health System, Statement by Harvey V. Fineberg, M.D., Ph.D., and Megan McHugh, M.P.P.

APPENDIX A

Sixth EMTALA TAG Meeting
May 3–4, 2007
HHS Headquarters
705A Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Day 1 **Thursday, May 3, 2007**

9 – 9:15	Welcome, call to order, and opening remarks
9:15 – 9:45	Summary Reports of On-Call and Action Subcommittees (excluding enforcement issues)
9:45 – 10:30	Scheduled Public Testimony by Registered Speakers
10:30 – 10:45	Break
10:45 – 12:00	Discussion and Action on On-Call and Action Subcommittee Recommendations, rotating between subcommittees
12:00 – 1:00	Lunch
1:00 – 1:15	**CMM Summary of Status of TAG Recommendations** ***(NRPM Provision on Revisions for Pandemic and All-Hazards Protection Act)***
1:15 – 2:30	Continued Discussion and Action on On-Call and Action Subcommittee Recommendations, rotating between subcommittees
2:30 - 2:45	Break
2:45 – 4:30	Continued Discussion and Action on On-Call and Action Subcommittee Recommendations, rotating between subcommittees
4:30 – 5:00	Public comment (unscheduled), time permitting.
5:00	Adjourn

Day 2	**Friday, May 4, 2007**
9 – 9:15	**Summary** Report of the Action Subcommittee—Enforcement Issues only
9:15 – 9:45	CMS/CMSO Discussion of Enforcement **--Overview of Process, including statutory vs. regulatory mandates** **--Presentation of Data from RO survey** **--Role of the QIOs**
9:45 – 10:00	Continuation of Scheduled Public Testimony by Registered Speakers *(Dr., Ferdinand Richards, AHQA)*
10:00 – 10:30	Discussion and Action on Action Subcommittee Enforcement Issues
10:30 – 10:45	Break
10:45 – 12:00	Report of Framework Subcommittee/TAG Questions and Discussion of Framework Issues
12:00 – 1:00	Lunch
1:00 – 2:45	Continued Discussion and Action on On-Call and Action Subcommittee Recommendations, rotating between subcommittees
2:45 – 3:00	Break
3:00 – 4:30	Continued Discussion and Action on On-Call and Action Subcommittee Recommendations, rotating between subcommittees
4:30 – 5:00	Public comment (unscheduled, time permitting)
5:00	Adjourn

APPENDIX B

EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP (TAG) Recommendations and Action Items May 3–4, 2007

Recommendations to CMS

Telehealth and Telemedicine
The TAG recommends that HHS reach out to providers to remind them that they can contact their Regional Offices for clarification of the Interpretive Guidelines or any other regulations regarding EMTALA, such as acceptable uses of telehealth for communication under the current Interpretive Guidelines.

On-Call Subcommittee Report
The TAG reiterates its previous recommendation that HHS move 42 C.F.R. 489.24(j)(1), the provision dealing with maintaining a list of on-call physicians, to 42 C.F.R. 489.20(r)(2), which relates to the Medicare provider agreement.

The TAG recommends HHS change 42 C.F.R. 489.20(r)(2) to read: "Each hospital must maintain an on-call list of physicians on its medical staff who are available to examine and stabilize the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians."

The TAG recommends HHS change the Interpretive Guidelines to state the following:

- If a hospital offers a service to the public, this service should be available for emergency care through on-call coverage.
- To satisfy the requirement for on-call coverage, at least annually, hospital and medical staff must develop a plan for on-call coverage that includes, at a minimum, evaluation of the following factors:
  - hospital capabilities/services provided (advertised/licensed)
  - community need for ED services as determined by ED visits
  - transfers out of hospital for emergency services
  - physician resources
  - past call plan performance
- The hospital must have a backup plan for patient care when it lacks capacity to provide services or on-call physician coverage is not available. The backup plan should consist of viable patient care options, such as the following:
  - telemedicine
  - other staff physicians
  - transfer agreements designed to ensure that the patient will receive care in a timely manner

- regional or community coverage arrangements

- A hospital may satisfy its on-call coverage obligation by participation in an approved community/regional call coverage program (*CMS to determine appropriate approval process*).

EMTALA Education

The TAG recommends that HHS take the following steps to improve understanding about EMTALA:

More Comprehensive, Prominent, User-Friendly CMS EMTALA Website, including the following:

- Statutes
- Regulations
- Interpretive guidance
- Current CMS/Office of the Inspector General (OIG) program memoranda/guidance letters
- EMTALA questions and answers
- Link to Medicare Conditions of Participation
- Enforcement statistics
- "Top 10" cited EMTALA deficiencies
- Special advisories of potential EMTALA violations
- Link to OIG website
- Topical cross-references
- EMTALA 101 "basics"
- Document downloads

Standardized Regional Office/State Surveyor Education

- Institute annual EMTALA surveyor education sessions (currently offered every 2 years).
- Establish a system to improve consistency in Regional Office EMTALA interpretations and enforcement (e.g., assign CMS central office person to monitor deficiency statements for consistency with CMS policy and consistency among jurisdictions and remedy concerns).
- Establish a system to monitor effectiveness of surveyor education.
- Establish a system to demonstrate surveyor competencies.
- Confirm prompt distribution of CMS EMTALA guidance, including EMTALA opinion letters and program memoranda, to Regional Offices and state agencies.

Provider Education

- Designate/approve specific CMS/OIG personnel to participate in provider education through various educational forums (e.g., American Health Lawyers Association, hospital/physician association meetings). Consider joint presentations by both agencies and establish a process to confirm consistency of information provided.

- Ensure a timely response to provider queries regarding EMTALA compliance and interpretation questions.
- Establish a timely process to address new obstacles to EMTALA compliance and remedy through regulatory or interpretive guidance change.
- Establish listservs or other mechanism so that interested parties can receive regular updates and information regarding EMTALA from CMS/OIG.
- Consider EMTALA training by quality improvement organizations (QIOs).

Patient Education

- Provide information about EMTALA rights and consequences (e.g., EMTALA requires hospitals to provide care irrespective of the patient's ability to pay; however, the hospital may still expect the patient to pay for services rendered). This information should be provided outside of the context of an ED visit.

Enforcement

The TAG recommends that HHS establish an appeals processes for hospitals/providers before making a termination decision.

a. Hospitals should be allowed to request QIO review for medical issues prior to termination.
b. Hospitals should be allowed to request an appeal from the CMS Regional Office on factual, policy, and legal issues before submission of a plan of correction or a decision to terminate. For example:
    - If the Regional Office believes a violation has occurred, a hospital is first given a draft statement of deficiencies, after which it has 10 days to provide CMS with any objections or additional information. CMS would have 10 days to consider the additional information and issue a final statement of deficiencies that responds to it. An expedited appeals process should be in place for hospitals to be placed on a 23-day termination track.
    - Region VI process (to be submitted by TAG member Dodjie Guioa).

The TAG recommends that HHS establish intermediate sanctions, such as an opportunity to correct with follow-up inspection or a system of warnings, for less serious EMTALA violations. Hospitals with technical violations (e.g., signage, log books) should receive lower sanctions.

The TAG recommends that HHS establish a method for consistent data collection of all EMTALA violations and central evaluation of the information, in a format determined by CMS to improve consistency of enforcement across the regions and that can serve as a resource for providers.

Administrative Items

The TAG recommends the Secretary extend the charter of the TAG for 1 year to allow the TAG to continue its work.

Action Items

Framework Subcommittee Papers
The TAG Chair will write a letter of commendation to the Harvard University School of Public Health and the Johns Hopkins University School of Public Health acknowledging the student writers' efforts and recognizing their assistance in addressing health care problems in the United States.

Duty to Accept Transfers
The Action Subcommittee will make the following specific revisions to the document "Duties of Hospitals with Specialized Capabilities to Accept Patient Transfers," further revise the document as needed, and present a final proposal at the next TAG meeting.

> Duties of Transferring Hospital
> Item 2. Revise the phrase "unless doing so would cause harm to the patient or undue delay in the patient's care" to "unless doing so would cause harm to the patient in the best judgment of the physician."
>
> Item 4. Revise to "The transfer must be an appropriate transfer, i.e., the transferring hospital lacks the capacity or capability to stabilize the patient's unstable emergency medical condition (EMC) or to perform a complete medical screening examination (MSE)."
>
> Item 6. Revert to the language used in the current Interpretive Guidelines, but specify that "capabilities" refers to capability to treat the specific patient in question (not a general expansion of capabilities).
>
> Item 7. Add the statement, "In determining the appropriateness of the transfer, surveyors will take into account the distance, hospital availability, and patient's needs."
>
> Duties of Receiving Hospital
> Item 4. Revert to the language used in the current Interpretive Guidelines, but specify that "capabilities" refers to capability to treat the specific patient in question (not a general expansion of capabilities).
>
> Item 8. Clarify that this duty does not exclude the duty to maintain a list of on-call physicians.

Public Comments
The TAG requests that the Action Subcommittee continue to address the meaning of the term "stable," particularly the distinction between stabilizing an EMC and resolving it.

At the next meeting, the TAG will discuss the recommendation that a hospital's governing body has the authority to approve qualified medical personnel and that the

authority to do so can appear in any hospital communication, not just hospital bylaws, rules, or regulations.

The OIG will evaluate the current regulations to determine whether and at what point patients can be advised that a hospital is not a participating provider under the patient's health plan.

The TAG requests that the Action Subcommittee consider the EMTALA regulations guiding the responsibility of the ED staff to intervene with police officers who want to remove a patient from the ED.

The TAG requests that the On-Call Subcommittee consider recommending that specialty hospitals be required to maintain a list of on-call physicians.

APPENDIX 1

Report of the

On-Call Subcommittee

of the

Emergency Medical Treatment and Labor Act

Technical Advisory Group

Teleconference: March 30, 2007

ON-CALL SUBCOMMITTEE REPORT
(Emergency Medical Treatment and Labor Act [EMTALA]
Technical Advisory Group [TAG])
Teleconference: March 30, 2007

Introduction

John A. Kusske, M.D., chair of the subcommittee confirmed that a quorum was present. The agenda for the teleconference is provided in Appendix A. See Appendix 1 of the agenda for additional information from Dr. Kusske.

Old Business

A. On-Call Physician as "Specialized Capability," Tag A411 §489.24(f) and Interpretive Guidelines §489.24(e)

At the November 2006 meeting the TAG was asked to reconsider its recommendation from the May 2006 TAG meeting that:

> The presence of a specialty physician on the call roster is not by itself, sufficient to be considered a specialized capability. At the time of transfer, the receiving hospital should also have available the necessary equipment, space, staff etc., to accommodate the patient transfer.

At the November meeting TAG members agreed that better definitions are needed of what constitutes an adequate and appropriate call list, and what constitutes a specialized capability. It was noted that in the past hospitals were obligated to establish a call roster that mirrored the services it provided during normal business hours.

Dr. Kusske requested input from the subcommittee on the specific recommendations regarding on-call obligations contained in the March 15, 2007 letter from Alan Steinberg and Susan Lapenta (see Appendix 1 of the attached agenda).

The subcommittee agreed that restoring the prior language in the Guidelines that a hospital which provides a service to the public should provide that service through on-call coverage seems reasonable. Adding a list of safe-harbors, as suggested by Steinberg and Lapenta, such as providing specialty coverage six days per month if only one specialist is available, is not practical. Exceptions to the safe harbors based on considering other "relevant factors" adds to the uncertainty about EMTALA rules and requirements.

Concerning the recommendation that EMTALA call responsibilities, which currently apply to hospitals, be extended to physicians, the subcommittee notes that this was previously voted down.

The subcommittee continues to support some sort of liability protection for EMTALA-mandated services provided by on-call physicians but recognizes that CMS has no authority to provide it.

Concerning the recommendation that more specificity is needed concerning the on-call responsibilities of specialty hospitals with specialized capabilities, the subcommittee noted that specialty hospitals are required to meet the same Medicare Hospital Conditions of Participation as other hospitals.

> *Action Item*
> Dr. Kusske will draft comments and e-mail them to the On-Call Subcommittee on an expanded definition of specialized capabilities that includes more than the mere availability of an on-call physician.

George Morey of CMS confirmed that there has never been a so-called "three-physician rule" that if a hospital has three physicians on staff in any one specialty, it must provide uninterrupted emergency department on-call coverage for that specialty, as is stated in the Steinberg-Lapenta letter.

Dr. Kusske asked members to consider why hospitals do not support call sharing arrangements such as on-call community calendars and systems for providing emergency care. Dr. Tuggle said such a system is in place in Oklahoma City. Subcommittee members discussed ways of encouraging establishment of call schedules that would reflect hospitals' resources to provide coverage. They also discussed the issue of whether or not EMTALA can design guidance around a call schedule.

> *Action Item*
> Dr. Tuggle will try to obtain a copy of the Oklahoma City call-sharing plan for the next meeting. Dr. Kusske will e-mail the On-Call Subcommittee more information on the issue of call sharing. Dr. Kusske will put call sharing on the agenda for the next meeting.

B. Duties of Hospitals with Specialized Capabilities to Accept Transfers
Tag A411, Interpretive Guidelines pp 53-54, 42 U.S.C. § 1395dd(g); 42 C.F.R. §489.24(f)

Dr. Kusske asked the subcommittee to review the request contained in Appendix 10 of EMTALA Report Number 5 that "hospitals and physicians need more guidance regarding whether a hospital's on-call list is adequate. Some members urged that the on-call list reflect a hospital's inpatient and outpatient services routinely offered at the hospital."

During the last On-Call Subcommittee conference call, Julie Nelson informed the subcommittee that some hospitals are refusing to accept EMTALA transfers on the basis that:

- The hospital does not have the appropriate specialist on call *at the time of transfer*, although the specialist will, in fact, be on call within an appropriate treatment window for the patient.
- The specialist will not be available, on call, to provide continued care or monitor the patient.
- The hospital will not have other specialists on call that may be needed at some point to assist in the patient's care.

Subcommittee members cited a variety of factors that affect call lists, including more doctors dropping off calls lists, the aging of the physician population, and other changes in the medical landscape. Members agreed that medical and hospital associations are the most appropriate groups to develop guidance on call issues, not EMTALA.

It would be useful to collect data on the frequency of transfers to and from hospitals to get a better understanding of how well hospitals are meeting the needs of the community. Often it is the sickest of the sick who are transferred. Members agreed that EMTALA transfer patients should not be included in the overall quality data on hospitals that is reported online.

> *Recommendation*
> The On-Call Subcommittee recommends developing a database for EMTALA transfers that will give future evaluators a better understanding of how the system is working.
>
> *Action Item*
> Dr. Kusske will summarize the On-Call Subcommittee's recommendations for the next TAG meeting.

C. Availability of On-Call Physicians, Tag A404 §489.24(j)(1)

At the last TAG meeting the following language was presented to replace the current requirements that hospitals maintain a list of on-call physicians that "best meets the needs of the hospitals patients who are receiving services…."

> "Each hospital must maintain an on-call list of physicians on its medical staff who are available to examine and stabilize the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians."

The TAG stated that the phrase "best meets the needs" should be retained but better defined. The TAG has already recommended that the language be moved from the EMTALA regulations into the Medicare Conditions of Participation.

Subcommittee members agreed that Dr. Kusske should make a summation of the subcommittee's recommendation and rationale for the next TAG meeting.

Action Item
Dr. Kusske will summarize the On-Call Subcommittee's rationale for revising the "best meets the need" language and its suggestions for revisions to the Interpretive Guidelines that clarify hospitals' obligations to maintain an on-call list.

D. Call Sharing/Community Call

Subcommittee members agree that a better definition of call sharing is needed. Although this issue did not make the agenda for the last TAG meeting, Dr. Kusske proposes to raise it at the next meeting. He would include the following points for consideration by the TAG and inclusion in the Interpretive Guidelines:

- CMS should clarify that it does not require shared call arrangements to involve simultaneous call at multiple hospitals.
- Guidelines should describe how a shared call arrangement can be used to reduce a hospital's obligation to ensure backup coverage.
- When a call sharing arrangement is in place the Guidelines should describe who is responsible for performing the medical screening examination—emergency services medical personnel or the transferring hospital.
- The Guidelines should describe the appropriate method for consulting (or informing) the CMS regional offices before shared call arrangements are established.
- The Guidelines should describe the required elements of a formal shared call arrangement.
- CMS should clarify, in the Guidelines, those situations in which transfer of a patient whose condition is not stabilized is considered not to be a violation of EMTALA because a shared call arrangement is in place.
- The On-Call Subcommittee believes that CMS should ensure anti-trust immunity and protection to those coordinating and providing shared call coverage.

Action Item
Dr. Kusske will put call sharing on the agenda for the next TAG meeting.

E. Continuous Call

Dr. Kusske raised the question whether CMS should prohibit involuntary continuous call. Surveys of neurosurgeons across the country reveal that about one third are forced to take continuous call, sometimes for weeks at a time. Members agreed this is incompatible with patient safety, but cautioned that there may be some instances and locations where continuous call works.

F. Tag A404, § 489.24(j)(1): Referral of Patients from the Emergency Department to the On-Call Physician's Office

This issue was discussed at the September 2006 conference call but it did not make it to the TAG agenda. The Interpretive Guidelines state that it is "generally not acceptable" for a physician on call to have emergency cases referred to his or her office for examination. The subcommittee believes there are situations in which a patient in the emergency department is considered by the treating physician to be stable for travel to the specialist physician's office for treatment. Revising the Interpretive Guidelines to allow such referrals may encourage more specialists to take call.

> *Recommendation*
> The On-Call Subcommittee recommends revising the interpretive guidelines to support patient referral to physicians' offices when appropriate, with the following caveats: the emergency physician must notify the on-call doctor and the referral must be irrespective of the patient's ability to pay.

G. Medical Liability Protection

The On-Call Subcommittee previously requested that the TAG consider Federal liability protection for physicians and hospitals acting under EMTALA requirements, but this issue did not make it onto the agenda of the last TAG meting.

Subcommittee members continue to believe that liability protection will provide incentives for physicians to take calls and thereby assist in alleviating the present on-call shortage of specialist physicians. The specifics of liability protection still need to be worked out. Among the issues to consider are:

- Under most state laws a physician will not be protected if it is determined that the physician was already legally bound to deliver the care in question.
- Also the Good Samaritan statutes typically bar from qualification under the statute persons who accept compensation for the emergency care delivered.
- Under these protections any physician or hospital that provides emergency services pursuant to obligations imposed by state or federal EMTALA requirements would not be liable for civil damages unless they acted with gross negligence.

Dr. Tuggle suggested that the June 2006 IOM Report: *Future of Emergency Care, Hospital-Based Emergency Care at the Breaking Point* supports providing liability protection.

Using Good Samaritan laws as a reference point is somewhat problematic, as they typically don't apply to those who receive payment for their services.

H. Specialized Capabilities

At the time of the last call, the subcommittee agreed that more discussion is needed as to whether or not CMS should provide written guidance on the specialized capabilities requirements. At the last conference call a significant amount of material was received regarding hospitals with specialized capabilities.

The subcommittee's impression is that the situation regarding hospitals and specialized capabilities is becoming untenable. Dr. Kusske was informed of a hospital in Idaho that was facing CMS sanctions because it refused to accept transfers from a hospital well beyond its catchment area with which it had no relationship. It is noted that under present regulations no geographic boundaries are applicable to specialized capabilities requirements. Furthermore regional offices are not required to consider the fairness and appropriateness of a transfer from the perspective of the receiving hospital.

The subcommittee recommended that the TAG discuss:

- Whether geographic limitations should apply to transfers to hospitals with specialized capabilities.
- Whether transferring hospitals should alert recipient hospitals of potential transfers (for a patient who may need specialty care) or of the lack of specialty coverage at the transferring hospital (in case patients come to the transferring hospital in need of that specialty coverage).
- Whether notification should be part of the specialized capabilities requirement.
- Whether other, less punitive mechanism can be used to enforce EMTALA regulations and prevent potential violations.
- Whether CMS should provide more written guidance on the specialized capabilities requirement.

Dr. Tuggle said that this speaks to need for regionalization of emergency services and said that the presumption that services exist in all or most counties is incorrect.

Action Item
Dr. Kusske will draft a statement and send it to the subcommittee by e-mail. Dr. Kusske will also send David Siegel M.D., J.D., all the background materials.

I. Limits of EMTALA on the Care of Stabilized Patients

The Committee agreed that follow-up care by the on-call physician following treatment in the emergency department is not governed by EMTALA. Under the Conditions of Participation, all patients leaving an emergency room should have adequate discharge planning

New Business

J. Telemedicine (e-medicine)

Dr. Kusske said the current guidelines almost preclude telemedicine except in specific circumstances such as rural health. Since those guidelines were written, telemedicine has changed and there are many more applications, including in crowded urban environments. Telemedicine can expedite the care of the patient, without having the doctor present in the ER.

Dr. Tuggle suggested NIH grant money be used to explore the expansion of telemedicine techniques. He believes this is important since the number of specialists in remote areas is not increasing

Dr. Thorward sent information on a bill, HB 0462, introduced in the Illinois General Assembly on January 29, 2007 that provides Medicaid coverage for telepsychiatry. See Appendix 2 for the full bill language.

Other New Business

- Dr. Siegel reported that the final TAG meeting will be fall of 2007. He expects to submit the final report to the Secretary soon after the meeting. Mr. Morey said that legislative authority for the TAG expires 30 months from the time of the first meeting, which would be at the end of September.
- The American Academy of Orthopedic Surgeons and the Orthopedic Trauma Association have expressed desire to present at the next meeting in May.
- Brian Robinson left the TAG. The Committee will find a hospital representative to participate for the remainder of the TAG.

Adjournment

The teleconference was adjourned at 2:50 p.m. The collected recommendations and action items of the subcommittee are listed in Appendix B.

Note: Interpretive guidelines and regulations noted above are from the *State Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases* (Rev. 1, 05-21-04) available at http://www.cms.hhs.gov/manuals/107_som/som107ap_v_emerg.pdf

EMTALA TAG Members Participating in the On-Call Subcommittee March 30, 2007 Teleconference

Participants
(Alphabetical order)

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APPENDIX A
Agenda
On-Call Subcommittee of the EMTALA TAG
March 30, 2007

1) Introductions

2) Old Business

A) Tag A411 §489.24(f) and Interpretive Guidelines §489.24(e).
At the November 2006 meeting of the TAG the following occurred:
The TAG was asked to reconsider its recommendation from the TAG meeting of May 1-2, 2006 that "the presence of a specialty physician on the call roster is not, by itself, sufficient to be considered a specialized capability. At the time of transfer, the receiving hospital should also have available the necessary equipment, space, staff, etc., to accommodate the patient transfer."

The TAG was asked to consider how the recommendation would apply to the following situation: Two hospitals in the same area have equivalent capacity and capability. One has a specialist on call, the other has the same type of specialist on its staff but that specialist does not wish to take call. Therefore, when a patient needs the services of a particular specialty, the specialist on call must accept that patient, while the specialist who does not wish to take call avoids any EMTALA obligation.

At the November 2006 meeting members agreed that better definitions are needed of what constitutes an adequate and appropriate call list and what constitutes a specialized capability. It was noted that in the past, hospitals were obligated to establish a call roster that mirrored the services it provided during normal business hours. Ms. Godfrey of Florida Hospital Association described a situation in which a hospital had 11 urologists on staff but did not have any urologists' on-call and so transferred emergency patients out. She said CMS investigated the situation and determined that no EMTALA violation occurred.

In Appendix 1 of this agenda please review the recent letter of Alan Steinberg and Susan Lapenta directed to David Siegel and me, which gives their recommendations to this issue. Also review item D under old business as well.

Comments and discussion on the recommendations of the Steinberg/Lapenta letter (the numbers correspond to the recommendation numbers)

1) This seems reasonable on its face to have this as a general principle. However this general rule ultimately becomes somewhat meaningless when you add a list of safe harbors, at which point you have no certainty of rules and just as much confusion as has always existed.
2) The safe harbor of minimum call doesn't necessarily fix the problems with on-call availability. Six days of call per month for a neurosurgeon sounds great, but if there

aren't enough neurosurgeons (or any other specialists) to serve the hospitals in the community, and many are currently serving on-call to more than one hospital at a time, what happens then?

3) Recommending exceptions to the safe harbors, again begs the question of how this scheme is providing hospitals and physicians with more certainty of rules and requirements.
4) The statute does not state that EMTALA mandates on-call responsibilities on physicians unless they are on their hospital's on-call roster, PERIOD. To try to bootstrap this requirement by regulatory change is inappropriate. What do you do about physicians that no longer practice at hospitals? Mandating this will only make things worse, not better. Keep in mind the TAG already dealt with this concept of mandatory coverage of Emergency Departments as a Condition for Participation in Medicare. The TAG did not endorse this concept.[1]
5) We have recommended this before. CMS has no authority to provide liability change, which I know of, absent statutory change. I believe the On-Call Subcommittee should continue to support some sort of liability protection for EMTALA mandated services provided by on-call physicians.
6) This may be a fair point, but we certainly have to give thought to considering an expanded definition of specialized capabilities that includes the mere availability of on-call physicians. Given the list of several examples in the statute, it seems clear that Congress was talking about burn centers, psychiatric hospitals, neonatal intensive units, etc. and now specialty hospitals like spine and heart hospitals.

Also the authors of the letter state on page 2, paragraph 3, that: "Prior to the 2003 changes in the EMTALA regulations, most hospitals operated under the "three physician" rule. This rule provided a known standard, a level playing field, and something of a safe harbor by which hospitals and physicians knew how to comply with EMTALA. When CMS revised the EMTALA regulations in 2003, it disavowed the three physician rule and decided not to include specific requirements or a safe harbor for adequate call coverage." This statement is incorrect. There never has been a regulation or a guideline promulgated by HCFA or CMS that says that. As far back as 1990 this was discussed because many hospitals and medical staffs defined their emergency department call requirements, leading to the so-called "three specialists rule". This approach says: "if you have three physicians on staff in any one specialty, you must provide uninterrupted emergency department on-call coverage for that specialty." This approach was talked about so much that many assumed it actually came from HCFA, but HCFA specifically denied that such a rule existed.[2] CMS has simply continued the same dialogue.

Should further questions be asked?

- Why don't (or won't) hospitals support call sharing arrangements, and joint ventures, with one another and the community physicians to develop on call community on-call calendars and systems for providing emergency care? The On-Call Subcommittee's

[1] EMTALA Meeting Report no 3. At p 7 and Appendix 15 at pp 108 and 109, October 26-28, 2005
[2] Bitterman, RA. Providing Emergency Care Under Federal Law: EMTALA. American College of Emergency Physicians, Dallas TX, 2000. Chapter 6: Medical Staff and On-Call Physician Obligations, at pp 85-86.

recommendations on shared call should be looked at carefully so that this can occur, without looming questions of EMTALA violations by participating institutions.

- Don't hospitals have responsibilities to not duplicate services that already exist at other hospitals?
- What is their obligation to not promise full-service emergency care, when there aren't enough providers in the community to provide these services?

The Committee needs to give more thought to "inappropriate transfers" to "higher level of care" facilities since there appears to be more abuse of this since the regulations were revised. However this issue may be better resolved with regionalized systems for emergency care delivery, rather than an EMTALA regulatory approach. This needs further discussion.

B) Notification of Potential Transfer

The TAG was asked to discuss whether a hospital should notify another hospital to which it transfers patients if the first hospital anticipates that it *might* need to transfer patients, e.g. when the first hospital lacks coverage for a certain specialty on a given night.
Further discussion by the On-Call Subcommittee is needed.

C) Availability of On-Call Physicians, Tag A404 §489.24(j)(1)

At the last TAG meeting the following language was presented to replace the current requirements that hospitals maintain a list of on-call physicians that "best meets the needs of the hospitals patients who are receiving services…."

The subcommittee proposes revising the Interpretive Guidelines to remove the controversial phrase, "best meets the needs of the hospital's patients," while maintaining accountability among hospitals. The following language would replace the sentence at §489.24(j)(1):

> Each hospital must maintain an on-call list of physicians on its medical staff who are available to examine and stabilize the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

The subcommittee believes the consequences for failing to have sufficient on-call coverage should include regulatory discipline and/or civil monetary penalties but not civil liability. Dr. Kusske noted that the TAG has received a great deal of testimony about the ambiguity of the phrase "best meets the needs of the hospital's patients."

The TAG opined that the phrase "best meets the needs" should be retained but better defined. The TAG has already recommended that the language be moved from the EMTALA regulations into the Medicare Conditions of Participation.

Action Item:
Dr. Kusske will summarize the On-Call Subcommittee's rationale for revising the "best meets the need" language and its suggestions for revisions to the Interpretive Guidelines that clarify hospitals' obligations to maintain an on-call list. The summary will be posted by CMS for public comment. TAG members who wish to solicit comments from particular specialty societies or organizations should provide specific contact information to Dr. Siegel and CMS staff.

The following language was discussed at the last On-Call Subcommittee Conference Call: (See Interpretive Guidelines §489.24(j)(1) at Tab 5, page 23 of the CMS Resources Book Updated October 2005.

It is proposed that the On-Call Subcommittee recommend to the TAG that the language "best meets the needs" be eliminated and further proposes that another approach be established which continues to hold hospitals accountable for providing a complement of on-call specialty physician services within its capabilities and resources.

This should be done, as testimony by interested groups has indicated in the past in order to avoid overly broad interpretation, inconsistent enforcement, and unwarranted litigation risk. The alternate approach still holds the hospital responsible for providing a complement of on-call physician specialty services within its capability and resources, but does so only with regulatory consequences or civil money penalties, not with civil liability.

It has been enunciated in testimony to the TAG that the 'best meets the need standard' makes the provision of on-call physicians services too complex, too variable, and apparently has generated multiple lawsuits against the hospitals who are alleged to have provided inadequate call coverage of specialists.

Testimony has indicated that physicians have devised ways to avoid ED services either by reducing the number of days they take call, or by curtailing their hospital privileges to specifically reduce their exposure to ED patients and on-call duties. Others have relinquished all hospital privileges since they no longer need hospital based resources to practice.

Bitterman points out that the fundamental issue which needs to be addressed is whether EMTALA actually requires hospitals to force members of its medical staff to provide on-call services.[3] The relevant statute is 42 USC 1395cc(a)(1)(I)(iii) which requires hospitals to "maintain a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition." The statutory language states that hospitals are only required to maintain a list of those physicians who have voluntarily or contractually agreed to take call, so that the ED is prospectively aware of what on-call physician resources are available for any given day. The language of the statute says "to maintain a list of physicians who are on call", it doesn't say that the hospital must actually provide on-call physicians.

It has been emphasized that the current regulatory language, "that best meets the needs of the hospital's patients, is an invitation to litigation and should be eliminated. As ACEP has stated it creates a slippery slope of near impossible compliance and unlimited, inconsistent retrospective enforcement and civil litigation. No hospital can know in

[3] Bitterman, RA. Providing Emergency Care Under Federal Law: EMTALA. American College of Emergency Physicians, Dallas Texas, 2000. Medical Staff and On-Call Physician Obligations, Chapter 6 at p 84.

advance what it must do to ensure compliance with the law. No hospital can possibly provide on-call coverage that 'best meets the needs' of all the hospitals ED patients, irrespective of the qualifying language in the regulations regarding 'resources available to the hospital, including the availability of on-call physicians.

In the past the On-Call Subcommittee has discussed this issue and has put forth the following suggested changes to the Interpretive Guidelines. A portion of these changes are included here including the paragraphs in the Guidelines that have been altered. The changes are underlined. It would seem that these changes, originally suggested might meet some of the needs of the revised regulation describing what hospital can do. I have not included the suggested sanctions against physicians since I think this requires further discussion.

1) At page 23, third paragraph. Hospitals have the ultimate responsibility for ensuring adequate on-call coverage. Hospitals participating in the Medicare Program must maintain a list of physicians' on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. Hospitals must have evidence of development, with medical staff input and involvement and Governing Body approval of a hospital plan for on-call coverage. The plan must be annually reviewed and updated, reflect the mechanisms for on call coverage for all hospital provided services and the effectiveness of the plan must be measured with reports to the hospital governing body of recommendations for improvement. Hospitals have an EMTALA obligation to provide on-call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual.

2) At page 25, fifth paragraph. CMS allows hospitals flexibility in the utilization of their medical personnel. Allowing exemptions to medical staff members (senior physicians) would not by itself violated EMTALA. Hospitals must identify in the facility plan for on-call coverage those services for which adequate call is not available. For each hospital provided clinical specialty either on-call coverage or a written transfer agreement must be in place to meet the needs of patients who present to the hospital for care and services. The written agreement must be collaboratively developed with another hospital in the same proximity with the receiving hospital agreeing to receive and treat all patients in the defined clinical specialty, who have had a MSE establishing a medical emergency, who have been stabilized, accepted by the receiving hospital and accompanied by copies of applicable patient records.

4) At page 25, sixth paragraph. Surveyors are to review the hospital policies or medical staff bylaws with respect to response time of the on-call physician. If a physician on the list is called by the hospital to provide emergency screening or treatment and either refuses or fails to arrive within the response time established by hospital policies or medical staff bylaws, the hospital and that physician may be in violation of EMTALA. Hospitals are responsible for ensuring that on-call physicians respond within a reasonable period of time. The expected response time should be stated in a range of minutes (e.g.,

30 to 60 minutes) in the hospital's policies based upon local conditions which impact upon the physician's ability to respond to the Emergency Department. The hospital quality assessment and performance improvement programs must include review of the measurement data from the analysis of physician response times. Physician specific response times shall be used in the data utilized for recommendation and approval of reappointment of medical staff membership or privilege renewals. Terms such as "reasonable" or "prompt" are not enforceable by the hospital and therefore inappropriate in defining physician's response time. Note the time of notification and the response (or transfer) time.

D) Duties of Hospitals with Specialized Capabilities to Accept Transfers
Tag A411, Interpretive Guidelines pp 53-54, 42 U.S.C. § 1395dd(g); 42 C.F.R. §489.24(f)

The On-Call Subcommittee should review Appendix 10 of EMTALA Report #5 at pp104-109. Note following recommendation #1 there is in italics the following statement: [*"Refer to on-call subcommittee; hospitals and physicians need more guidance regarding whether a hospital's on-call list is adequate. Some members urged that the on-call list reflect a hospital's inpatient and outpatient services routinely offered at the hospital.*]

Also note Recommendation #8 under the Column Duties of Receiving Hospitals:
8. " 'Specialized Capabilities' includes dedicated units, specialized equipment and personnel (including on-call physicians) available at the time of transfer or that will be available within the patient's treatment window. Specialized capabilities do not include medical staff members who are not on call."

Again the definition of an adequate call list is contemplated. Should the list reflect a hospital's inpatient and outpatient services that are routinely offered at the hospital?

Further during the last On-Call Subcommittee Conference Call Julie Nelson informed us that some hospitals are refusing to accept EMTALA transfers on the basis that:

- The hospital does not have the appropriate specialist on call *at the time of transfer*, although the specialist will, in fact, be on call within an appropriate treatment window for the patient.
- The specialist will not be available, on call, to provide continued care or monitor the patient.
- The hospital will not have other specialists on call who may be needed at some point to assist in the patient's care.

Action Item discussed during the Conference Call: Members of the On-Call Subcommittee will provide input at the next TAG meeting on this issue and on the Action's Subcommittee's proposed guidelines on the duties of hospitals with specialized capabilities to accept patient transfers under EMTALA.

E) Call Sharing/Community Call

During the last Telephone Conference Call of the Committee Call Sharing was discussed further. During the TAG meeting itself this was not an agenda item. The On-Call Subcommittee supports call sharing as a potential mechanism to enable more specialists to take call and to facilitate better use of scarce resources. Issues have been identified related to call sharing that should be considered by the TAG and addressed in the Interpretive Guidelines. Finally it should be clearly recognized that the basic dilemma regarding call coverage may be more readily solved outside the regulatory framework of EMTALA by widespread regionalization of trauma care throughout the United States.

Issues that are proposed to be considered by the TAG and to be addressed in the Interpretive Guidelines.

- CMS should clarify that it does not require shared call arrangements to involve simultaneous call at multiple hospitals.
- Guidelines should describe how a shared call arrangement can be used to reduce a hospital's obligation to ensure backup coverage.
- When a call sharing arrangement is in place the Guidelines should describe who is responsible for performing the medical screening examination—emergency services medical personnel or the transferring hospital.
- The Guidelines should describe the appropriate method for consulting (or informing) the CMS regional offices before shared call arrangements are established.
- The Guidelines should describe the required elements of a formal shared call arrangement.
- CMS should clarify, in the Guidelines, those situations in which transfer of a patient whose condition is not stabilized is considered not to be a violation of EMTALA because a shared call arrangement is in place.
- The On-Call Subcommittee believes that CMS should ensure anti-trust immunity and protection to those coordinating and providing shared call coverage.

The On-Call Subcommittee requests that the TAG review again these issues to encourage use of shared call coverage.

F) Continuous Call

The On-Call Subcommittee requests that the TAG reconsider the question of whether CMS should explicitly prohibit involuntary continuous call. Surveys of neurosurgeons across the country reveal that about one third are forced to take continuous call.

G) Referral of Patients from the Emergency Department to the On-Call Physician's Office. Tag A404, § 489.24(j)(1)

The Interpretive Guidelines state that it is "generally not acceptable" for a physician on call to have emergency cases referred to his or her office for examination. The subcommittee believes there are situations in which a patient in the emergency department is considered by the treating physician to be stable for travel to the specialist physician's office for treatment. Revising the Interpretive Guidelines to allow such referrals may encourage more specialists to take call.

The action item that was approved on the last conference call was to request that the TAG consider approving the revision of the Interpretive Guidelines to support referral of patients to physicians' offices when appropriate.

H) Medical Liability Protection

The On-Call Subcommittee requests that the TAG should explore means of encouraging physicians to take call in order to assist in alleviating the present on-call shortage of specialist physicians. To that end the On-Call Subcommittee recommends to the TAG that providing on-call physicians with federal liability protections similar to the Good Samaritan laws available to others who respond to emergencies under other circumstances would incentivize physicians to take call. These laws typically shield from civil liability a person who provides emergency assistance. Issues to consider:

- Under most state laws a physician will not be protected if it is determined that the physician was already legally bound to deliver the care in question.
- Also the Good Samaritan statutes typically bar from qualification under the statute persons who accept compensation for the emergency care delivered.
- Under these protections any physician or hospital that provides emergency services pursuant to obligations imposed by state or federal EMTALA requirements would not be liable for civil damages unless they acted with gross negligence.

Refer to AMA testimony given to the TAG in May 2006 regarding this issue.

The Action Item that was approved at the conference call of September 26, 2006 was to request that the TAG consider Federal liability protection for physicians and hospitals acting under EMTALA requirements.

I) Specialized Capabilities

At the time of the last conference call a significant amount of material was received regarding hospitals with specialized capabilities. The On-Call Subcommittee's impression is that the situation regarding hospitals and specialized capabilities is becoming untenable. Dr. Kusske was informed of a hospital in Idaho that was facing CMS sanctions because it refused to accept transfers from a hospital well beyond its catchment area with which it had no relationship. It is noted that under present regulations no geographic boundaries are applicable to specialized capabilities requirements. Furthermore regional offices are not required to consider the fairness and appropriateness of a transfer from the perspective of the receiving hospital.

The Subcommittee recommended that the TAG discuss:

- Whether geographic limitations should apply to transfers to hospitals with specialized capabilities.
- Whether transferring hospitals should alert recipient hospitals of potential transfers (for a patient who may need specialty care) or of the lack of specialty coverage at the transferring hospital (in case patients come to the transferring hospital in need of that specialty coverage).
- Whether notification should be part of the specialized capabilities requirement.

- Whether other, less punitive mechanism can be used to enforce EMTALA regulations and prevent potential violations.
- Whether CMS should provide more written guidance on the specialized capabilities requirement.

J) Conditions for which EMTALA regulations might apply to hospital inpatients.

The action item that was discussed at the last telephone conference call was to explore the situations in which it would be appropriate to apply EMTALA regulations to hospital inpatients.

K) Limits of EMTALA on the Care of Stabilized Patients

Discussion was accomplished regarding the issue of clarification of CMS policy regarding follow-up care by the on-call physician following treatment in the emergency department. This care is not governed by EMTALA. Previous testimony by the AMA pointed out that CMS language is ambiguous regarding when a hospital's EMTALA obligation to a patient seen in the ED is completed.

The action item that was discussed was for the Sub-Committee to recommend to the TAG that once a patient is stabilized there is no further EMTALA obligation.

3) New Business

- Procedures to finalize Committee Reports
- Proposed date for the last TAG Meeting
- Method for the formulation of the last report to the Secretary.

APPENDIX B

Emergency Medical Treatment and Labor Act (EMTALA)
Technical Advisory Group (TAG)
On-Call Subcommittee
Teleconference: March 30, 2007

Action Items

Action Items
Dr. Kusske will draft comments and e-mail them to the On-Call Subcommittee on an expanded definition of specialized capabilities that includes more than the mere availability of an on-call physician.

Dr. Tuggle will try to obtain a copy of the Oklahoma City call-sharing plan for the next meeting. Dr. Kusske will e-mail the On-Call Subcommittee more information on the issue of call sharing. Dr. Kusske will put call sharing on the agenda for the next meeting.

Dr. Kusske will summarize the On-Call Subcommittee's recommendations on guidance regarding whether a hospital's on-call list is adequate for the next TAG meeting.

Dr. Kusske will summarize the On-Call Subcommittee's rationale for revising the "best meets the need" language and its suggestions for revisions to the Interpretive Guidelines that clarify hospitals' obligations to maintain an on-call list.

Dr. Kusske will put call sharing on the agenda for the next TAG meeting.

Dr. Kusske will draft a statement on hospitals with specialized capabilities and send it to the subcommittee by e-mail. Dr. Kusske will also send David Siegel M.D., J.D., all the background materials.

Recommendations
The On-Call Subcommittee recommends developing a database for EMTALA transfers that will give future evaluators a better understanding of how the system is working.

The On-Call Subcommittee recommends revising the interpretive guidelines to support patient referral to physicians' offices when appropriate, with the following caveats: the emergency physician must notify the on-call doctor and the referral must be irrespective of the patient's ability to pay.

APPENDIX 1

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VIA ELECTRONIC MAIL

March 15, 2007

David Siegel, M.D.
Chairman, EMTALA Technical Advisory Group

John Kusske, M.D.
Chairman, On-Call Subcommittee

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Emergency Medical Treatment and Active Labor Act ("EMTALA") and On-Call Obligations

Dear Drs. Siegel and Kusske:

In all the work that the EMTALA Technical Advisory Group ("TAG") has done, there is probably no issue more important than recommending to the Centers for Medicare and Medicaid Services ("CMS") the terms of adequate on-call coverage under EMTALA. As described on page five of the TAG's Report Number Five of its November 2-3, 2006 meetings:

> Members agreed that better definitions are needed of what constitutes an adequate and appropriate call list and what constitutes specialized capability. It was noted that in the past, hospitals were obligated to establish a call roster that mirrored the

> services it provided during normal business hours. Ms. Godfrey of Florida Hospital described a situation in which a hospital with 11 urologists on staff did not have any urologists on call and so transferred emergency patients out. She said CMS investigated the situation and determined that no EMTALA violation occurred.

CMS's approach to on-call has changed over time. When there were better guidelines in place, the on-call system seemed to function more consistently and fairly. Now, many hospitals feel that their ability to provide adequate on-call coverage is severely compromised.

Prior to the 2003 changes in the EMTALA Regulations, the Interpretative Guidelines stated that "If a hospital offers a service to the public, this service should be available through on-call coverage of the emergency department." While the Guidelines did not say "must," the principle was quite clear. (This connects to the Report's statement: "Hospitals were obligated to establish a call roster that mirrored the services it provided during normal business hours.") The Guidelines' language was changed in 2004 and now provides: "On-call coverage should be provided within reason depending upon the number of physicians in a speciality."

Prior to the 2003 changes in the EMTALA Regulations, most hospitals operated under the "three-physician" rule. This rule provided a known standard, a level playing field, and something of a safe harbor by which hospitals and physicians knew how to comply with EMTALA. When CMS revised the EMTALA Regulations in 2003, it disavowed the three physician rule and decided not to include specific requirements or a safe harbor for adequate call coverage. Instead, CMS articulated the "all relevant factors" test (i.e., the number of physicians on staff, other demands on these physicians, frequency with which the hospital's patients typically require the services of on-call physicians, and provisions made for situations when on-call coverage is not available).

In adopting the 2003 Regulations, CMS was attempting to provide more flexibility for hospitals to comply with EMTALA. The unintended consequences, however, of greater flexibility are fewer known rules and greater ambiguity and uncertainty in terms of compliance. This has created an environment where many hospital and medical staff leaders feel pitted against the rank and file staff members who reasonably want to take as little call as possible.

Studies conducted by the American College of Emergency Physicians (the "ACEP") in 2004 and 2005 reflect the growing problems in emergency departments across the country including more and more physicians wanting to take less and less call. This has resulted in a growing number of patient transfers. (See the ACEP's survey entitled "On-Call Specialist Coverage in U.S. Emergency Departments," released in April 2006.)

As described in many sources, including the Institute of Medicine's report entitled "Hospital-Based Emergency Care: At the Breaking Point," published in June 2006, specialists are facing real difficulties and troubling events. The supply of specialists has significantly decreased, as has reimbursement, while professional liability (and the cost of insurance) has risen. With satisfaction from work down and continually growing on-call demands, call has become one more way physicians feel they are being stretched beyond a point of fairness and reasonableness.

The current situation is untenable. Change is necessary. The well-meant flexibility provided in the revised Regulations and Guidelines has contributed to uncertainty and more difficult relationships between hospitals and on-call specialists. This is an area in which certainty and rules are required in order for the on-call system to work.

Hospital and medical staff leaders who wish to see more adequate on-call coverage currently lack the compliance and enforcement tools they used to have under the prior Guidelines and the three-physician rule. Something is needed now or the crumbling on-call system will collapse.

The TAG's Report Number Five invited comments as to what constitutes an adequate and appropriate call list. As it relates to the on-call schedule and related issues, we offer a number of suggestions for consideration by the TAG:

(1) Restore the prior language in the Guidelines – that a hospital which provides a service to the public should provide that service through on-call coverage. Hospitals and on-call specialists are obligated to establish a call roster that mirrors the services provided during normal business hours. This change can be made to the Guidelines, with perhaps a similar change also proposed for the Regulations.

(2) Provide certainty that is needed to restore the balance, through an on-call "safe harbor." The health care field is quite familiar with safe harbors – now is the time to provide hospitals and physicians with a safe harbor for call coverage, to provide rules, expectations and clear areas of compliance.

We suggest, as a starting point, a six days a month safe harbor. Thus, for example, if a hospital had a single specialist (i.e., a single orthopedic surgeon), and that specialist practiced exclusively at its facility, the hospital would comply with EMTALA if its on-call schedule covered that specialty six days a month. With this kind of safe harbor, hospitals could then extrapolate to areas where they had two, three or more specialists and/or their specialists practiced (and had on-call responsibilities) at multiple facilities, and could develop policies with certainty.

(3) The impact of call on hospitals varies by factors, including hospital size, whether the specialists on call divide their practices among several hospitals, geographic barriers and distance. These factors could be used as "relevant factors" to justify why a hospital is operating outside of the safe harbor.

(4) EMTALA call responsibilities should apply directly to physicians, and not simply to hospitals. Perhaps this could be done through a regulatory change, and not require revisions to the Act itself. But even if statutory change is required, recommending to CMS that the problem has become that acute is a powerful statement.

(5) To protect the physicians (and hospitals) that comply with EMTALA requirements, CMS could develop some type of "Good Samaritan" liability protection for those who provide on-call services. Another alternative would be to provide protection, for physicians and hospitals, under a system modeled after the Federal Torts Claim Act.

(6) To help further level the playing field, more specificity is needed in the area of specialty hospitals with "specialized capabilities." CMS adopted the TAG's recommendation, that specialty hospitals are hospitals with specialized capabilities. This change is an important first step, but we are concerned that the specialized capabilities reality has not changed.

No hospital wants to try to transfer a patient to a specialty hospital that has not planned for receiving, let alone treating, unresolved emergency medical condition patients. No hospital wants to put its patients at risk in that manner. The outcome could too easily be a patient whose condition only worsens while the specialty hospital struggles (and perhaps argues) with a proposed EMC patient transfer. There simply is not enough certainty for community hospitals to feel comfortable that transferred patients will be appropriately received and cared for.

There has to be further clarification on how specialty hospitals will handle "specialized capabilities" transfers. We respectfully recommend that specialty hospitals be required to meet the same on-call coverage and lists as full-service hospitals. Otherwise, patient safety and care are put into jeopardy.

Thank you for the opportunity to provide these comments and recommendations. We hope that they further stimulate the good work being done by the TAG and its On-Call and Action Subcommittees.

Sincerely,

Alan Steinberg

Susan Lapenta

AS/SL/pam

161572.4

APPENDIX 2

AN ACT concerning public aid.

WHEREAS, Millions of adults and children are disabled by mental illness every year, with approximately 20% of the population annually affected; and

WHEREAS, Nationally, suicide is the leading cause of death for adolescents and young adults; and over 90% of youths committing suicide have experienced a mental disorder; and

WHEREAS, Rural teens and rural older adults have a much higher rate of suicide than do their urban peers, and many of these suicides could be prevented through treatment; and

WHEREAS, In addition to the loss of life, mental illness costs Illinois an annual economic, indirect cost which reflects the loss of productivity due to illness, premature death, incarcerated individuals, and those providing family care; and

WHEREAS, Individuals with mental illness in rural areas are much less likely to have access to the mental health services they need; and

WHEREAS, There is a specific need for more mental health workers to provide aftercare support; and

WHEREAS, Mental illness is a devastating illness that can

affect any member of any family, any student in the classroom, and any co-worker at a place of business; and

WHEREAS, All communities struggle to meet the needs of the mentally ill, especially in the rural and underserved areas of

Illinois; and

WHEREAS, Key findings from the Illinois Rural Health Association Mental Health Access Forum Report from 2006 recommend the increased use of telemedicine and technology to improve access to care, increase training opportunities, and evaluate quality of care; and

WHEREAS, There are mentally ill patients who live great distances from any mental health facility and, in rural areas, may have limited transportation or limited resources for transportation, or both, to obtain mental health care; and

WHEREAS, There are mentally ill patients with special needs issues including, but not limited to: deafness; limited hearing; blindness; patients who speak only a language other than English; physical disabilities; and developmental disabilities; and

WHEREAS, Hospital emergency rooms have become the default provider of mental health care to mentally ill patients with

acute crises and for whom no appropriate alternatives are available, and the majority of emergency rooms are not staffed with a psychiatrist; and

WHEREAS, Providing telepsychiatry services would provide cost-efficient mental health care to those in underserved areas or those who do not have access to providers with specialized skills such as sign language or foreign language skills; and

WHEREAS, Telepsychiatry has been shown to be an effective medium through which to deliver health and mental health care; therefore

Be it enacted by the People of the State of Illinois,

represented in the General Assembly:

Section 5. The Illinois Public Aid Code is amended by adding Section 5-5.25 as follows:

(305 ILCS 5/5-5.25 new)

Sec. 5-5.25. Access to psychiatric mental health services. The General Assembly finds that providing access to psychiatric mental health services in a timely manner will improve the quality of life for persons suffering from mental illness and will contain health care costs by avoiding the need for more costly inpatient hospitalization. The Department of Healthcare

and Family Services shall reimburse psychiatrists for mental health services they provide, as authorized by Illinois law, to recipients via telepsychiatry. The Department, by rule, shall establish a method to reimburse providers for mental health services provided by telepsychiatry. The reimbursement methodology for mental health services provided by telemedicine shall be comparable to the reimbursement methodology used by the Department for other services provided by telemedicine.

Section 99. Effective date. This Act takes effect upon becoming law.

TELEPSYCHIATRY: TALKING POINTS

Definition: Telepsychiatry is the delivery of healthcare and the exchange of healthcare information for purposes of providing psychiatric services across distances.

- 60% of rural areas in the United States are designated as Mental Health Professional Shortage Areas (MHPSA).
- 20% of rural counties have no mental health services at all and only 18% of rural hospitals offer emergency psychiatric services.
- 50 out of 102 counties in the State of Illinois do not have any psychiatrist.
- There is a shortage of child psychiatrists in the United States, including in the State of Illinois, and there are 84 counties in the State of Illinois without any child psychiatrist

This means that in farms and rural areas of Illinois, patients might have to drive between 50 to 100 miles to the nearest psychiatrist's office.

- 25% of rural and non metropolitan residents have no insurance.

This problem can be attributed, in part, to the domination of rural economy by small, low wage employers and self employed residents. Even when these residents try obtaining private insurance they spend a greater proportion of their lower incomes paying high premiums and administrative fees, they have fewer choices and run the risk of being under-insured. This reduces the capability of a rural community to support mental health services and pay high wage professionals and staff. Hence rural residents have to travel to urban mental health centers. However, frequent travel in the face of adverse weather, time constraints, financial restrictions, and child care and employment considerations is not always possible or convenient.

As a result, people are forced to seek help from primary care physicians, who are not adequately trained in the diagnosis and treatment of most psychiatric disorders or de facto services such as ministers, friends and family.

TELEPSYCHIATRY

- Patients and clinicians report high satisfaction with and acceptance of the use of remote technology for treatment and assessment.
- Telepsychiatry patients have been shown to be satisfied with the service, equipment, and setting.
- Some patients prefer telepsychiatry to in-person appointments.
- Also, some people from different cultures are more comfortable with the distance rather than having face-to-face interviews with psychiatrists. Specifically, high levels of satisfaction have been reported for patients in jail populations and in rural settings, child and adolescent patients and their

families, geriatric patients, nonpsychotic patients, and patients with limited access to health care.

In addition to helping provide access to psychiatric care in rural and underserved areas, telepsychiatry has a number of other applications. Telepsychiatry can be used to help:

- Deaf persons. There are few psychiatrists trained in sign language to treat deaf persons.
- Persons who do not speak English.
- Patients requiring culturally sensitive care
- Geriatric patients.
- School children. The Chicago Public School system has expressed interest in telepsychiatry to help students obtain needed psychiatric care in underserved areas.
- People with physical and developmental disabilities could be better accommodated by having their appointments from a central location rather than being required to travel which can be very difficult for them.
- Emergency Rooms.
- Children and Adolescents.

Telepsychiatry is but one way the Illinois Psychiatric Society seeks to improve access to psychiatric care in the State. The IPS is also pursuing redistribution strategies of psychiatrists through loan repayments and training opportunities in underserved areas, consultation and education opportunities for primary care physicians.

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APPENDIX 2

EMTALA TAG
ACTION SUBCOMMITTEE TELEPHONE CONFERENCE

Date: Thursday, February 22, 2007

Time: 2:00 pm MST (4:00 pm EST)

Members Present: Julie Nelson, Chair; Azzie Conley; S.R. Thorward, M.D.

Others Present: George Morey, CMS; Renate Rockwell, CMS; Irene Chan, Extern

Absent: Richard Perry, M.D.; Dodjie Guioa; Mark Pearlmutter, M.D.; Michael Rosenberg, M.D.; Rory Jaffe, M.D.; Brian Robinson

I. Administrative Issues

a. Ms. Nelson introduced the Action Subcommittee to extern Irene Chan, Harvard School of Public Health. who will be assisting the Action Subcommittee in developing and documenting its CMS, OIG, and private right of action enforcement recommendations. Ms. Nelson notified the Action Subcommittee that Jerica Peters, ASU Law Student, will also be an extern for the Subcommittee, assisting with a variety of other issues.

b. Ms. Nelson described the process and frequency for the Subcommittee's conference calls in preparation for the May 3-4, 2007 meeting.

II. Substantive Issues

a. Ms. Nelson proposed the following Action Subcommittee agenda for the May 3-4 meeting.

- Revised to "Duty of Hospitals with Specialized Capabilities to Accept Patient Transfer" Recommendations
- Revised EMTALA Education Recommendations
- Psychiatric Patient Recommendations
- Enforcement Recommendations
- Capacity vs. Capability Definition Recommendations

- Non-Emergency Patient MSE Recommendations
- Stabilization Recommendations
- Other

The members approved the proposed agenda and agreed that they would consider other issues for inclusion. Ms. Nelson stated that Ms. Peters would review all public comments submitted to the TAG to date and provide a summary of those issues that are within the Action Subcommittee's jurisdiction, but have not yet been addressed by the Action Subcommittee. Mr. Morey agreed to assist Ms. Peters as needed to confirm that she has all of the public testimony with respect to Action Subcommittee issues.

b. Discussion

- Revised "Duty of Hospitals" to Accept Document

  Ms. Nelson reviewed the document entitled *Duties of Hospitals With Specialized Capabilities to Accept Patient Transfers* and identified changes to that document, consistent with TAG input. *Subcommittee members agreed to review this document in more detail and provide input at the next conference call.*

- CMS Position on Application of "Duty to Accept" Provision to Hospital Inpatients

  Subcommittee members discussed whether the duty to accept provision should apply to hospital inpatients, since this matter is currently under review by CMS. The members agreed that there should be a mechanism in place to make sure that hospital inpatients that develop an emergency medical condition during their inpatient stay received the care that they required when the hospital to which they have been admitted lacks the capability to provide that emergency care, but there was variation with respect to the members' approaches as to where in the regulations that mechanism should be placed (*i.e.*, Medicare Conditions of Participation vs. EMTALA). Some of the concerns raised included: (1) whether inpatient requirements are within the scope of EMTALA; (2) whether the absence of such a provision would prevent hospitals from admitting patients to their hospital for care because of a concern with what condition the patient may develop later; (3) whether expanding the current "duty to accept" provision, which is already subject to abuse, to include hospital inpatients would make the patient transfer situation even worse; and (4) whether the Medicare Conditions of Participation would be a better place to regulate these patient transfers. *Subcommittee members*

agreed to consider this issue in more detail and be prepared to discuss the issue at the next conference call.

- Revised EMTALA Education Recommendations

  Ms. Nelson discussed the revisions to the document entitled EMTALA Education Recommendations. *Subcommittee members agreed that the changes appeared to be reflective of the TAG's comments, but would review this document in more detail before the next conference call.*

- Capacity vs. Capability Definition Recommendations

  Ms. Nelson introduced the document entitled Capability and Capacity, prepared by last semester's Action Subcommittee Extern. Ms. Nelson explained the need to review and reconsider the definitions of "capacity" and "capability" throughout the EMTALA statutes, regulations, and interpretive guidelines, since those definitions appear to overlap and have caused some confusion among hospitals and physicians with respect to their EMTALA obligations. *Subcommittee members agreed to consider this document in preparation for the next conference call.*

- Psychiatric Recommendations, Status and Definition of a Psychiatric Emergency Medical Condition (Gravely Disabled or Dead within 48 Hours Reference)

  Dr. Thorward provided an overview of the telephone conference that occurred with stakeholders in December 2006 with respect to EMTALA recommendations with respect to psychiatric patients. *Dr. Thorward requested that the Action Subcommittee be provided with a written summary of that conference call, which Mr. Morey will arrange. Dr. Thorward will work with Dr. Pearlmutter to consider and prioritize the next steps with respect to the Subcommittee's psychiatric patient recommendations.* Ms. Nelson stated that she supported not creating different definitions for psychiatric patients, but providing better clarity and examples, as proposed by stakeholders in the conference call. Ms. Nelson also emphasized the importance of considering community protocols in the Subcommittee's recommendations. Dr. Thorward expressed concern with respect to physical and chemical patient constraints and the members agreed that clarification is needed with respect to that treatment as it relates to the patient's stabilization. Dr. Thorward also expressed concern with respect to receipt of psychiatric patient transfers and some of the perceived abuses with respect to that provision. Ms. Nelson expressed the hope, seconded by Dr. Thorward, that if the "duty to accept"

provision could be improved an clarified, that there would be fewer concerns with patient acceptance.

c. Next Subcommittee Meeting Agenda

Ms. Nelson adjourned the meeting at 2:55pm (MST).

EMTALA TAG
ACTION SUBCOMMITTEE
TELEPHONE CONFERENCE

Date: Thursday, March 15, 2007

Time: 4:00 pm EDT

Members Present: Julie Nelson, Chair; Rory Jaffe, MD; Mark Pearlmutter, MD; Michael Rosenberg, MD

Others Present: George Morey, CMS; Marilyn Dahl, CMS; Irene Chan, Extern

Members Absent: Richard Perry, MD; Dodjie Guioa; Brian Robinson; Azzie Conley, RN; S.R. Thorward

I. Administrative Issues

a. Ms. Nelson inquired regarding whether CMS or any members have had contact with Brian Robinson.

II. Substantive Issues

a. Revised "Duty of Hospitals with Specialized Capabilities to Accept Patient Transfers" Recommendations.

Ms. Nelson presented the "duty to accept" recommendations for member input. Dr. Jaffe requested a revision on page 4 of the document, changing "serve as a resource for alternative stabilizing care" to "provide advice regarding stabilizing care." Dr. Jaffe expressed concern that the transfer distance was not sufficiently clear given the lack of a mileage limit, but agreed to defer this matter to CMS. Ms. Nelson agreed to make the change. Members may provide other comments to this document before the next meeting, but in the absence of additional comments, the document will be presented to the TAG, as revised, at the next meeting.

b. Revised EMTALA Education Recommendations.

Ms. Nelson presented the education recommendations for further member comment. There were no member comments. The document will be presented to the TAG at the next meeting.

c. Capacity vs. Capability Definition Recommendations.

Ms. Nelson presented the capability and capacity document for member comment. Members agreed that there is greater need for clearer definitions and more precise usage of the terms “capacity” and “capability.” Dr. Jaffe proposed revising the definition of capability to mean “capacity plus resources,” while Ms. Nelson stressed the need to differentiate the terms as follows: capability means services that the hospital is typically able to provide; capacity means resources available to the hospital within the time period necessary to stabilize the patient, including, for example, beds, equipment and staff.

Dr. Jaffe emphasized the importance of tying capacity to the patient’s window of time for care. Members explored whether the two definitions could be collapsed into one, but rejected that idea given the need for precision throughout the regulations and interpretive guidelines. Ms. Nelson agreed to circulate revised definitions based on member comments.

d. Psychiatric Recommendations and Status Report.

Dr. Pearlmutter confirmed that members had received the transcript of the public telephone conference on psychiatric issues that occurred in December 2006. Dr. Pearlmutter stated that he would circulate proposed recommendations based on that call for the subcommittee’s review.

e. EMTALA Enforcement: CMS Enforcement Process Recommendations.

Ms. Chan presented her draft overview of the CMS enforcement process with issues for discussion. Members expressed the need to establish a provider appeal process before termination and considered whether enforcement should be tied to the concepts of discrimination or improper motive. Ms. Dahl expressed concern that the members’ recommendations on enforcement not impact other CMS enforcement processes, since EMTALA enforcement is closely linked to these other processes.

Ms. Dahl also explained that EMTALA deficiencies are typically viewed as “condition-level” deficiencies which trigger the 23 and 90 day termination tracks. Ms. Nelson requested that members consider other alternatives with less severe and immediate consequences. Ms. Nelson asked members to review the CMS enforcement document and answer the questions presented.

f. Next Subcommittee Meeting.

Ms. Nelson reported that the next Subcommittee meeting had not yet been scheduled, but will be scheduled soon.

The meeting adjourned at 5:04 pm (EDT).

EMTALA TAG
ACTION SUBCOMMITTEE
TELEPHONE CONFERENCE

Date: Thursday, April 5, 2007

Time: 4:00 pm EDT

Members Present: Julie Nelson, Chair; Rory Jaffe, MD; Mark Pearlmutter, MD; Azzie Conley, RN; S.R. Thorward, M.D.

Others Present: David Siegel, M.D.; George Morey, CMS; Irene Chan, Extern; Jerica Peters, Extern

Members Absent: Michael Rosenberg, MD; Richard Perry, MD; Dodjie Guioa; Brian Robinson

I. Administrative Issues

a. Ms. Nelson inquired regarding whether members would like to continue the conference calls or would prefer to meet one day earlier in May before the full TAG meeting to address the subcommittee issues. The subcommittee will continue with its weekly calls.

II. Substantive Issues

a. Discussed the application of "Duty of Hospitals with Specialized Capabilities to Accept Patient Transfers" Provision to Hospital Inpatients

Ms. Nelson presented the issue of whether the transfer of hospital inpatients should be addressed by expanding EMTALA's duty to accept provision, by recommending changes to the Medicare Conditions of Participation, or by continuing with current regulations based on the assumption that inpatient transfers are not subject to EMTALA. Dr. Pearlmutter, Dr. Thorward, and Dr. Siegel recommended that EMTALA not apply to inpatient transfers. Ms. Nelson agreed and recommended addressing inpatient transfers in the Medicare Conditions of Participation and advising hospitals to enter into contractual or informal relationships with other hospitals as needed. The subcommittee will recommend that the "duty to accept" provision not apply to inpatients and the Medicare Conditions of Participation be changed to confirm that hospitals have made appropriate plans for inpatients who require emergency stabilizing services beyond a hospital's capabilities.

b. Revised Capacity vs. Capability Definitions

Ms. Nelson deferred this discussion until the next subcommittee meeting.

c. Psychiatric Recommendations

Dr. Pearlmutter stated that he was drafting 2-3 different options to present to the TAG on this issue. He will work with Dr. Thorward to have the options completed for review by the subcommittee members at the next meeting.

d. CMS EMTALA Enforcement Recommendations

Ms. Chan presented her issues and comments from action subcommittee members. Members discussed the comments related to the issue of whether EMTALA enforcement should be limited to cases in which discrimination based or financial status is demonstrated. Members considered whether the statute should be changed to remove the word "appropriate" from the screening examination requirement.

Members also discussed the need to establish a provider appeal process before termination and considered whether enforcement should be tied to the concepts of discrimination or improper motive. The subcommittee agreed that there must be some pre-determination review process so that providers have an opportunity to challenge CMS's interpretation of the law or survey findings.

The rest of the issues and comments were deferred until the next subcommittee meeting. Ms. Chan will highlight key areas for members to focus the discussion on those issues needing member input.

III. Next Subcommittee Meeting.

Ms. Nelson reported that the next Subcommittee meeting had not yet been scheduled, but will be scheduled soon.

The meeting adjourned at 5:05 pm (EDT).

EMTALA TAG
ACTION SUBCOMMITTEE
TELEPHONE CONFERENCE

Date: Thursday, April 19, 2007

Time: 2:00 pm EDT

Members Present: Julie Nelson, Chair; Rory Jaffe, MD; Mark Pearlmutter, MD; S.R. Thorward

Others Present: David Siegel, MD; Edith Hambrick, CMS; Irene Chan, Extern; Jerica Peters, Extern

Members Absent: Michael Rosenberg, MD; Richard Perry, MD; Dodjie Guioa; Brian Robinson; Azzie Conley, RN

I. Administrative Issues

a. No issues were discussed during this subcommittee.

II. Substantive Issues

a. Revised Capacity vs. Capability Definitions

Ms. Nelson presented the revised capacity and capability definitions. Dr. Jaffe recommended adding "patient care" to describe the services in the definitions. Dr. Jaffe and Ms. Nelson discussed the need to clarify that hospitals with specialized capabilities should not include in an assessment of their capacity any modifications that have been made as a result of surge capacity. Ms. Nelson will revise the definitions in response to the discussion. She and Dr. Jaffe will review the interpretive guidelines to confirm that the terms (capacity and capability) are used correctly throughout the document.

b. Psychiatric Recommendations

Dr. Pearlmutter presented the psychiatric options that represented a summary of a December phone conference involving various psychiatric organizations. Dr. Jaffe, Dr. Thorward, Dr. Siegel, Dr. Pearlmutter, and Ms. Nelson preferred option C in clarifying the psychiatric EMC. Option C recommended removal of the current separate guidance on psychiatric EMCs, so that the remaining rules would apply equally to EMCs of either psychiatric or medical origin. A recommendation was made to present this

option to the TAG committee. Ms. Nelson recommended that this option be accompanied by education for providers.

In defining an appropriate medical screening examination for psychiatric patients, Dr. Thornton noted that psychiatric patients should be screened to determine if they are a danger to self, a danger to others, or gravely disabled. Ms. Nelson suggested that these three factors should be included in the screening exam to ascertain if psychiatric patients have an EMC. A recommendation was made to present Option A, in which a minimum MSE for psychiatric conditions would be developed to include the 3 screening factors above, to the TAG committee. This recommendation would support enabling hospitals to utilize community protocols.

The third option addressing the use of Qualified Medical Personnel will be discussed at the next subcommittee meeting.

c. CMS EMTALA Enforcement Recommendations

Ms. Nelson recommended that subcommittee members review the enforcement procedures and e-mail Ms. Chan with any comments.

III. Next Subcommittee Meeting

Ms. Nelson reported that the next Subcommittee meeting will be next week at 2:00 pm (EDT).

The meeting adjourned at 3:05 pm (EDT).

DUTIES OF HOSPITALS WITH SPECIALIZED CAPABILITIES TO ACCEPT PATIENT TRANSFERS

CURRENT RULE:

42 U.S.C. § 1395dd(g); 42 C.F.R. § 489.24(f)
A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

EMTALA Interpretive Guidelines, Tag A411 (see Interpretive Guidelines, page 53-54)

NEED FOR CHANGE:

Hospitals and physicians have expressed confusion with respect to their duty to accept patient transfers and there has been relatively little guidance on this subject. The term "specialized capabilities" is not clearly defined. In addition, the current interpretation is subject to abuse, which has resulted in improper transfers.

RECOMMENDATION:

The Action Subcommittee recommends that the Interpretive Guidelines with respect to a hospital's duty to accept patient transfers if it has specialized capabilities be replaced with language that more clearly reflect the responsibilities of both the transferring and receiving hospital, as follows:

DUTIES OF TRANSFERRING HOSPITAL*
1. Maintain a call list that best meets the needs of hospital patients. (Transfers out for conditions hospital normally capable of handling may suggest inadequate call list, as will an increased number of transfers on weekends, vs. weekdays.) [*Pending on-call sub-committee review; hospitals and physicians need more guidance regarding whether a hospital's on-call list is adequate. Clarify that while the duty to maintain an on call list is a Medicare Provider Agreement requirement, transfers based on lack of on-call coverage in a specialty may trigger a review of the transferring hospital's compliance with this provider agreement requirement.]*
2. Provide appropriate medical screening examination and stabilizing care within the transferring hospital's capabilities prior to transfer, in accordance with 42 C.F.R. 489.24(d)(1) and (e)(2)(i). *[Note: recommend revising (e)(2)(i) to state that the "transferring hospital provides medical treatment within its capability" (instead of "capacity).]* The extent of the medical screening examination and stabilization will depend on the

DUTIES OF TRANSFERRING HOSPITAL*
patient's needs and the hospital's capabilities. When determining a hospital's capabilities, the critical question is whether the hospital has the capabilities to provide the services that are necessary to stabilize the patient's emergency medical condition. It would not be acceptable for a hospital to transfer a patient solely because it does not have capabilities that the patient requires, but are not essential to stabilize the patient's emergency medical condition. When the hospital does not have the capability to completely stabilize the patient's emergency medical condition, the hospital must complete necessary stabilizing steps within its capability unless doing so would cause <u>harm to the patient or</u> an undue delay in the patient's care and transfer (*e.g.*, severe head trauma patients that do not present to a trauma center may require basic stabilization, then transfer). <u>The treating physician at the transferring hospital determines the stabilizing steps necessary within the hospital's capability given the patient's medical condition</u>.
3. The physician's decision as to whether or not to transfer may not be based on insurance status/financial means (number of transfers of patients without insurance evidences possible abusive transfers.). *[The Action Subcommittee supports an exception for community protocols (e.g., psychiatric patients who are a part of a state-wide psychiatric program based on indigent status). <u>Note: the EMTALA TAG has not addressed this concept. Hold for future discussion.]</u>* Patients may request transfer based upon insurance/financial reasons, but the hospital should not present financial information to the patient in a manner that would discourage the patient from receiving stabilizing care from the hospital. If a patient requests transfer, the hospital must comply with the EMTALA requirements for patient requests for transfer set forth in 42 C.F.R. § 489.24, which includes a requirement to inform the patient of the risks and benefits of the transfer decision. *<u>[This latter concept not yet approved by the EMTALA TAG.]</u>*
4. The transfer must be an appropriate transfer, as defined in 42 C.F.R. § 489.24(e)(2).
5. The determination of whether patient is unstable, requires a higher level of care, and whether the transferring hospital has the capability to provide stabilizing treatment, the treating physician's judgment rules, but may be questioned later by receiving hospital and reviewed by CMS surveyors for potential abusive transfer decisions. *<u>[Teaching points:</u>* *(1) <u>when in doubt, accept patient transfers;</u>* *(2) <u>when question regarding appropriateness of transfer, encourage communication with transferring hospital or EMTALA report, as required by law.]</u>*
6. In determining whether hospital has the capabilities to provide stabilizing care to the patient, surveyors look at capabilities of hospital at the time of the transfer and period thereafter consistent with the patient's "window" for required emergency care. Availability of additional care that will be or may be required once the patient's emergency medical condition is stabilized is not a basis for determining that the hospital lacked the capability to stabilize the patient's EMC. This recommendation is intended to prevent hospitals that typically have the capability to stabilize a particular emergency medical condition (*e.g.*, appendectomy) from transferring patients to another hospital simply because the hospital currently does not have the on-call

DUTIES OF TRANSFERRING HOSPITAL*
physician resources or equipment to stabilize the patient's medical condition, but when the hospital's resources are likely to be available within the timeframe necessary to stabilize the patient's emergency medical condition. This recommendation is not intended to delay the care and treatment for patients who must be treated immediately, when the hospital does not have the capability to stabilize the patient's medical condition immediately.
7. The transferring physician must take into account the distance that the patient will travel in his/her certification that the benefits of the transfer outweigh the risks. If the transfer destination is outside of the hospital's local region, the transferring hospital must attempt to transfer patients to the nearest appropriate hospital with the specialized capabilities to stabilize the patient's emergency medical condition, consistent with the patient's health care needs, transfers over great distances in which closer, appropriate hospitals are bypassed may violate EMTALA. This provision does not apply to established pre-determined transfer arrangements designed to meet patient care needs.

DUTIES OF RECEIVING HOSPITAL
1. No obligation to accept hospital in-patients, consistent with 42 C.F.R. 489.24(d)(2) and CMS interpretation. *[Consider imposing a requirement in the Medicare Conditions of Participation to protect inpatients with emergency medical conditions.]*
2. Only required to accept emergency department patient transfers when the transferring hospital does not have the capability to stabilize the patient's emergency medical condition. In other words, a hospital is not required to accept a patient transfer simply because the patient would like to be transferred to the receiving hospital. The physician must certify that the transfer is necessary because the transferring hospital does not have the capability to stabilize the patient's emergency medical condition and the benefits of the transfer outweigh the risks, consistent with the physician certification requirements set forth in 42 C.F.R. § 489.24(e)(1)(B).
3. No obligation to accept if the only basis for the transfer is patient request (must be physician certified of higher level of care).
4. Receiving hospitals are not obligated to accept a patient transfer if the basis for the transfer is lack of capacity, except in unusual circumstances. The transferring hospital makes the determination that it lacks capacity and unusual circumstances justify patient transfer under this provision. As an example, if the transferring hospital is experiencing surge capacity, a disaster situation, or lacks critical equipment or space due to an equipment or physical plant failure, the receiving hospital may also have an obligation to accept a patient if, despite taking all reasonable actions to maintain adequate capacity, the transferring hospital cannot stabilize the patient's care due to overcapacity, as determined by the

DUTIES OF RECEIVING HOSPITAL
transferring hospital, assuming the receiving hospital has capacity to accept the patient. If a transferring hospital has demonstrated the ability to accommodate additional patients by whatever means (*e.g.*, moving patients to other units, calling in additional staff, borrowing equipment from other facilities), it has demonstrated the ability to operate in an overcapacity situation and the receiving hospital would not be obligated to accept this patient transfer. This requirement is consistent with the current EMTALA Interpretive Guidelines, Tag A411. Receiving hospitals are not required to accept patient transfer if they lack the capacity to do so. The receiving hospital is under no duty to expand its existing capacity to accept patient transfers as described above. This is a recommended departure from the current EMTALA Interpretive Guidelines, which appear to require such efforts on behalf of a receiving hospital. Finally, a receiving hospital is under no EMTALA obligation to accept transfers of patients who do not require stabilization services for an emergency medical condition, even if the transferring hospital lacks capacity, irrespective of extenuating circumstances.
5. Receiving hospital may provide advice regarding stabilizing care or transport options, as long as these communications do not unduly discourage patient care, but the transferring hospital is not required to accept the receiving hospital's recommendation. *[possible medical liability impact, depending on state law.]*
6. Receiving hospitals should have systems in place to communicate with admissions staff and on call physicians to confirm that they have the capacity and capability to provide stabilizing care to the patient before accepting a patient. Receiving hospital must make the decision as to whether it will accept/reject transfer within a "timely" manner, based on the patient's condition as reported by the transferring hospital.
7. Duty to report improper transfers, which includes abuses of this provision, in accordance with 42 C.F.R. § 489.20(m). *[Enforcement consideration: informal QIO process to address patient transfers when there is a question with respect to whether the patient's clinical condition warranted a higher level of care and dispute regarding the hospital's capabilities.]*
8. "Specialized capabilities" includes dedicated units, specialized equipment and personnel (including on call physicians) available at the time of transfer or that will be available within the patient's treatment "window." Specialized capabilities do not include medical staff members who are not on call. *[On-Call Subcommittee evaluation pending regarding whether an on-call physician is a specialized capability.]*
9. Failure to accept an unstable patient who requires the hospital's specialized capabilities available at the time of transfer may be an EMTALA violation if the hospital has the capacity to accept the transfer.

EMTALA EDUCATION RECOMMENDATIONS

1. More Comprehensive, Prominent, User Friendly CMS EMTALA Website That Includes:

   A. Statutes
   B. Regulations
   C. Interpretive Guidance
   D. Current CMS/OIG Program Memoranda/Guidance Letters
   E. EMTALA Questions and Answers
   F. Link to Medicare Conditions of Participation
   G. Enforcement Statistics
   H. "Top 10" Cited EMTALA Deficiencies
   J. Special Advisories of Potential EMTALA Violations
   K. Link to OIG Website
   L. Topical Cross-References
   M. EMTALA 101 "Basics"
   N. Document Downloads

2. Standardized Regional Office/State Surveyor Education

   A. Annual EMTALA surveyor education sessions (currently offered every two years)
   B. Establish a system to improve consistency in regional office EMTALA interpretations and enforcement (*e.g.*, assign CMS central office person to monitor deficiency statements for consistency with CMS policy and consistency among jurisdictions and remedy concerns).
   C. Establish a system to monitor effectiveness of surveyor education.
   D. Establish a system to demonstrate surveyor competencies.
   E. Confirm prompt distribution of CMS EMTALA Guidance, including EMTALA opinion letters and program memoranda, to Regional Offices and state agencies.

3. Provider Education

   A. Designate/approve specific CMS/OIG personnel to participate in provider education through various educational forums (*e.g.*, AHLA, hospital/physician association meetings). Consider joint presentations by both agencies and establish a process to confirm consistency of information provided.
   B. Timely response to provider queries regarding EMTALA compliance and interpretation questions.
   C. Establish a process to address new obstacles to EMTALA compliance and remedy through regulatory or interpretive guidance change.

D. Establish List-Servs or other mechanism so that interested parties can receive regular updates and information regarding EMTALA from CMS/OIG.

E. Consider EMTALA Training by QIO.

4. Patient Education

A. EMTALA rights and consequences (*e.g.*, EMTALA requires hospitals to provide care irrespective of the patient's ability to pay, however, the hospital may still expect the patient to pay for services rendered). This information should be provided outside of the context of an emergency department visit.

B. Hospitals may request social security numbers and citizenship documentation in order to receive payment for care rendered to undocumented patients (Section 1011 requirements). *[This section requires further consideration. This may not be an issue.]*

CMS Enforcement of EMTALA
Action Subcommittee Recommendations and Discussion Issues[4]

Action Subcommittee Recommendations

Recommendation 1: There should be appeal processes for hospitals/providers prior to a termination decision.

c. Hospitals should be allowed to request QIO review for medical issues prior to termination.
d. Hospitals should be allowed to request an appeal from the CMS RO on factual, policy and legal issues prior to the submission of a plan of correction or a decision to terminate. For example:
    i. If the RO believes a violation has occurred, a hospital is first given a draft statement of deficiencies, after which it has 10 days to provide CMS with any objections or additional information. CMS would have 10 days to consider the additional information and issue a final statement of deficiencies that responds to it. An expedited appeals process should be in place for hospitals to be placed on a 23-day termination track.
    ii. Region VI process (to be submitted by Dodjie Guioa).

Recommendation 2: Intermediate sanctions, such as an opportunity to correct with follow-up inspection or a system of warnings, should be available for less serious EMTALA violations. Hospitals with technical violations (e.g. signage, log books) should receive lower sanctions.

Recommendation 3: There should be consistent data collection of all EMTALA violations and central evaluation of the information, in a format determined by CMS to improve consistency of enforcement across the Regions and serve as a resource for providers.

Discussion Issues

General:

- Should EMTALA enforcement be limited to cases where discrimination based on financial status is demonstrated, rather than poor quality of care?

[4] Prepared by Irene Chan, Esq., Action Subcommittee Extern

- Should determinations on law/policy be reviewed by RO or central office in order to avoid conflicting pronouncements from local agencies?

Survey Issues:

- Should hospitals that self-report be less likely terminated and have its cases forwarded to OIG? Should a hospital not be terminated if it self-reported and self-corrected prior to the survey?

- Should ROs conduct a preliminary review of complaints to achieve greater consistency and to focus resources? If a desk review suggests no violation, should the RO not authorize a survey?

- Should investigations be initially limited to the complaint case (unless the proper method for investigation of the complaint entails using sampling (e.g., a complaint that a disproportionate number of non-paying patients are transferred))? Should the investigation be extended only when there is either 1) a preponderance of evidence that an EMTALA violation occurred in the initial case or 2) review of the initial case demonstrates that the initial complaint cannot properly be evaluated without reviewing more records?

QIO Review Issues:

- Should there be uniform CMS training of QIOs and QIO physicians?

Termination Issues:

- Should CMS be required to inform the affected hospital/provider of no violation within a certain timeframe, e.g. 10 days from SA report?

EMTALA TAG
ACTION SUBCOMMITTEE
TELEPHONE CONFERENCE

Date: Thursday, April 26, 2007

Time: 2:00 pm EDT

Members Present: Julie Nelson, Chair; Mark Pearlmutter, MD; S.R. Thorward, Dodjie Guioa, CMS

Others Present: David Siegel, MD; George Morey, CMS; Sandra Sands, OIG; Irene Chan, Extern; Jerica Peters, Extern

Members Absent: Michael Rosenberg, MD; Richard Perry, MD; Brian Robinson; Azzie Conley, RN, Rory Jaffe, MD

I. Administrative Issues

a. No issues were discussed during this Subcommittee meeting.

II. Substantive Issues

a. Revised Capacity vs. Capability Definitions

Ms. Nelson presented the revised capacity and capability definitions based on the previous week's conference call. Ms. Nelson stated that she and Dr. Jaffe would work to finalize the document for presentation to the TAG. Ms. Nelson raised the issue with respect to whether hospitals should be required to provide medical screening and stabilization services within their "capabilities" or "capacity" based on the revised definitions. Members agreed to consider this issue in preparation for the next TAG meeting.

b. Psychiatric Recommendations

Dr. Pearlmutter presented a document for discussion by the Action Subcommittee that addressed whether psychiatric patients that have been provided with physical or chemical restraints have been "stabilized." Subcommittee members discussed this issue in detail, with some members preferring to view chemical and physical restraints as services provided to "minimize transfer risks" and not "stabilize" the patient under the EMTALA definition. Accordingly, these patients would still be deemed to have an emergency medical condition. Members also discussed the relative merits of addressing psychiatric patient issues in the interpretive

guidelines or developing general guidelines that apply to both medical and psychiatric patients. Some members believed that the two types of patients are very different and should be treated accordingly in the interpretive guidelines.

In preparation for next week's TAG meeting, Dr. Pearlmutter agreed to combine the two documents that he has prepared regarding psychiatric patient issues and to revise them to summarize the Action Subcommittee recommendations and the various psychiatric issues still under discussion by the Subcommittee.

c. CMS EMTALA Enforcement Recommendations

Ms. Chan presented her revised document on the Action Subcommittee's enforcement recommendations. Mr. Guioa noted that Region VI has an enforcement and informal appeal process that may address some the Action Subcommittee's concerns. Mr. Guioa will prepare of a summary of this process, which Action Subcommittee's may elect to adopt as a model for its recommendation. Ms. Chan agreed to revise the document based on the members' comments for review by the TAG.

d. Public Comments

Ms. Nelson stated that she has e-mailed Action Subcommittee members a list of all of the public comments received to date. Ms. Nelson requested that members review the list and help her identify issues that fall within the Action Subcommittee's scope that have not yet been addressed or issues that do not appear on the list. Dr. Pearlmutter noted that a public comment related to "triage out" was not on the list and needed to be included in this list. Ms. Nelson agreed to add that comment to the list and stated that it is important that the Subcommittee consider all public comments.

The meeting adjourned at 3:00 pm (EDT).

CAPABILITY AND CAPACITY

CURRENT RULE:

42 C.F.R. § 489.24(b)

"Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits."

Interpretive Guidelines, Tag A407

"Capabilities of a medical facility mean that there is physical space, equipment, supplies, and specialized services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care).

Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. This includes coverage available through the hospitals on-call roster."

NEED FOR CHANGE:

The current regulation and interpretive guidelines defining a hospital's capacity and capabilities is not entirely clear. The two definitions appear to overlap in some ways, creating confusion regarding what is being required when only one term is being used. In addition, there are several instances within the interpretive guidelines where it appears that either the wrong term is being used or only one term is being used where both seem to be required. The Action Subcommittee believes that hospitals and physicians need better guidance with respect to their obligations regarding what determines whether a particular patient's care is within their capacity and capabilities and whether an obligation or exemption is based upon capacity or capability.

RECOMMENDATION:

The Action Subcommittee recommends that the definitions of a hospital's capabilities and capacity be better defined in the EMTALA statute, regulations, and interpretive guidelines as follows:

Capability means the inpatient and outpatient patient care services that a hospital typically has the resources to provide, irrespective of whether those resources are available at a specific time or within a specific period of time. These services include, but are not limited to: (1) health care services that a hospital routinely provides; (2) core hospital services (e.g., general surgery); (3) services that a hospital is licensed by state

law to provide; and (4) services that the hospital holds itself out to the public as capable of providing (e.g., advertised services or centers of excellence).

Capacity means that resources are available to a hospital to provide patient care services at a specific time or within a specific period of time consistent with the needs of the patient. A hospital lacks capacity when the resources necessary to complete a medical screening examination or to stabilize an emergency medical condition within the time period consistent with the needs of the patient are not available. These resources may include, for example, beds, qualified staff, equipment, operating rooms, and on-call physician services.

The fact that a hospital does not have all of the necessary resources to provide definitive care to a patient or the best possible care does not mean that the hospital lacks the capacity to provide a medical screening examination or stabilizing treatment to a patient. As long as the hospital has the resources to determine whether the patient has an emergency medical condition and stabilize the patient's emergency medical condition within the period of time dictated by the patient's needs, the hospital has the capacity to provide the required service.

If the treating hospital has routinely accommodated additional patients in excess of its resources in the past, then there is a presumption that it has the resources to expand to the same scale as it routinely does for any given patient, provided that the expansion could be accomplished within the time period dictated by the patient's medical screening examination and stabilizing treatment needs.

A potential recipient hospital with specialized capabilities is not deemed to have the capacity to accept a patient transfer when receipt of the patient would cause the hospital to operate beyond its licensed capacity or violate other legal requirements.

STATUTORY, REGULATORY, AND INTERPRETIVE GUIDELINE REFERENCES TO THE TERMS "CAPACITY" AND "CAPABILITY"[5]

STATUTE: 42 U.S.C. § 1395dd

(a) Medical screening requirement

In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the **capacity** of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (e)(1) of this section) exists.

(c)(2) Appropriate transfer

An appropriate transfer to a medical facility is a transfer –

> **(A)** in which the transferring hospital provides the medical treatment within its **capacity** which minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(g) Nondiscrimination

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. *[Subject to TAG Action Subcommittee recommendation regarding Duties of Hospitals with Specialized Capabilities]*

REGULATIONS: 42 C.F.R. § 489.24

(a) Applicability of provisions of this section.

> (1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must--

[5] The Action Subcommittee has not reached consensus on the proposed usage of the terms capacity and capability in the statute, regulations, and interpretive guidelines referenced below. This matter is still under discussion by the Action Subcommittee.

(i) Provide an appropriate medical screening examination within the **capacity** of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of § 482.55 of this chapter concerning emergency services personnel and direction;

(b) Definitions. As used in this subpart –

Capability *[see above]*

Capacity *[see above]*

(d) Necessary stabilizing treatment for emergency medical conditions.--

(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either--

(i) Within the **capacity** of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(e) Restricting transfer until the individual is stabilized--

(2) A transfer to another medical facility will be appropriate only in those cases in which –

(i) The transferring hospital provides medical treatment within its **capacity** that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(f) Recipient hospital responsibilities. A participating hospital that has specialized **capabilities** or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at § 412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized **capabilities** or facilities if the receiving hospital has the **capacity** to treat the individual. This requirement applies to any participating hospital with specialized **capabilities**, regardless of whether the hospital has a dedicated emergency department. *[Subject to TAG Action Subcommittee recommendation regarding Duties of Hospitals with Specialized Capabilities]*

INTERPRETIVE GUIDELINES

Revise interpretive guidelines consistent with revised regulatory language.

APPENDIX 3

EMTALA TAG

Dear Committee Members:

Problem
EMTALA regulations result in transfer of patients to our hospital that for some specialists, overwhelm the capacity of the physicians to provide the required care.

Background
Broward General Medical Center, one of the largest hospitals in Broward County (population of 1.8 million) is a tax-supported urban hospital that serves both an insured and non-insured population. It operates a level 1 adult and pediatric trauma center. Some specialists are in short supply, such as one pediatric orthopedist, and two neurosurgeons who provide on-call services. My associate and I provide 24/7 neurosurgery coverage for the trauma centers, all non-trauma emergencies, the brain attack program; and neurosurgical consultations for in-patients. We provide neurosurgery services for a branch of a state operated program for children with long-term congenital and developmental medical conditions. Finally, we maintain an elective general adult and pediatric neurosurgical practice.

As full time hospital employed physicians (we enjoy liability protection under sovereign immunity) we have contractual obligations to provide emergency on-call services. I cannot drop of the emergency room call roster and maintain my current employed status.

Transfers to Broward General
Broward General receives daily transfer of patients from hospitals as far away as Tallahassee to the north Key West to the south. Patients in the entire spectrum of medical care are received, but we see particularly large volume of patients with cardiac problems, patients with infected pacemaker wires, pediatric patients and in particular, children with long bone fractures, neurosurgical and neurological problems. For those specialists with the necessary manpower, the transfer may be beneficial (to some extent) to both hospital and physician. For other specialists it creates an unacceptable increased workload.

Reasons for Increased Transfers
Specialists in our area have concentrated on an elective surgical practice, and so improve their life-style by dropping off emergency room call. Many patients seeking emergency treatment are not insured, thus making emergency call not only burdensome but also financially unrewarding. Although Broward General receives patients that clearly are in need of services not available at the transferring hospital, many patients have simple and routine problems that are transferred simply because the transferring hospital is having difficulty finding physicians to provide emergency care. Other patients may have acute life-threatening problems such as neurosurgical emergencies that make them entirely unsuitable for transfer.

It has become commonplace for the larger local hospital to pay for on-call services. Periodically local hospitals loose their specialty coverage because the physicians may be negotiating to be paid for on-call services, or to be paid at a higher rate. The hospital is able to maintain operations without that particular coverage, since 24/7 coverage is not required by EMTALA. Furthermore, EMTALA provides for an escape mechanism, by mandating that a hospital that has the required specialist on call must take the patient in transfer.

I ask for you help and advice on behalf of our medical staff and myself.

Amos Stoll MD, FACS
Broward General Medical Center
Ft Lauderdale, Florida

APPENDIX 4

To: EMTALA TAG

Re: The negative effects of EMTALA and regionalization of emergency medical and trauma care on the tertiary referral trauma center.

The following is in reference to the effects of interfacility transfer of patients on the regional trauma center. Although these issues apply to emergency medical conditions in general, the experience of trauma centers in recent years serves as a model for the larger emergency medical system.

EMTALA was designed to ensure that patients in need of emergency medical treatment would receive care regardless of their ability to pay. EMTALA mandates that emergency care centers provide treatment within their medical capabilities to an extent that stabilizes the patient's emergency medical condition, or transfer patients whose needs exceed their capabilities to higher levels of care after initial stabilization efforts. EMTALA further requires that tertiary referral centers accept patients in transfer that need specialty services provided at such centers.

The spirit of the legislation assures that patients with emergency medical conditions will have access to the full spectrum of emergency medical care. It also provides acute care centers with limited medical capabilities an additional resource for patients requiring higher levels of care.

The Level I Trauma Center serves as a regional resource and tertiary referral hospital for the entire trauma system. Level I trauma centers are generally located in population dense areas and accept injured patients needing specialty trauma care from referring hospitals within a defined geographic region. The majority of trauma patients suffers only minor injuries and receives definitive care outside of Level I and Level II trauma centers. Severely injured patients generally receive initial evaluation and stabilization at a referring center before transfer to the regional trauma center for definitive care. The Level I trauma center also serves as a primary receiving facility for a local community, caring for all injured patients including those with minor injuries which arrive directly from the scene.

In an inclusive trauma system, other hospitals within the geopolitical boundaries of that trauma system are designated at lower levels which define these centers' treatment capabilities and commitment of resources to the trauma patient. Organization of acute care facilities into an inclusive trauma system reduces injury related morbidity and mortality and decreases the cost of care of the population served. Over the last three decades, formal trauma systems have been established in 36 states and enabled 86% of the US population to reach a Level I or Level II trauma center within one hour of injury. [1]

The decision and responsibility to transfer patients to higher levels of care rests with the initial evaluating physician at the community center. In many cases reasons to transfer patient are clearly evident in those patients with severe multisystem injuries and those needing specialist care available at Level I trauma centers. Indeed, many Trauma systems mandate transfer of severely injured patients that have specific injury patterns or meet physiologic criteria to the Level I trauma center. A second category of trauma patients transferred to regional trauma centers can be defined as those that may not have severe injuries, but require treatment by a specialist that is not available at the community hospital. Common examples include patients with isolated head injuries who are initially treated in a hospital with no neurosurgical capabilities, or patients with facial bone fractures that present to hospitals without specialists on call for these injuries. An extension of this category would include patients with injuries requiring treatment by specialists that may practice at the community center, but do not participate in trauma or emergency department call. Examples include patients with closed extremity fractures or abdominal injuries treated at hospitals where orthopedic and general surgeons do not participate in trauma coverage. This group constitutes the fastest growing cohort of patients transferred to tertiary care centers. The recent changes in EMTALA that no longer require hospitals to maintain call panels for services they routinely provide electively has encouraged this practice. A final category of transferred patients could be defined as those who have injuries that could be definitively treated at the community level, but who are transferred for non-medical reasons such as convenience of the treating physician or financial considerations.

By design, the regional trauma center represents a higher level of trauma care than lower level trauma centers and undesignated hospitals within a system. Even when referring hospitals have specialist capability, it can be argued that the Level I trauma center represents a higher level of care due to the requirement that specialists be immediately available. As a result, immediate availability has been used to justify transfer of patients that could receive definitive care locally. [2] The particular difficulty in trauma care is the determination of which patients truly need Level I trauma resources, and which could receive definitive care at the community level within their treatment window.

Decisions to transfer the severely injured are relatively straightforward. In contrast, decisions to transfer the less severely injured are much more subjective and heavily influenced by practice patterns at the community level.[3] EMTALA appropriately places the authority to transfer patients in the hands of the transferring physician. This individual is on scene and has first hand information on the clinical condition of the patient. Unfortunately, patients are increasingly being transferred for reasons other than medical necessity. [4] A number of recent reports describe the transfer of such patients to be influenced by insurance status, gender, ethnicity, patient age, and time of day. [4, 5] Our own trauma center has witnessed an 83% increase in the number of patients transferred from referring facilities since 2000 but a 20% decrease in the proportion of transfer patients with severe injuries. In other words, we are seeing

more and more patients with minor injuries transferred from the community hospitals to the regional trauma center.

The benefits of transfer to a regional trauma center have been well established in patients with severe multisystem trauma, complex fractures, and patients with head and spinal cord injuries. [6] However, a similar benefit to patients with less severe injuries has not been established. A number of studies report that severity adjusted outcomes at Level III and Level IV trauma centers are similar to those reported in the Level I and Level II regional trauma centers. [7] [6] It has been argued that this is a result of improved care in the community trauma center due to participation in the regional trauma system with its attendant improvements in trauma outreach and education. Indeed, trauma care delivered at level III trauma centers is superior to trauma care delivered at non designated community hospitals of similar size and care improves in hospitals that have undergo formal trauma center designation. [8] [9] Thus it appears that the key to improved trauma care within a trauma system is access to Level I care for the severely injured and participation in the trauma system by community hospitals for the less severely injured.

Lowering the threshold for transfer of injured patients has a profound impact on the regional trauma centers. Since the majority of trauma patients suffer only minor injuries, increased transfer would greatly increase Level I resource consumption by this cohort relative to the severely injured cohort. Taken in the context of an already strained emergency medical care delivery system, this shift towards lower acuity care threatens the availability of scarce high acuity resources to those in the most need. If the regional referral center becomes inundated with patients having only minor injuries, the trauma receiving unit is more likely to be overwhelmed prompting ambulance diversion. Emergency Department closure of a regional Level I resource not only denies access to Level I care for the region, but also denies all trauma care to the local community served by the regional trauma center. In such cases, transfer patients are diverted to more distant centers or kept in community centers that may be ill equipped to manage complex multisystem trauma. Moreover, patients in the local community normally served by the Level I trauma center must be taken to more distant facilities potentially delaying care. Use of EMS for transport also occupies a unit and decreases the EMS resources available to respond to scene calls. Still undefined is the impact of unnecessary transport on the patient and the patietn's family.

Excessive interfacility transfer also affects the Level I trauma center beyond the initial evaluation and management phase of trauma care. With most hospitals operating near or at capacity, additional redistribution of community patients to referral centers threatens inpatient bed availability. Although patients with minor injuries have shorter lengths of stay compared to those with severe injuries, there are many more patients with minor injuries admitted to the hospital and they consume approximately 35% of hospital bed days. Decreased bed availability directly affects patient throughput in the emergency department and trauma receiving unit which in turn increases the need for ambulance diversion. Repatriation of the more severely

injured patient to the community hospital once need for Level I care is resolved has been proposed but is generally not part of interfacility transfer agreements nor is it part of the referring hospital responsibilities defined by EMTALA.

In addition to delaying treatment and concentrating low acuity resource use at the regional referral center, inappropriate transfer of patients dramatically increases the cost of delivering care. Overall costs are not only increased by the cost of transport and secondary evaluation at the receiving center, but also the costs of caring for patients transferred to Level I trauma center are increased compared to the costs of caring for similar patients that are transported directly from the scene. [10, 11 12] The Medicare prospective payment system does not recognize this difference in cost and resource consumption in its diagnosis related groups and thus regional trauma centers are reimbursed at levels that may not cover costs. This has raised the concern that this payment structure subjects regional trauma centers to considerable financial risk and may in part be responsible for the many trauma center closures witnessed in the recent past. [10]

Concentration of trauma patients at regional referral trauma centers naturally results in concentration of the economic responsibility for trauma care at these same trauma centers. Thus the receiving center assumes both the medical and economic responsibility of inpatient care even in cases of inappropriate transfer. By transferring all trauma patients, the community hospital is able to defer the costs of further care to the regional trauma center and improver its case mix. Although some states and trauma systems recognize this imbalance and provide funding for trauma system development and trauma patient care, many trauma centers receive limited public support and are in danger of economic collapse. Although this appears to be solely an economic issue, it is quickly translated into an access to emergency medical care issue once it is realized that financial instability is the chief reason for trauma center closure. Once a trauma center closes, it is closed to all and while the community hospitals may be able to avoid the direct financial consequences, they will face an inability to transfer patients truly in need to a higher level of care.

In summary, acutely ill patients must be afforded access whatever level of care is needed to treat their emergency medical condition. Trauma care within an inclusive trauma system aims to bring the injured patient and definitive care together in the shortest practical time. Rapid transfer to Level I trauma centers improves outcomes of severely injured patients and those with specific injury patterns, but its benefit to the patient with minor injuries has not been established. Inappropriate transfer of patients to Level I centers that do not require Level I care consumes scarce Level I resources, shifts the economic burden to the regional referral center, and threatens trauma system viability. Economic collapse of the trauma center leaves the local community and the region without any Level I trauma care. The medical community has historically focused on the effects of undertiage and the inadequate use of trauma systems. Increasing strains on the national emergency medical care delivery system demand that the effects of overtriage and the threats to system integrity also be considered. EMTALA was created to assure that individual patients receive proper

emergency medical care. By doing so in an environment with finite medical resources, EMTALA and the recent clarifications that no longer require hospitals to maintain specialty call coverage has allowed emergency care to be shifted to regional centers. Faced with increasing requests for transfer and fear of suffering the consequences of an EMTALA violation, the regional referral centers have very little ability to control the volume and acuity of patients that they accept in transfer. Review of EMTALA practices must include cases of inappropriate overtriage as well as cases where patients in need were denied access to higher levels of care. A mechanism must be established to determine if referring hospitals are indeed living up to the expectation that they deliver care within their medical capabilities inside the patient's treatment window. The resource and economic burden of providing emergency medical care must be shared by the by the communities being served and not be left to the tertiary care center.

Future efforts should be directed at defining treatment capabilities of community acute care centers and encouraging participation in regional trauma systems. A key aspect of trauma system design provides regular assessments of resource utilization and overall population outcomes. Patient care outside the regional referral center is improved though standardization of care and transfer expectations according to center designation, outreach and educational activities, and improved interfacility communication and prearranged transfer protocols. Transfer agreements between hospitals should be individualized to account for the site specific care limitations and include repatriation agreements so that patients are returned to their home communities once the need for Level I resources has passed.

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APPENDIX 5

Testimony
Of
Jeffrey O. Anglen, MD

On behalf of the

Orthopaedic Trauma Association (OTA)
&
American Association of Orthopaedic Surgeons (AAOS)

Presented during the EMTALA TAG Meeting
May 3-4, 2007

INTRODUCTION

Members of the EMTALA TAG, my name is Dr. Jeff Anglen. I would to thank you for the opportunity to present. I work for Indiana University as Chairman of the Department of Orthopaedic Surgery, and I am a practicing orthopaedic trauma surgeon as well as a teacher. I am also the current President of the Orthopaedic Trauma Association, a professional society composed mostly of North American orthopaedic trauma surgeons, and dedicated to the mission of promoting excellence in the care of injured patients through education, research and clinical service.

Today, I am presenting this statement on behalf of OTA with input from the American Association of Orthopaedic Surgeons or AAOS. As orthopaedic trauma surgeons, our members, many of whom work at our nation's trauma centers, are frequently on the receiving end of patient transfers. Unfortunately, our experience is that the problem of inappropriate patient transfer has not been eliminated by EMTALA legislation. In fact, many of our members think it is increasing.

In 2005, Dr. Jason Nascone, testified on behalf of the OTA and AAOS regarding EMTALA and the work of this TAG. Dr. Nascone pointed out the many and increasing difficulties of the nation's orthopaedic trauma surgeons in providing care to injured Americans and made some specific suggestions about the ways in which both the EMTALA TAG and CMS could help the situation. I will not recount those recommendations today, but just remind you of them; they are still relevant today as the entire orthopaedic community attempts to address this important health policy issue. I would like to give you a brief update on the view of this problem from the field, and inform you about some of our initiatives to address it.

As everyone in this room is aware, throughout the nation, hospital emergency departments (EDs) continue to suffer from increasing patient loads, and decreasing specialist availability. This has been recently and exhaustively detailed in the Institute of Medicine Report *Hospital-Based Emergency Care: At the Breaking Point*. Patients are finding it difficult and sometimes impossible to obtain emergency care services in a timely manner because of a variety of factors. One of these factors is access to specialists, such as orthopaedic surgeons, willing and able to take emergency call.

The orthopaedic surgeon on call for the emergency department is subjected to multiple pressures including an increasing workload of complex patient problems with a high percentage of uncompensated care, increased liability risk, disrupted elective practice, disrupted personal life and loss of sleep, and the perceived risk of blood borne illness exposure. As a result of these pressures, many orthopaedic surgeons have left the call schedules of local trauma centers and other hospitals. This leads to unnecessary tranfer of patients, delays in care, inefficiencies and worse outcomes.

In my own practice, this is a common problem. Many hospitals in central Indiana and even within Indianapolis do not have an orthopaedic surgeon on call who is willing to

treat fractures, and must refer these patients to the county trauma center, Wishard Hospital. Because our orthopaedic clinic is overloaded and understaffed, timely access is often impossible and patient care is delayed. As a result of access related treatment delays, patients with fractures have more difficult treatment, prolonged disability, and worse outcomes. By the time that I or my partners get to treat these patients, a simple problem may have become a difficult one.

There is recent evidence from the medical literature that the transfer of orthopaedic patients is sometimes motivated not only by lack of specialist availability or specific skills but by economic or other factors. We have included in your packets two recently published articles from the orthopaedic literature which suggest that various non-medical factors, including insurance status, may still significantly influence transfer of injured patients. Patient dumping, which EMTALA was partially designed to prevent, appears to be alive and well.

While we are very aware that hospitals, communities and governmental bodies have important duties and roles in addressing these issues, the OTA has focused on what we as physicians and surgeons can contribute to the solution. In December of 2005, the OTA adopted an official position statement regarding On-call issues. This has been provided to you, and I hope you will read it, as time today prohibits me from covering it in detail. A few of the principles included are that we believe that orthopaedic surgeons are uniquely qualified to provide emergency care for patients with musculoskeletal conditions, including musculoskeletal trauma. Therefore, orthopaedic surgeons have a responsibility to work in their communities with each other and their hospitals to make sure that mechanisms are in place so that emergency patients with musculoskeletal problems receive timely and appropriate care. Similarly, hospitals have a duty to provide adequate resources, and the government has a duty to provide adequate compensation for the care of the indigent. Orthopaedic surgeons also have a duty to use the unique skills and knowledge that they have been given to serve the injured in their community. We believe all trained orthopaedic surgeons should maintain the skills and knowledge to provide basic emergency care of the injured musculoskeletal system.

The OTA believes that while this crisis in the care of injured patients is not entirely of our making, we must acknowledge the vital role of our profession in solving it. We ask the EMTALA TAG to help us by supporting measures that will lower the burdens and decrease the disincentives to physicians who provide call coverage. Some measures to do that would be:

- Make the rules and regulations of EMTALA as clear and as simple as possible, and utilize physician panels to help clarify the specifics of EMTALA requirements. Uncertainty and lack of clarity increase the perception of risk and the burden on surgeons taking call, and allow a paradoxical use of EMTALA to enable patient dumping. For example, it should be made clear to all that communications between transferring physicians and receiving specialists, done for the purpose of obtaining information or giving

instructions in the best interest of the patient, is never a violation of EMTALA. Similarly, which orthopaedic conditions represent medical emergencies covered by EMTALA, and what constitutes stabilizing treatment for them should be made explicit.

- Encourage liability reform in the states and nationwide to provide "Good Samaritan" protection for physicians who willingly serve the community by taking call.
- Support improved compensation for physicians caring for injured patients, who are more commonly young and poor. Recognize the public health burden of injury, and find a way to prioritize funding for physicians who serve this vital public need. A system similar to DSH funding for physicians should be considered.
- Seek alternatives to a regulatory approach to enforcement, which can be perceived as heavy handed and punitive, and encourages people to drop off the call schedule. Seek and develop models for cooperative local solutions between hospitals and physicians, such as local call-sharing arrangements.
- Promote regionalization of trauma systems, such as statewide programs which clarify transfer criteria to optimize efficiency in use of high level services and provide for re-patriation of patients into their local communities as soon as possible.

The orthopaedic community has been working diligently to address EMTALA issues, including the areas of call coverage and appropriate transfers. The OTA and AAOS look forward to working with the EMTALA TAG to solve this critical health policy issue for our nation.

OTA ON-CALL POSITION STATEMENT

As part of its stated mission, the *Orthopaedic Trauma Association (OTA)* is committed to excellence in the treatment of patients with musculoskeletal injuries. Recent reports indicate that emergency departments and hospitals are experiencing difficulty finding specialty surgeons including orthopaedic surgeons to provide on-call services.

The OTA believes that Orthopaedic Surgeons are the most appropriate provider of acute Musculoskeletal Care. A loss of the availability of this resource in Emergency Departments will negatively impact the quality of musculoskeletal trauma care delivered in the United States.

This access problem is exacerbated by several factors:

Many hospitals do not apply sufficient resources to allow quality care delivery to the trauma patients. Working within such a compromised system provides disincentive to surgeons who attempt to provide such care. In the context of overall rising cost and decreasing reimbursement, the financial burdens associated with provision of on-call services have become difficult for orthopaedic practices to bear. Many uninsured and underinsured patients now use Emergency Departments as a primary source of health care leaving those covering these facilities with a disproportionate burden of providing uncompensated service.

There is a perceived increase in liability associated with the treatment of higher risk problems such as severe trauma which is predisposed toward poorer outcome. This has influenced orthopaedic surgeons to avoid such activity.

The combined effect of these factors as well as others has resulted in decreasing access to orthopaedic surgeons for patients with musculoskeletal injuries. Analysis of these issues suggests that such access is likely to further decrease in the future without changes in the emergency healthcare environment.

The *Orthopaedic Trauma Association* believes that the following principles are paramount in the development of a solution to this developing health care crisis:

1. Orthopaedic surgeons are the best trained caregivers to evaluate and treat patients with significant musculoskeletal injuries

2. Orthopaedic surgeons, hospitals and legislators share a duty to the community in which they serve to provide timely services to patients with musculoskeletal injury.

3. Musculoskeletal trauma care from a qualified orthopaedic surgeon should be available to individuals with significant injuries 24 hours per day and 7 days per week within their communities. If these responsibilities cannot be met, appropriate need based transfer policies should be established.

4. Access to specialized high-level care from orthopaedic trauma specialists should be available on a primary or referral basis for those patients with severe injuries to the musculoskeletal system that cannot be adequately managed by a non-trauma specialist orthopaedic surgeon.

5. Orthopaedic surgeons have been trained in basic musculoskeletal trauma care and should maintain the skills needed to provide basic musculoskeletal trauma care services (i.e. splinting, fasciotomies, debridement of open wounds and basic internal and external fixation application.)

In support of these principles, we support adoption of the following specific guidelines with regard to provision of emergency musculoskeletal trauma services:

1. Emergency care for injuries to the musculoskeletal system should be provided by a properly trained orthopaedic surgeon prepared to consider both the acute as well as the long term reconstructive and rehabilitative needs associated with musculoskeletal injury.

2. Meaningful liability reform is necessary to reduce physicians risk associated with the delivery of emergent care and prevent attendant insurance costs from driving orthopaedic surgeons away from providing necessary emergency musculoskeletal care.

3. The financial burden for provision of emergency musculoskeletal services on-call should be borne jointly by hospitals, the public and physicians. The challenges associated with disruption in medical practice and lifestyle are borne by the physicians alone. Therefore orthopaedic surgeons must be compensated for their on-call services. Payment for such services should reflect the work and liability risk associated with these services.

4. Hospitals need to provide adequate resources both in terms of personnel and facilities to ensure that provision of emergency musculoskeletal trauma care can be accomplished in a safe and timely fashion regardless of the time of the day at which that care is needed. Non-emergent conditions requiring surgery should be addressed during regular working hours when regular staffing and ancillary help is available. Emergency conditions should be addressed surgically within a medically appropriate timeframe. The responsibility for determination of the distinction between urgent and emergent conditions must rest with the treating orthopaedic surgeon, as he or she is best capable of combining information about the individual patient's condition, the treatment options for that condition and the available evidence in the medical literature.

5. Hospitals without continuous availability of musculoskeletal trauma specialists should develop transfer agreements with centers where such specialists practice to allow for the appropriate transfer of patients with musculoskeletal injuries whose complexity exceeds the capability of the initial treating institution. Such transfers should always be based on complexity of injury and the best interest of the injured patient's musculoskeletal condition. Such transfers should never be based on an injured patient's ability (or lack thereof) to pay for such services. Transfers other than those prearranged by standing hospital agreements should be communicated from the consulting orthopaedic surgeon to the receiving orthopaedic surgeon after an

appropriate evaluation (history and physical exam) by the referring physician.

6. All orthopaedic surgeons should make themselves available to their hospital's on-call list during the active years of their practice at that institution. In providing emergency department coverage, hospitals should not impose an undue burden on orthopaedic surgeons offering such coverage. Hospitals and orthopaedic staff should negotiate an appropriate amount of on-call coverage that is not burdensome to either party.

7. Hospital systems MUST provide necessary facilities, equipment, and ancillary services necessary to provide emergent care to those with musculoskeletal injury. A general scheme of these elements may be seen in the OTA created optimum resource guidelines, which are the minimum standard.

8. The *Orthopaedic Trauma Association* calls on the American Academy of Orthopaedic Surgeons (AAOS), the American Board of Orthopaedic Surgeons (ABOS), the American Orthopaedic Association (AOA), and all specialty societies to work toward mechanisms to assure the sufficient participation of their membership on-call lists at their institutions including evidence of such participation as a qualification for membership and certification.

9. AAOS and the ABOS must monitor the orthopaedic workforce to insure availability and distribution of orthopaedic surgeons to meet the needs of the nation's Emergency Departments.

James V. Nepola, MD
Health Policy Committee Chairman
Orthopaedic Trauma Association

Paul Tornetta, III, MD, President
Orthopaedic Trauma Association

December 2, 2005

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Are Patients Being Transferred to Level-I Trauma Centers for Reasons Other Than Medical Necessity?

Kenneth J. Koval, Chad W. Tingey and Kevin F. Spratt, *Journal of Bone and Joint Surgery*, 2006;88:2124-2132.

A Prospective Evaluation of Patients With Isolated Orthopedic Injuries Transferred to a Level I Trauma Center

Charles A. Goldfarb, MD, Joseph Borrelli, Jr, MD, Michael Lu, BS, and William M. Ricci, MD, *Journal of Orthopaedic Trauma*, 2006;20:613–617

APPENDIX 6

TESTIMONY ON BEHALF OF

THE CENTER FOR TELEHEALTH & E-HEALTH LAW

TO THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

TECHNICAL ADVISORY GROUP (TAG)

Presented by:

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May 3, 2007

TESTIMONY ON BEHALF OF

THE CENTER FOR TELEHEALTH & E-HEALTH LAW

TO THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

TECHNICAL ADVISORY GROUP (TAG)

My name is Robert Waters. I serve as Counsel for the Center for Telehealth & E-Health Law (CTeL). CTeL is a non-profit organization created to examine legal and regulatory barriers to telehealth and related e-health services. CTeL's founding members included the Mayo Clinic, Cleveland Clinic Foundation, Texas Children's Hospital, and the Midwest Rural Telemedicine Association. Our membership includes leading medical centers from across the United States, both urban and rural. We appreciate the opportunity to testify before the EMTALA Technical Advisory Group (TAG) on the issue of on-call physicians and methods of communicating with emergency room physicians.

My testimony today will be quite brief. Approximately nine months ago, we identified a problem with the EMTLA interpretative guidelines involving on-call physicians. The Centers for Medicare and Medicaid (CMS) informed us that the quickest way to resolve this problem would be to appear before the EMTALA Technical Advisory Group (TAG). We appeared before this Committee at your November 2, 2006 meeting. Copies of our testimony and power point from that meeting are attached along with the relevant interpretative guideline. Testimony was also presented by the Lehigh Valley Hospital and Health Network.

We have serious concerns that the two paragraphs in the interpretative guidelines that relate to telehealth services actually limit the care that can be provided to patients presenting at an emergency department and restrict the quantity, quality and timeliness of information that is available to the treating physician in the emergency room. At the November 2, 2006 meeting, CMS representatives indicated that they were not sure why the language regarding telemedicine was included in the interpretative guideline. Marilyn Dahl, the Director of the Division of Acute Care Services, said the language was never intended to preclude consultation with the on-call physician via electronic methods.

The TAG recommended that HHS strike the language in the Interpretive Guidelines on telehealth/telemedicine (Sec 489.2(j)(1)) and replace it with language that clarifies that the treating physician ultimately determines whether the on-call physician should come to the emergency department and that the treating physician may use a variety of methods to communicate with the on-call physician. A potential violation occurs only if the treating physician requests the on-call physician come to the ED and the on-call physician refuses. We agree with this recommendation.

Since that time, we have been trying to convert the TAG recommendation into CMS policy or otherwise obtain from CMS a written statement that it is acceptable for emergency rooms to use advanced communications technologies to communicate with on-call physicians. Unfortunately, we have not been successful.

We arranged two subsequent meetings with CMS on this topic. The first occurred on January 30, 2007 in Baltimore. The second was set up as a teleconference between Joe Tracy, CTeL's President and Tom Gustafson, who was then the Acting Director of the Center for Medicare Management. In both meetings, we were told that while there might be agreement in CMS with our concerns, these issues were not a high priority within the agency. CMS has suggested that our best avenue to advance this issue would be to re-appear before the EMTALA TAG at this meeting. That is why we are here today.

CMS needs to take action as soon as possible to clarify how responsive the agency would like on-call physicians to be when contacted by the emergency room. If the emergency room physician requests that the on-call physician report to the ER, this should happen as quickly as humanly possible. If the emergency physician needs to communicate with the on-call physician on a stat basis there should not be federal regulatory barriers to this interaction. Such communication could occur via phone, pager, e-mail, or videoconferencing. It might also be supported by the transmission of faxed patient information, electronic patient records, or digital images.

Minutes can save lives. Information is critical to appropriate decision-making. New technologies make it possible for on call physician to instantaneously pull up images and information not only in their offices but also while they are in-transit to the ER. EMTALA should fully support the use of this technology as determined necessary by the emergency and on-call physicians. We need to enhance rather than limit the responsiveness of on-call physicians.

Unfortunately, the existing interpretative guidelines limit the use of telehealth technologies by on-call physicians to rural areas and non-metropolitan statistical areas. The guidelines introduce inappropriate considerations regarding the geographic location and Medicare reimbursement status of the patient. These factors should have no place in EMTALA guidance regarding the potential use of available technology. Stabilizing the patient should be the top priority. If the Medicare reimbursement rules are used to constrain the type of information that can be transmitted it raises a number of very serious questions. They are detailed in length in our prior testimony. In our discussions with CMS staff, we have been unable to identify any other situation where the EMTALA guidelines are constrained by Medicare reimbursement rules.

We hope that the advice we have received by CMS is correct and that some further action by this committee will ensure that CMS acts promptly to correct this problem. We would appreciate any insight from the TAG or CMS on the timeline for changes to the guidance and what advice in the interim we should offer on-call physicians who routinely rely on

the transfer of electronic information to treat patients. Is this transmittal of these images (live or static) acceptable or prohibited by CMS?

Thank you for the opportunity to present this testimony. I would be pleased to answer any questions.

Centers for Medicare and Medicaid Services, *States Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases (Rev. 1, 05-21-04)*, Part II, § 489.24(j)(1) - Availability of On-Call Physicians

> On-call physicians may utilize telemedicine (telehealth) services for individuals in need of further evaluation and/or treatment necessary to stabilize an EMC. Individuals are eligible for telemedicine services only when, because of the individual's geographic location, it is not possible for the on-call physician to physically assess the patient. Permissible situations under which on-call physicians may access telemedicine include the case of an individual who presents to an originating hospital located in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). The RO is to consult with Health Resources Service Administration (HRSA) personnel...or RO staff working with rural health issues to determine if a hospital is located in a rural HPSA or MSA to be eligible for telemedicine services and therefore not be in violation of EMTALA on-call requirements.
>
> Reimbursement for such telemedicine services are limited, therefore it is in the best interest of the provider to be knowledgeable concerning coverage and payment for Medicare telehealth services (see Medicare Benefit Policy Manual, Pub. 100-2, Chapter 18 [sic], Section 270).

DC01/ 524737.1

TESTIMONY ON BEHALF OF

THE CENTER FOR TELEHEALTH & E-HEALTH LAW

TO THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

TECHNICAL ADVISORY GROUP (TAG)

Presented by:

Robert J. Waters

Gardner Carton & Douglas

November 2, 2006

TESTIMONY ON BEHALF OF

THE CENTER FOR TELEHEALTH & E-HEALTH LAW

TO THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

TECHNICAL ADVISORY GROUP (TAG)

My name is Robert Waters. I serve as Counsel for the Center for Telehealth & E-Health Law (CTeL). CTeL is a non-profit organization created to examine legal and regulatory barriers to telehealth and related e-health services. CTeL's founding members included the Mayo Clinic, Cleveland Clinic Foundation, Texas Children's Hospital, and the Midwest Rural Telemedicine Association. Our membership today includes leading medical centers from across the United States, both urban and rural. We appreciate the opportunity to testify before the EMTALA Technical Advisory Group (TAG) on the issue of on-call physicians and emergency room telehealth services.

CTeL has carefully reviewed the two paragraphs referencing telemedicine under the Center for Medicare and Medicaid's (CMS) Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases Section 489.24(j)(1) (hereinafter, the "Interpretive Guidelines"). Two paragraphs involving Medicare requirements for telemedicine reimbursement appear to have been inserted into EMTALA guidelines. We have serious concerns that these two paragraphs that reference Medicare reimbursement policies may actually limit the care provided to patients presenting at an emergency department. Therefore, we propose eliminating these two paragraphs from the Interpretative Guidelines.

The two paragraphs referencing telemedicine state the following:

On-call physicians may utilize telemedicine (telehealth) services for individuals in need of further evaluation and/or treatment necessary to stabilize an EMC. Individuals are eligible for telemedicine services only when, because of the individual's geographic location, it is not possible for the on-call physician to physically assess the patient. Permissible situations under which on-call physicians may access telemedicine include the case of an individual who presents to an originating hospital located in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). The RO is to consult with Health Resources Service Administration (HRSA) personnel...or RO staff working with rural health issues to determine if a hospital is located in a rural HPSA or MSA to be eligible for telemedicine services and therefore not be in violation of EMTALA on-call requirements.

Reimbursement for such telemedicine services are limited, therefore it is in the best interest of the provider to be knowledgeable concerning coverage and payment for

Medicare telehealth services (see Medicare Benefit Policy Manual, Pub. 100-2, Chapter 18 [sic], Section 270).1

The insertion of these two paragraphs will unintentionally undermine the objectives of EMTALA for the following reasons:

1. The language inappropriately limits the amount and format of information that can be transmitted to on-call physicians.

Modern communications technology permits emergency departments to have almost instantaneous contact with on-call physicians. Information on a patient's condition can be transmitted to on-call physicians via a phone call, pager, computer link, the Internet, or a video link. All of these forms of communication are telemedicine. The Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services defines telehealth broadly, stating on their website that telehealth is "the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration."2

Communications technologies are extremely important to convey information and instructions needed to appropriately treat the patient while the on-call physician is in-transit to the emergency department. If a patient presents at an emergency room, the hospital has a professional and legal obligation to take those actions necessary to stabilize the patient.

Minutes can save lives. Information is critical to appropriate decision-making. Telemedicine reduces the time to the Emergency Department (ED) and enhances the information available to the on-call physician. EMTALA should fully support the use of this technology as determined necessary by the emergency and on-call physicians. We need to enhance rather than limit the responsiveness of on-call physicians.

If the current guideline is not modified the only action an on-call physician can take in response to call from the emergency room is to report to emergency room without asking additional questions or receiving additional information critical to the patient's care.

2. The language inappropriately limits emergency telehealth services to only those areas currently covered by the Medicare program.

EMTALA applies to all individuals, regardless of whether or not they are beneficiaries of any program under the Social Security Act Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867.3 Furthermore, according to EMTALA, the scope or nature of the emergency care rendered should not be constrained by the patient's ability to pay, such as whether they have Medicare, Medicaid, or private insurance.4

It is our understanding that CMS's objective in issuing these Interpretive Guidelines for EMTALA was to ensure that a patient presenting at an emergency department with an

emergency medical condition would be stabilized by the emergency department and any on-call physicians or appropriately transferred to another facility.5 The current language of the Interpretive Guidelines, however, permits an on-call physician to only access telemedicine based upon the geographic location of the patient, such as a patient who presents to an originating hospital located in a rural HPSA or in a county outside of an MSA. This language is based upon Medicare reimbursement rules for telehealth that were created and defined by Congress.6 The reimbursement rules do not reflect any form of professional judgment regarding appropriate care. They are simply situations where Congress and the Executive Branch have authorized Medicare payment.

In our discussions with CMS staff, we have been unable to identify any other situation where the EMTALA guidelines are constrained by Medicare reimbursement rules.

3. Even in areas covered by Medicare payment policy, the EMTALA interpretative guideline could constrain appropriate care.

Medicare reimbursement is available for certain telehealth services in rural health professional shortage areas and non-metropolitan statistical areas. The payment is further constrained based on the originating site of the patient and the type of procedure. For example, Medicare does not pay for "store and forward" telehealth encounters outside of Alaska and Hawaii.

The store and forward situation would include any time that information or images are transmitted electronically to a physician for review. If there is not two-way interaction between the physician and patient, this activity is not reimbursable by Medicare. If this reimbursement rule were applied to EMTALA, an on-call physician would be prohibited from reviewing a patient record, an x-ray, CT scan, or an EKG unless he is engaged in a two-way video interaction with the patient.

4. Telemedicine is a valuable tool in urban as well as rural areas.

Communications tools may be particularly important in urban areas. The response time for an on-call physician in urban area could actually be greater than in rural area due to congestion and traffic patterns. In rural area, two miles may be two minutes. In an urban area at rush hour, two miles might be an eternity.

5. An on-call physician may not be able to utilize the same telemedicine tools available to a physician who is not on-call at the hospital.

If an emergency room physician needs to consult immediately with a specialist, they will have contact a physician who is not "on-call" if they would like to have a meaningful interaction or discussion regarding the patient's care or transmit any information to the remote specialist. This undermines the whole objective of establishing and maintaining on-call providers.

The language in the Interpretive Guidelines allows a physician who is not on-call at the hospital to use telemedicine services without restrictions. The inconsistent language within the Interpretive Guidelines is contrary to current practice and to physician professional responsibilities in handling emergency situations.7

Telemedicine is used extensively as part of emergency care. There are many examples throughout the country. Three illustrative examples have been provided by Lehigh Valley Hospital and Health Network. They are set out below:

1. An ED without an open heart surgery program transmits, via a telecommunications system, an EKG strip and echocardiogram ahead of sending a patient to a larger center for a balloon angioplasty procedure. The receiving ED is better prepared to care for the patient.

2. A stroke patient in an ED who receives Tissue Plasminogen Activator (tPA) within the three-hour window of opportunity and then transported to a certified stroke center is better off, because telehealth technologies were used to connect that patient to a neurologist and stroke team that was not otherwise available in the remote ED. In many cases the 3-hour window of opportunity to receive tPA often closes on a patient, because of the transport time needed for the patient to get to a center capable of administering that agent.

3. A pediatric cardiology patient in an ED without a pediatric cardiologist is much better off if a pediatric cardiologist were made available via an interactive video link to a larger center that has that level of expertise available.

In closing, we believe that the EMTALA Interpretive Guidelines on On-Call Physicians, Section 489.24(j)(1), are appropriate as long as the two paragraphs referencing telemedicine are eliminated. Emergency department physicians should be able to avail themselves of all information and tools necessary to assist them in treating patients. Telemedicine is one of these critical tools.

Thank you for the opportunity to present this testimony. I would be pleased to answer any questions.

October 17, 2006

1 Centers for Medicare and Medicaid Services, States Operations Manual, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases (Rev. 1, 05-21-04), Part II, § 489.24(j)(1) - Availability of On-Call Physicians, (hereinafter Interpretive Guidelines). As noted, there appear to be two typographical errors in various published versions of this section.

2 Health Resources and Service Administration, What is Telehealth, at http://www.hrsa.gov/telehealth.

3 68 Fed. Reg. 53,223 (Sept. 9, 2003) (codified at 42 C.F.R. pts. 413, 482, and 489).

4 Centers for Medicare and Medicaid Services, EMTALA OVERVIEW, available at, http://www.cms.hhs.gov/EMTALA, stating, "In 1986, Congress enacted the Emergency Medical Treatment & Labor Act (EMTALA) to ensure public access to emergency services regardless of ability to pay."

5 42 C.F.R. § 489.24(a) (2005).

6 See Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, Section 270.

7 American College of Emergency Physicians, Policy Statement: Availability of Hospital Diagnostic and Therapeutic Services, stating, "The American College of Emergency Physicians supports policies that endorse consistent 7-days a week availability of hospital diagnostic and therapeutic services in order to facilitate timely disposition of emergency department patients and to minimize hospital crowding," available at, http://www.acep.org/webportal/PracticeResources/PolicyStatements/hosp/availhospdiagthersvs.htm.

APPENDIX 7

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June 13, 2007

David Siegel, MD, JD
c/o Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. Siegel:

It is our understanding that the EMTALA TAG is seeking further input from interested parties on the proposed language to further define what constitutes a psychiatric medical emergency. The TAG is looking closely at individuals with psychiatric complaints and has charged a subcommittee specifically with this task. Clarification or guidance on individuals with psychiatric complaints has long been forthcoming from CMS and would be greatly appreciated by those who serve this vulnerable population. We respectfully submit the following concerns based on our experience with hospital clients and on specific enforcement actions.

Many hospitals struggle with complying with the EMTALA regulations and providing appropriate stabilization and referral of individuals with behavioral health complaints to the facility that best serves the individual's needs. These two issues may not always neatly converge as community resources decrease and the population in need of these same services increases. This issue is further complicated by the fact that in many states, the existing State law dictating the appropriate placement and admission of psychiatric and substance abuse patients into the state mental health system is in opposition to the EMTALA requirements.

In Report Number Five from the TAG's November 2-3, 2006 meeting, the term "gravely disabled" was proposed to describe those individuals who are determined to be "a danger to self and may die without emergency care provided in 48 hours." This implies that individuals with behavioral health complaints may exist on a continuum and seems to attempt to categorize individuals based on dire need for psychiatric intervention.

Categorization of a specific group of patients is best exemplified by well defined and accepted trauma classification protocols. Patients with behavioral health complaints have

not been clearly categorized or delineated in the same way that trauma patients have and thus there is much confusion regarding the classification and subsequent appropriate screening and treatment of these individuals. CMS makes clear that appropriate referral, screening and treatment are required by EMTALA. However, CMS has yet to clarify specific requirements for classification, screening and referral of these individuals.

Medical Screening:

EMTALA in part requires that hospitals with emergency departments (ED) provide a medical screening examination (MSE) within the capability of the hospital's ED to determine whether or not an emergency medical condition (EMC) exists to any individual who comes to the ED and requests such an examination.

> "A MSE is the process required to reach with reasonable clinical confidence, the point at which it can be determined whether a *medical emergency* does or does not exist. If a hospital applies in *a nondiscriminatory manner*…a screening process that is reasonably calculated to determine whether an EMC exists, it has met its obligations under the EMTALA. Depending on the individual's presenting symptoms, the MSE represents *a spectrum ranging from a simple process involving only a brief history and physical examination* to a complex process..." Centers for Medicare and Medicaid Services (CMS) EMTALA Interpretative Guidelines at 42 CFR §489.24(a)(1)(i)

Screening individuals with behavioral health complaints may be complex and not clearly defined. Psychiatric illness can coexist with or be caused by medical disease. Individuals with behavioral health complaints are often sent to the emergency room for "medical clearance" prior to a prearranged inpatient admission into a psychiatric facility. The question remains, *how exactly does CMS define this medical clearance*? The standard of care for patients with psychiatric disturbances in emergency medicine varies significantly than the standard of care for psychiatric illness being treated on a long term basis. It is widely acknowledged that emergency room physicians and emergency departments face these issues every day in an environment that is as a whole arguably overburdened and under-funded. *Do CMS' expectations differ from those of emergency room physicians?*

The American College of Emergency Physicians' (ACEP) Clinical Policy on Critical Issues in the Diagnosis and Management of the Adult Psychiatric Patient in the ED, published January 2006, proposes the language "focused medical assessment better describes the process in which a *medical etiology for the patient's symptoms is excluded* and *other illness and/or injury in need of acute care* is detected and treated [*emphasis added*]."

CMS has had the longstanding position that an appropriate MSE for individuals with behavioral health complaints must be two pronged, medical and psychiatric. The goal of such screening is to establish if the patient's symptoms are caused or exacerbated by an underlying medical condition; assess and treat any medical situation that needs acute

intervention (e.g., injuries from suicide attempts or from accidents); determine if the patient is acutely intoxicated or abusing substances; and lastly determine if the individual is a danger to himself or others.

Stabilization:

The regulation sets the standard determining when a patient is stabilized:

> "... that no material deterioration of the condition is likely, within reasonable medical probability, to result from, or occur during, the transfer of the individual from a facility, or with respect to an "emergency medical condition" as defined in this section under paragraph (1) of that definition, that a woman has delivered the child and the placenta. 42 CFR §489.24(b)"

To be considered stable the EMC that caused the individual to seek care in the ED must be resolved, although the underlying medical condition may persist. The Interpretive Guidelines provide as way of example a case in which the patient presents complaining of chest tightness, wheezing, and shortness of breath and has a medical history of asthma. The physician completes a MSE and stabilizing treatment is provided to alleviate the acute respiratory symptoms. In this scenario, the EMC is resolved and the hospital's EMTALA obligation is fulfilled, even though the underlying medical condition of asthma still exists.

In the State Operations Manual, Appendix V - Interpretive Guidelines - Responsibilities of Medicare Participating Hospitals in Emergency Cases §489.24(d)(1)(i) it appears that CMS acknowledges that EDs are not required nor are they expected to resolve complex psychiatric emergencies. Further, it seems that CMS takes the position that psychiatric patients are considered stable when they are protected and prevented from injuring or harming him/herself or others. It can be inferred that CMS even goes as far as stating that for purposes of transferring, the administration of chemical or physical restraints may stabilize a psychiatric patient for a period of time and remove the immediate EMC. In this scenario, it is a realistic expectation that the exacerbation of the EMC (e.g., agitation, hallucinations) may be treated but the medical condition or psychiatric diagnosis may still exist. Psychiatric diagnoses tend to be life long conditions, much like asthma. It is an unrealistic expectation that the psychiatric illness itself be resolved before a psychiatric patient may be considered stable and discharged. If the standard of care would be such, would EDs then to be required to hold these individuals in perpetuity?

An individual is considered stabilized if the QMP has determined, within reasonable clinical confidence, that the EMC has been resolved. For those individuals whose EMCs have been resolved the QMP may discharge home or *may admit for continued inpatient care*. This further supports CMS' opinion that medical condition need not be resolved in order for the EMTALA obligation be considered fulfilled. "The hospital must provide care until the condition ceases to be an emergency ***or*** until the individual is properly [i.e., appropriately] transferred to another facility [emphasis added]."

Transfer:

> "[If] any individual… comes to a hospital and the hospital determines that the individual has an EMC, the hospital must provide either within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition or transfer of the individual to another medical facility in accordance with paragraph (e) of this section." **42 §489.24(d)(1)(i)**

For purposes of EMTALA, a psychiatric patient is considered stable when that person is protected and prevented from harming him or herself or others. It may be argued that if at all times the individual at issue is properly supervised by a licensed physician, registered nurse, a law enforcement officer, deputy and/or psychiatric counselor while in the ED, that, the patient is protected and prevented from harming themselves or others and thus stabilized under the requirements of the EMTALA statute.

We respectfully request, then making determinations regarding stabilizing treatment or whether the individual's emergency condition was stabilized, that CMS keep in mind that **no material deterioration was likely or probable resulting in or occurring from transport of these individuals.** CMS should note what the hospital did in fact do to minimize the risk of harm to the individual or others by initiating or continuing the plan for inpatient care and providing for a supervised, safe, and secure transport. Again, CMS has previously acknowledged that all medical conditions may not be resolved in the emergency department ("ED"). We propose that psychiatric diagnoses, such as schizophrenia or major depression are complex and in many instances life long illnesses, with episodes of exacerbation be considered similar to other life long conditions such as asthma. Specifically, we propose that CMS expect that the *emergency* condition be treated and resolved in the ED, *for example*, agitation, and patient safety, safety of others, even though the medical condition or psychiatric illness may persist.

CMS is of the view that a hospital's EMTALA obligation ends when the QMP has made a determination that no EMC exists (even though the underlying medical condition may persist); or *an EMC exists and the individual is appropriately transferred to another facility [emphasis added]*; or an EMC exists and the individual is admitted to the hospital for further stabilizing treatment.

Transfer According to Existing State Law:

In the State Operations Manual, Appendix V - Interpretive Guidelines - Responsibilities of Medicare Participating Hospitals in Emergency Cases §489.24(d)(1)(i), CMS states that hospitals are not relieved of their EMTALA obligation because of prearranged community or State plans that require particular individuals, such as psychiatric or indigent individuals, to be evaluated and treated at designated facilities/hospitals. However, CMS further asserts though that if, after conducting the MSE and ruling out an EMC (or after stabilizing the EMC) the sending hospital needs to transfer an individual to another hospital for treatment, it may elect to transfer the individual to the hospital so designated by these State or local laws.

The Interpretive Guidelines State that community plans are designed to provide an organized, pre-planned response to patient needs to assure the best patient care and efficient use of limited health care resources. CMS acknowledges that patient health status frequently depends on the appropriate use of the community plans. The matching of the appropriate facility with the needs of the patient is the focal point of this plan and assures that every patient receives the best care possible. Therefore, CMS is of the opinion that a sending hospital's appropriate transfer of an individual in accordance with community-wide protocols in instances where it cannot provide stabilizing treatment would be deemed to indicate compliance with §1867 of the Act.

If you have questions or would like to discuss further, please do not hesitate to contact me.

Very truly yours,

Ann M. Pfeiffer, RN, MS
Compliance Consultant

AP:mkh

APPENDIX 8

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-20

DATE: **April 27, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: EMTALA Issues Related to Emergency Transport Services

Memorandum Summary

- Hospitals may not condition their acceptance of an Emergency Medical Treatment and Labor Act (EMTALA)-related transfer upon the sending hospital's agreement to use a specific transport service designated by the receiving hospital.
- S&C-06-21 should not be interpreted to mean that a hospital cannot ever ask Emergency Medical Services (EMS) staff to stay with an individual transported by EMS to the hospital when the hospital does not have the capacity or capability to immediately assume full responsibility for the individual.

The Emergency Medical Treatment and Labor Act Technical Advisory Group (EMTALA TAG) received testimony indicating that instances have occurred where a hospital has refused to accept an appropriate transfer of an individual with an emergency medical condition unless the sending hospital used an air medical service owned by the receiving hospital for the transfer. The EMTALA TAG recommended that the Centers for Medicare & Medicaid Services (CMS) issue guidance on this matter.

It is a violation of the EMTALA requirements for a receiving hospital to condition its acceptance of an appropriate transfer of an individual with an emergency medical condition upon the sending hospital's use of a particular transport service to accomplish the transfer. Specifically, 42 CFR 489.24 (f) reads in pertinent part as follows:

> *Recipient hospital responsibilities. A participating hospital that has specialized capabilities…may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.*

If in the course of an EMTALA investigation there is evidence that a hospital with specialized capabilities or facilities and the necessary capacity to treat an individual with an emergency medical condition conditioned, or attempted to condition, its acceptance of an appropriate transfer of the individual on the use by the sending hospital of a particular transport service instead of the transport arrangements made by the attending physician at the sending hospital, then the receiving hospital is to be cited for violation of EMTALA Tag A411.

The EMTALA TAG also requested that CMS issue a clarification of the guidance provided in S&C-06-21, issued on July 13, 2006, concerning "parking" of individuals transported by emergency medical services (EMS) to hospitals. The memorandum was intended to address the specific concern that some hospital Emergency Department (ED) staff may deliberately delay the transfer of individuals from the EMS provider's stretcher to an ED bed under the mistaken impression that the ED staff is thereby relieved of their EMTALA obligation. However, it was reported to the TAG by hospital representatives that some EMS organizations have cited this memorandum as requiring hospitals to take instant custody of all individuals presenting via EMS transport at the hospital's dedicated emergency department.

The memorandum was intended to reinforce that the EMTALA responsibility of a hospital with a dedicated ED begins when an individual arrives on hospital property (ambulance arrival) and not when the hospital "accepts" the individual from the gurney. An individual is considered to have "presented" to a hospital when he/she arrives at the hospital's dedicated ED or on hospital property and a request is made by the individual or on his/her behalf for examination or treatment of an emergency medical condition. (42 CFR 489.24(b)). Once an individual comes to the emergency department of the hospital, whether by EMS or otherwise, the hospital has an obligation to provide an appropriate medical screening examination and, if an emergency medical condition is determined to exist, provide any necessary stabilizing treatment or an appropriate transfer. (42 CFR 489.24(a) and (b)). Failure to meet these requirements constitutes a potential violation of EMTALA.

On the other hand, this does not mean that a hospital will necessarily have violated EMTALA if it does not, in every instance, immediately assume from the EMS provider all responsibility for the individual, regardless of any other circumstances in the ED. For example, there may be situations when a hospital does not have the capacity or capability at the time of the individual's presentation to provide an immediate medical screening examination (MSE) and, if needed, stabilizing treatment or an appropriate transfer. So, if the EMS provider brought an individual to the dedicated ED at a time when ED staff was occupied dealing with multiple major trauma cases, it could under those circumstances be reasonable for the hospital to ask the EMS provider to stay with the individual until such time as there were ED staff available to provide care to that individual. However, even if a hospital cannot immediately provide an MSE, it must still triage the individual's condition immediately upon arrival to ensure that an emergent intervention is not required and that the EMS provider staff can appropriately monitor the individual's condition. All cases of this kind will be reviewed on a case-by-case basis and any decision regarding EMTALA compliance will be made by the CMS Regional Office only after a full review of all relevant facts and circumstances.

For questions on this memo, please contact Donna Smith at (410) 786-3255 or by email at Donna.Smith@cms.hhs.gov.

Effective Date: Immediately. State agencies should disseminate this information within 30 days of the date this memorandum.

Training: The information contained in this announcement should be shared with all survey and certification staff, surveyors, their managers, and with managers who have responsibility for processing EMTALA complaints.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

APPENDIX 9

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-19

DATE: **April 26, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Provision of Emergency Services - Important Requirements for Hospitals

Memorandum Summary

- All hospitals are required to appraise medical emergencies, provide initial treatment and referral when appropriate, regardless of whether the hospital has an emergency department.
- A hospital is not in compliance with the Medicare Conditions of Participation (CoPs) if it relies on 9-1-1 services as a substitute for the hospital's own ability to provide services otherwise required in the CoPs. This means, among other things, that a hospital may not rely on 9-1-1 services to provide appraisal or initial treatment of individuals in lieu of its own capability to do so.

In this memorandum we affirm and explain current regulatory requirements pertaining to a hospital's ability to meet the emergency needs of individuals. Any hospital participating in Medicare, regardless of the type of hospital and regardless of whether the hospital has an emergency department must have the capability to provide basic emergency care interventions.

Requirements Applicable to All Hospitals (except Critical Access Hospitals)

The following Medicare hospital Conditions of Participation (CoP) apply to all participating hospitals (except Critical Access Hospitals) and provide a foundation for safe care for all persons, including those with emergency care needs. Critical Access Hospitals (CAHs) are governed by regulations separate from those governing hospitals, and may be found at 42 CFR 485.618.

- ***Physician On Duty or On Call:*** The Governing Body CoP at 42 CFR 482.12(c)(3) requires hospitals to have a physician either on duty (onsite) or on call at all times.

- ***A Responsible Physician for Each Patient:*** The Governing Body CoP at 42 CFR 482.12(c)(4) requires that an MD/DO is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or that develops during the hospitalization.

- ***RN Supervision & Availability 24/7:*** The Nursing Service CoP at 42 CFR 482.23(b) requires hospitals to provide 24-hour nursing services furnished by or supervised by an RN[1], that an RN supervise and evaluate the care of each patient, and that an RN be immediately available, when needed, to provide bedside care to any patient.

- ***Right to Care in a Safe Setting:*** The Patients' Rights CoP at 42 CFR 482.13(c)(2) states: "the patient has a right to receive care in a safe setting."

- ***Governing Body Ensures Accountability***: The Governing Body CoP at 42 CFR 482.12(a)(5) states: "[The governing body must:] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients."

- ***Medical Staff - Organized & Accountable:*** The Medical Staff CoP at 42 CFR 482.22(b) states: "The medical staff must be well organized and accountable to the governing body for the quality of care provided to patients."

- ***Quality Assessment and Performance Improvement (QAPI):*** The CoP at 42 CFR 482.21(e) requires that the hospital's governing body, medical staff, and administrative officials are responsible and accountable for ensuring that clear expectations for safety are established and that adequate resources are allocated for reducing risk to patients.

- ***Appraisal, Initial Treatment, Referral***: The Governing Body CoP at 42 CFR 482.12(f)(2) states: "If emergency services [i.e., department] are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for ***appraisal of emergencies, initial treatment, and referral when appropriate***." [emphasis added]

- ***Off-Campus Locations:*** For hospitals that do have an emergency department(s) but also have off-campus hospital location(s) that do not have an emergency department, the governing body must still assure that the medical staff has written policies and procedures for each off-campus location's appraisal of emergencies and referral when appropriate (42 CFR 482.12(f)(3)).

Explanation of Appraisal, Initial Treatment, and Referral

We emphasize that hospitals without emergency departments must nonetheless have appropriate policies and procedures in place for addressing individuals' emergency care needs 24 hours per day and 7 days per week), including the following:

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[1] Rural hospitals that have in effect a 24-hour nursing waiver granted under 42 CFR 488.54(c) are excepted from this requirement.

- ***Appraisal of Persons with Emergencies:*** A hospital must have medical staff policies and procedures for conducting appraisals of persons with emergencies. The policies and procedures must take into account all of the other CoP requirements mentioned above and ensure that:

  - An RN is immediately available, as needed, to provide bedside care to any patient and that,
  - Among such RN(s) who are immediately available at all times, there must be an RN(s) who is/are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care.

  The policies and procedures for appraisal should provide that the MD/DO (on-site or on call) would directly provide appraisals of emergencies or provide medical direction of onsite staff conducting appraisals.

- ***Initial Treatment***: A hospital must have medical staff policies and procedures for providing the initial treatment needed by persons with emergency conditions. Among the RN(s) who must be available at all times in a hospital, there must be RN(s) who are qualified, through a combination of education, licensure, and training, to provide initial treatment to a person experiencing a medical emergency. The on-site or on-call physician could provide initial treatment directly or provide medical oversight and direction to other staff. This requirement, taken together with the other regulatory requirements described above, suggests that a prudent hospital would evaluate the patient population the hospital routinely cares for in order to anticipate potential emergency care scenarios and develop the policies, procedures, and staffing that would enable it to provide safe and adequate initial treatment of an emergency.

- ***Referral when Appropriate:*** A hospital must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the hospital's capabilities. The policies and procedures should be designed to enable hospital staff members who respond to emergencies to (a) recognize when a person requires a referral or transfer and (b) assure appropriate handling of the transfer. This includes arrangement for appropriate transport of the patient. Further, in accordance with the Discharge Planning CoP at 42 CFR 482.43(d), the hospital must transfer patients to appropriate facilities, i.e., those with the appropriate capabilities to handle the patient's condition. The regulation also requires that necessary medical information be sent along with the patient being transferred. This enables the receiving hospital to treat the medical emergency more efficiently.

What Is An Emergency?

The hospital CoPs do not include a definition of a medical emergency. However, the Emergency Medical Treatment and Labor Act (EMTALA) statute and regulations offers insight into emergency medical conditions. Although this definition is tailored to the specific requirements of EMTALA, it also might be a helpful reference when considering a hospital's compliance with the regulatory requirements for emergency services. This definition is attached as Appendix A, but please observe the cautionary note provided at the end.

Hospitals With Emergency Departments - Other Specific Requirements

Hospitals are not required to have an emergency department. The regulations refer to this as "offering emergency services" and the term "offer emergency services" is treated in the regulations as synonymous with having an emergency department. In accordance with the Governing Body CoP at 42 CFR 482.12(f)(1), a hospital that offers emergency services (i.e., has an Emergency Department) must be in compliance with the Emergency Services CoP at 42 CFR 482.55, including the following requirements:

- ***Meeting Emergency Needs of Patients:*** "The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice." (42 CFR 482.55)

- ***Direction by Qualified Medical Staff:*** "The services must be organized under the direction of a qualified member of the medical staff." (42 CFR 482.55(a)(1))

- ***Integration with Other Departments***: "The services must be integrated with other departments of the hospital." (42 CFR 482.55(a)(2))

- ***Supervision***: "The emergency services must be supervised by a qualified member of the medical staff." (42 CFR 482.55(b)(1))

- ***Adequate Personnel Qualified in Emergency Care***: "There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility." (42 CFR 482.55(b)(2))

Patient Transportation and Emergency Medical Services (EMS)

A hospital may arrange transportation of the referred patient by several methods, including using the hospital's own ambulance service, the receiving hospital's ambulance service, a contracted ambulance service, or, in extraordinary circumstances, alerting EMS via calling 9-1-1. There is no specific Medicare prohibition on a hospital with or without an emergency department calling 9-1-1 in order to obtain transport of a patient to another hospital. Use of 9-1-1 to obtain transport does not, however, relieve the hospital of its obligation to arrange for the patient's transfer to an appropriate facility and to provide the necessary medical information along with the patient.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is required to maintain, as described above, is not consistent with the Medicare CoPs. For example, a hospital may not rely upon 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the hospital. Such policy or practice should be considered as condition-level non-compliance with the applicable COP, 42 CFR 482.55 or 42 CFR 482.12(f).

Surveys

Surveyors are to evaluate each hospital's capability to address emergencies as required by the applicable regulations. In addition to complying with the requirements in the CoPs referenced on pages 1-2 of this memorandum, hospitals with emergency departments must comply with 42 CFR 482.55 and the EMTALA requirements at 42 CFR 489.24. Hospitals without emergency departments must comply with 42 CFR 482.12(f)(2). Surveyors should consider the discussion above when determining hospital compliance with these requirements. Hospitals that do not demonstrate full compliance with these requirements may be placing their patients' safety at significant risk.

Condition-level noncompliance with 42 CFR 482.55 also indicates condition-level noncompliance with 42 CFR 482.12(f)(1). Hospitals that are not in compliance with emergency services requirements in 42 CFR 482.12 or 42 CFR 482.55 should also be carefully surveyed for compliance with the closely-related CoPs that are referenced in this memo, and areas of noncompliance with these CoPs should also be cited, as appropriate.

If you have additional questions or concerns, please contact David Eddinger at 410-786-3429 or via email at david.eddinger@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Appendix A
EMTALA Definition of "Emergency Medical Condition"
42 CFR 489.24(b) Definitions

"Emergency medical condition means –

"(1) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in__

(i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
(ii) Serious impairment to bodily functions; or
(iii) Serious dysfunctiton of any bodily organ or part; or

"(2) With respect to a pregnant woman who is having contractions -

(i) That there is inadequate time to effect a safe transfer to another hospital before delivery; or
(ii) That transfer may pose a threat to the health or safety of the woman or the unborn child."

Note: We emphasize that the hospital conditions of participation do not contain or mandate the above EMTALA definition for non-EMTALA issues. We include the EMTALA definition here only as a general guide because the hospital CoPs have no definition and the EMTALA definition is the only one in the Medicare regulations.

APPENDIX 10

Excerpts from Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Available at: http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1533-P.pdf

occur during other times during an approved residency training program. We are proposing to amend the definition of "patient care activities" at §413.75(b) as follows: "the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities as defined at §413.75(b)." In addition, we are proposing to amend the regulations at §§412.105(f)(1)(iii)(A) and 413.78(b) to specify that "Vacation and sick leave are not included in the determination of full-time equivalency.

d. Proposed Regulation Changes

In summary, we are proposing, for cost reporting periods beginning on or after October, 1, 2007, for direct GME and IME, that time spent by residents on vacation or sick leave would not be included in the determination of what constitutes an FTE resident (or would be removed from both the numerator and denominator of the FTE count) for both IME and direct GME payment purposes. In addition, we are proposing to continue to count time spent by residents in orientation activities for both IME and direct GME payment purposes. We are proposing to amend the regulations at §§412.105(f)(1)(iii)(A) and 413.78(b). Lastly, we are proposing to amend §413.75(b) to include the definition of the term "orientation activities" and to amend the definition of "patient care activities" to add "orientation activities."

E. Hospital Emergency Services under EMTALA (§489.24)

(If you choose to comment on issues in this section, please include the caption "EMTALA" at the beginning of your comments.)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on certain Medicare-participating hospitals and CAHs. (Throughout this section of this proposed rule, 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 emergency department and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether they are beneficiaries of any program under the Act.

The statutory provisions cited above are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99-272. Congress enacted these antidumping provisions in the Social Security Act to ensure that individuals with emergency medical conditions are not denied essential lifesaving services because of a perceived inability to pay.

Under section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill its EMTALA obligations under these provisions may be liable for termination of its Medicare provider agreement, which would result in loss of all Medicare and Medicaid payments.

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 emergency condition, 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.

2. Recent Legislation Affecting EMTALA Implementation

a. Secretary's Authority to Waive Requirements During National Emergencies

Section 1135 of the Act authorizes the Secretary to temporarily waive or modify the application of several requirements of titles XVIII, XIX, or XXI of the Act (the Medicare, Medicaid, and State Children's Health Insurance Program provisions) and their implementing regulations in an emergency area during an emergency period. Section 1135(g)(1) of the Act defines an "emergency area" as the geographical area in which there exists an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act (subsection A) and a public health emergency declared by the Secretary pursuant to

section 247d of Title 42 of the United States Code. Section 1135(g)(1) of the Act also defines an "emergency period" as the period during which such a disaster exists. Section 1135(b) of the Act lists the actions for which the otherwise applicable statutory provisions and implementing regulations may be waived. Included among these actions are, in subparagraph (b)(3)(A), a transfer of an individual who has not been stabilized in violation of the EMTALA requirements restricting transfer until an individual has been stabilized (section 1867(c) of the Act) and, in subparagraph (b)(3)(B) , the direction or relocation of an individual to receive medical screening in an alternate location, in accordance with an appropriate State emergency preparedness plan.

Section 1135(b) of the Act further states that a waiver or modification provided for under section 1135(b)(3) of the Act shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. All other waivers arising out of section 1135(b) of the Act (except for section 1135(b)(7)) ordinarily may continue in effect for the duration of the declaration of emergency or disaster, or the declaration of a public health emergency, or for 60-day periods as described in section 1135(e)(1) of the Act.

To take into account the effect of section 1135 waivers on the EMTALA requirements, §489.24(a)(2) of our regulations specifies that sanctions under the EMTALA regulations for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act.

For further information about section 1135 of the Act and its applicability, we refer readers to the CMS Web site: http://www.cms.hhs.gov/Emergency/02_Hurricanes.asp.

b. Provisions of the Pandemic and All-Hazards Preparedness Act

On December 19, 2006, Congress enacted the Pandemic and All-Hazards Preparedness Act, Pub. L. 109-417. Section 302(b) of Pub. L. 109-417 makes two specific changes that affect EMTALA implementation in emergency areas during an emergency period.

As noted above, section 1135(b)(3) of the Act authorizes the Secretary to waive sanctions for either the transfer of an unstabilized individual in violation of the requirements of section 1867(c) of the Act where such transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period or the direction or relocation of an individual to receive medical screening in an alternate location in accordance with an appropriate State emergency preparedness plan. Section 302(b)(1)(A) of Pub. L. 109-417 amended section 1135(b)(3)(B) of the Act to state that sanctions for the direction or relocation of an individual for screening may be waived where, in the case of a public health emergency that involves a pandemic infectious disease, that direction or relocation occurs pursuant to a State pandemic preparedness plan or to an appropriate State emergency preparedness plan. In addition, sections 302(b)(1)(B) and (b)(1)(C) of Pub. L. 109-417 amended section 1135(b) of the Act to state that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification for such

emergency shall be determined in accordance with section 1135(e) of the Act as that subsection applies to public health emergencies. The amendments to section 1135(b) of the Act made by section 302(b) of Pub. L. 109-417 are effective as of the date of enactment of that legislation (December 19, 2006) and apply to public health emergencies declared pursuant to section 247d of Title 42 of the United States Code.

c. Proposed Revisions to the EMTALA Regulations

Currently, the EMTALA regulation at 42 CFR 489.24(a)(2) specifies that sanctions under this section (§489.24) for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. To implement the changes made by section 302(b) of Pub. L. 109-417 and to ensure that our regulations accurately reflect section 1135 of the Act, we are proposing to make two changes to paragraph (a)(2) of §489.24. First, we would specify that the sanctions that do not apply are those for either the inappropriate transfer of an individual who has not been stabilized or those for the direction or relocation of an individual to receive medical screening at an alternate location. We also are proposing to revise §489.24 by adding a second sentence to paragraph (a)(2) to state that a waiver of these sanctions for EMTALA violations is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the duration of the waiver will be determined in accordance with subsection (e) of section 1135 of the Act as that subsection applies to public health emergencies. This proposed change would clarify that, in the case of public

health emergencies involving pandemic infectious diseases, the waiver of EMTALA sanctions is not limited to 72 hours, but will remain in effect until the termination of the applicable declaration of a public health emergency as described in section 1135(e)(1)(B) of the Act.

F. Disclosure of Physician Ownership in Hospitals and Patient Safety Measures

1. Disclosure of Physician Ownership in Hospitals

(If you choose to comment on issues in this section, please include the caption "Physician Ownership in Hospitals" at the beginning of your comment.)

Section 1866 of the Act states that any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e) of the Act) shall be qualified to participate in the Medicare program and shall be eligible for Medicare payments if it files a Medicare provider agreement and abides by the requirements applicable to Medicare provider agreements. These requirements are incorporated into our regulations in 42 CFR Part 489, Subparts A and B (Provider Agreements and Supplier Approval). Section 1861(e) of the Act defines the term "hospital." Section 1861(e)(9) of the Act defines a hospital and authorizes the Secretary to establish requirements as he finds necessary in the interest of patient health and safety. Section 1820(e)(3) of the Act authorizes the Secretary to establish criteria necessary for an institution to be certified as a critical access hospital.

Section 5006 of Pub. L. 109-171 (DRA) required the Secretary to develop a "strategic and implementing plan" to address certain issues related to physician investment in "specialty hospitals." In the strategic and implementing plan included in

our "Final Report to the Congress and Strategic and Implementing Plan Required under Section 5006 of the Deficit Reduction Act of 2005" issued on August 8, 2006 (page 69), available on our Web site at:

http://www.cms.hhs.gov/PhysicianSelfReferral/06a_DRA_Reports.asp (hereinafter referred to as the "DRA Report to Congress"), we stated that our plan for addressing issues related to physician investment in specialty hospitals involved promoting transparency of investment. Consistent with that approach, we stated that we would adopt a disclosure requirement that would require hospitals to disclose to patients whether they are physician-owned, and if so, disclose the names of the physician owners. Accordingly, we are proposing changes to regulations governing Medicare provider agreements to effectuate this change, under our authority at sections 1861(e)(9), 1820(e) and 1866 of the Act and under our rulemaking authority at sections 1871 and 1102 of the Act. We are seeking comment as to whether these changes best effectuated through changes to the Medicare provider agreement regulations or whether it would be more appropriate to include these changes in the conditions of participation requirements applicable to hospitals and critical access hospitals.

Specifically, we are proposing to amend §489.3 to define a "physician-owned hospital" as any participating hospital (as defined in §489.24) in which a physician or physicians have an ownership or investment interest. We solicit comments on whether, for purposes of the ownership disclosure requirements only, the definition of "physician-owned hospital" should exclude certain physician ownership or investment interests based on the nature of the interest or the relative size of the interest or the

entity's assets (for example, whether the interest would satisfy the exception at §4111.356(a) for physician ownership or investment interest in public-traded securities and mutual funds).

We are proposing to add a new provision at §489.20(u)(1) to require that patients be given written notice that a hospital is physician-owned and that the list of physician owners is available upon request. We are proposing to require that the notice, in a manner reasonably designed to be understood by all patients, disclose the fact that the hospital meets the Federal definition of a "physician-owned hospital" and that patients will be provided the list of the hospital's physician owners upon request. In addition, we are proposing to add a new provision at §489.20(u)(2) which will require hospitals to require that all physician owners who are also members of the hospital's medical staff disclose, in writing, their ownership interest in the hospital to all patients they refer to the hospital, as a condition of continued medical staff membership. Patient disclosure would be required at the time a physician makes a referral. We believe that these provisions are in the interest of the health and safety of individuals who are furnished services in these institutions. This notice requirement will permit individuals to make more informed decisions regarding their treatment and to evaluate whether the existence of a financial relationship, in the form of an ownership interest, suggests a conflict of interest that is not in their best interest.

In order to enforce these proposed requirements, we are proposing to amend §489.12 to deny a provider agreement to a hospital that does not have procedures in place to notify patients of physician ownership in the hospital. In addition, we are proposing to

amend §489.53 to permit CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements of §489.20(u).

2. Patient Safety Measures

(If you choose to comment on issues in this section, please include the caption "Patient Safety Measures" at the beginning of your comment.)

In the DRA Report to Congress (page 67), we stated that it was appropriate to issue further guidance on what we expect of all hospitals with respect to the appraisal, initial treatment, and referral, when appropriate, of patients with medical emergencies. The Medicare hospital conditions of participation regulations at 42 CFR Part 482 impose requirements on hospitals that have emergency departments, as well as requirements on hospitals without emergency departments. We believe that hospitals should be required to disclose to patients at the time of inpatient admission or registration for an outpatient service information concerning whether a physician is available on the premises 24 hours a days, 7 days a week. Under the authority at sections 1861(e)(9), 1820(e)(3), 1866, 1871, and 1102 of the Act (described previously), we are proposing to add a new provision at §489.20(v)(1) to require that hospitals furnish all patients notice at the beginning of their hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days a week, and to describe how the hospital will meet the medical needs of any patient who develops an emergency medical condition, at a time when no physician is present in the hospital. We are seeking comment as to whether this change best effectuated through changes to the Medicare

provider agreement regulations or whether it would be more appropriate to include this change in the conditions of participation requirements applicable to hospitals and critical access hospitals.

It has also come to our attention that some hospitals have called 9-1-1 when a patient has gone into respiratory arrest, a physician has not been on the premises, and the onsite clinical personnel have lacked the requisite equipment or training to provide the required assessment, initial treatment, and referral that are required of all hospitals. In some cases, required interventions to initiate emergency treatment may be outside the scope of practice of the clinical personnel onsite. This has occurred even in hospitals that operate emergency departments. Therefore, in this proposed rule, we are soliciting comments on whether current requirements for emergency service capability in hospitals with or without emergency departments should be strengthened in certain areas. Specifically, we are seeking feedback on whether present regulatory provisions should be expanded with respect to the type of clinical personnel that must be present at all times in hospitals with and without emergency departments; the competencies that such personnel must demonstrate, such as training in Advanced Cardiac Life Support, or successful completion of specified professional training programs; the type of emergency response equipment that must be available and the manner in which it must be available, such as in each emergency department, or inpatient unit, among others; and whether emergency departments must be operated 24 hours/day, 7 days a week. After evaluating the comments we receive, we will consider whether we should amend the Medicare hospital

conditions of participation related to provision of emergency services in hospitals with and without emergency departments.

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CMS-1533-P 514
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CMS-1533-P 515
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In the DRA Report to Congress (page 67), we stated that it was appropriate to issue further guidance on what we expect of all hospitals with respect to the appraisal, initial treatment, and referral, when appropriate, of patients with medical emergencies. The Medicare hospital conditions of participation regulations at 42 CFR Part 482 impose requirements on hospitals that have emergency departments, as well as requirements on hospitals without emergency departments. We believe that hospitals should be required to disclose to patients at the time of inpatient admission or registration for an outpatient service information concerning whether a physician is available on the premises 24 hours a days, 7 days a week. Under the authority at sections 1861(e)(9), 1820(e)(3), 1866, 1871, and 1102 of the Act (described previously), we are proposing to add a new provision at §489.20(v)(1) to require that hospitals furnish all patients notice at the beginning of their hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days a week, and to describe how the hospital will meet the medical needs of any patient who develops an emergency medical condition, at a time when no physician is present in the hospital. We are seeking comment as to whether this change best effectuated through changes to the Medicare

provider agreement regulations or whether it would be more appropriate to include this

change in the conditions of participation requirements applicable to hospitals and critical access hospitals.
It has also come to our attention that some hospitals have called 9-1-1 when a patient has gone into respiratory arrest, a physician has not been on the premises, and the onsite clinical personnel have lacked the requisite equipment or training to provide the required assessment, initial treatment, and referral that are required of all hospitals. In some cases, required interventions to initiate emergency treatment may be outside the scope of practice of the clinical personnel onsite. This has occurred even in hospitals that operate emergency departments. Therefore, in this proposed rule, we are soliciting comments on whether current requirements for emergency service capability in hospitals with or without emergency departments should be strengthened in certain areas. Specifically, we are seeking feedback on whether present regulatory provisions should be expanded with respect to the type of clinical personnel that must be present at all times in hospitals with and without emergency departments; the competencies that such personnel must demonstrate, such as training in Advanced Cardiac Life Support, or successful completion of specified professional training programs; the type of emergency response equipment that must be available and the manner in which it must be available, such as in each emergency department, or inpatient unit, among others; and whether emergency departments must be operated 24 hours/day, 7 days a week. After evaluating the comments we receive, we will consider whether we should amend the Medicare hospital CMS-1533-P 518
conditions of participation related to provision of emergency services in hospitals with and without emergency departments.

PART 489--PROVIDER AGREEMENTS AND SUPPLIER APPROVAL
18. The authority citation for part 489 is amended to read as follows:
Authority: Secs. 1102, 1819, 1820(e),1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (41 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh)
19. Section 489.3 is amended by adding a definition of "physician-owned hospital" in alphabetical order to read as follows:
§489.3 Definitions.
* * * * *
Physician-owned hospital means any participating hospital (as defined in §489.24) in which a physician or physicians have an ownership or investment interest. The ownership or investment interest may be through equity, debt, or other means, and CMS-1533-P 591
includes an interest in an entity that holds an ownership or investment interest in the hospital.
20. Section 489.12 is amended by--
a. Revising paragraph (a)(2).
b. Redesignating paragraph (a)(3) as paragraph (a)(4).
c. Adding a new paragraph (a)(3).
The revision and addition read as follows:

§489.12 Decision to deny an agreement.

(a) * * *

(2) The prospective provider has failed to disclose ownership and control interests in accordance with §420.206 of this chapter;

(3) The prospective provider is a physician-owned hospital as defined in §489.3 and does not have procedures in place for making physician ownership disclosures to patients in accordance with §489.20(u) of this chapter; or

* * * * *

21. Section 489.20 is amended by adding new paragraphs (u) and (v) to read as follows:

§489.20 Basic commitments.

* * * * *

(u) In the case of a physician-owned hospital as defined in §489.3--

(1) To furnish all patients notice, in accordance with §482.13(b)(2), at the beginning of their hospital stay or outpatient visit that the hospital is a physician-owned

CMS-1533-P 592

hospital. The notice should disclose, in a manner reasonably designed to be understood by all patients, the fact that the hospital meets the Federal definition of a physician-owned hospital specified in §489.3 and that the list of the hospital's physician owners or investors is available upon request. For the purposes of this paragraph, the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service.

(2) To require all physician owners who also are members of the hospital's medical staff to agree, as a condition of continued medical staff membership, to disclose in writing their ownership interest in the hospital to all patients they refer to the hospital. Disclosure shall be required at the time the referral is made.

(v) In the case of a hospital as defined in §489.24(b), to furnish all patients written notice, in accordance with §482.13(b)(2), at the beginning of their hospital stay or outpatient visit if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, seven days per week. The notice must indicate how the hospital will meet the medical needs of any inpatient who develops an emergency medical condition, as defined in §489.24(b), at a time when there is no physician present in the hospital. For purposes of this paragraph, the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or the provision of a package of information regarding an outpatient service.

APPENDIX 11

DRAFT
PROPOSED RECOMMENDATION AND RATIONALE
FROM THE EMTALA TAG ON-CALL SUBCOMMITTEE
Adequate and Appropriate Call Lists

At the November 2006 meeting of the TAG the On-Call Subcommittee requested the TAG to review an earlier recommendation made by the TAG that: "The presence of a specialty physician on the call roster is not by itself, sufficient to be considered a specialized capability. At the time of transfer, the receiving hospital should also have available the necessary equipment, space, staff etc., to accommodate patient transfer."

The TAG was asked to consider how the recommendation would apply to the following situation: Two hospitals in the same area have equivalent capacity and capability. One has a specialist on call, the other has the same type of specialist on its staff but that specialist does not wish to take call. Therefore, when a patient needs the services of a particular specialty, the specialist on call must accept that patient, while the specialist who does not wish to take call avoids any EMTALA obligation.

It was noted that when two hospitals have equivalent facilities, staff and capacity, the hospital with the relevant physician on call is obligated to accept the transfer. The Action subcommittee has opined that this allows hospitals that want to avoid accepting transfers under EMTALA do so by not having specialists on call. Physicians who do take call feel they are being forced to take on the additional burden of accepting patients from outside the community whose local physicians do not want to take call.

TAG members agreed that better definitions are needed of what constitutes an adequate and appropriate call list, and what constitutes a specialized capability for a hospital. The TAG has heard through testimony, and through anecdotal reports, that specialists are not taking call even though they provide services to the hospital's patients during 'normal' business hours. The present notes summarize the On-Call Subcommittees deliberations on what constitutes an adequate and appropriate call list for a hospital. In a separate discussion the topic of "specialized capabilities" will be addressed.

Adequate or appropriate call list:
This issue is central to the theme of all deliberations of the TAG and may be one of the most important. At present the CMS position is defined at §489.24(j).
(j) Availability of on-call physicians

> **(1) Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.**
> **(2) The hospital must have written policies and procedures in place—**

(i) 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; and

(ii) To provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

The Interpretive Guidelines at page 23:

Interpretive Guidelines: §489.24(j)(1)

"Hospitals have the ultimate responsibility for ensuring adequate on-call coverage….Hospitals have an EMTALA obligation to provide on-call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual." (The On-Call Subcommittee has already recommended that the phrase "best meets the needs" be dropped and a rationale for that will follow in a separate communication.)

What is an adequate or appropriate call list?

Several comments were reviewed by the On-Call Subcommittee relative to this issue. It was noted that prior to the 2003 change in EMTALA regulations, the Interpretive Guidelines stated that "If a hospital offers a service to the public, this service should be available through the on-call coverage of the emergency department." In the present Guidelines there is a statement that: "The best practice for hospitals, which offer particular services to the public, should be available through on-call coverage of the emergency department." **See TAG A404 Interpretive Guidelines: §489.20(r)(2).** See Interpretive Guidelines at p 23. The Action Committee has also raised the issue of whether such a statement should reflect a hospital's inpatient and *outpatient* services as well.

CMS introduced the concept that: "CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patients typically require services of on-call physicians, and the provisions the hospital has made for situations in which a physician is the specialty is not available or the on-call physicians are unable to respond."[6] Of course all of these factors, that CMS reviews, are related to the availability of on call physicians. Some commenters, however, have suggested that: "The unintended consequences of greater flexibility are fewer known rules and greater ambiguity and uncertainty in terms of compliance. This has created an environment where many hospital and medical staff leaders feel pitted against the rank and file staff members who reasonably want to take as little call as possible."[7]

[6] P.23 Interpretive Guidelines—Responsibilities of Medicare Participating Hospitals in Emergency Cases. (Rev. 1, 05-21-04)

[7] Steinberg, A. and Lapenta, S. Communication received March 15, 2007 to Drs Siegel and Kusske.

The On-Call Subcommittee has opined that the simplest means of establishing an adequate or appropriate call schedule would be to restore the prior language in the Guidelines that a hospital which provides a service to the public should provide that service through on-call coverage. In fact, as noted above, a similar statement appears in the present Guidelines. This however raises issues:

Start with the example of the hospital that provides neurosurgical services. A recent Institute of Medicine study noted that there are about 3,200 neurosurgeons practicing in the United States and there are about 5,759 hospitals in the U.S. recognized by the American Hospital Association that accept trauma.[8] If all those hospitals required on-call coverage it would be basically impossible for neurosurgery to offer such a service. So even though a given hospital provides neurosurgical services that service could be supplied by only one or two neurosurgeons (and of course this same reasoning applies to other specialties as well) and therefore there would not be enough neurosurgeons, or other on-call physicians, to provide coverage continually. Finally this seems circular and forever in a loop. Nevertheless the approach the On-Call Subcommittee recommends seems more appropriate than the complicated safe harbor approach. Consider:

1. Having an on-call list that is adequate requires physicians willing and able to provide that coverage. If there are only one or two specialists providing care at a hospital they cannot be expected to provide extended coverage for days at a time.
2. Should a hospital that has neurosurgical capabilities but only has neurosurgeons (or any other group of specialists) doing cases one or two days a week be expected to have an Emergency Department that provides neurosurgical coverage (or other surgical specialty coverage) seven days per week?
3. Another issue raised is related to the hospitals. Do the hospitals have responsibilities for not duplicating services that already exist at other hospitals?
4. What is their obligation not to provide full service emergency care when there are not enough providers in the community to provide that care?
5. Should hospitals be more pro-active into working on joint ventures with one another and community physicians to attempt to develop community on-call calendars and systems to provide emergency care community wide?

The comment that a hospital which provides a service to the public should provide that service through on call coverage is reasonable on its face to have this as a general principle. However this general rule ultimately becomes somewhat meaningless when a list of safe harbors is added, at which point the On-Call Subcommittee believes that you have no certainty of rules and just as much confusion as has existed previously.

The safe harbors[9] described were discussed by the On-Call Subcommittee. The numbers correspond to the recommendation numbers in the Steinberg-Lapenta communication.

2 The safe harbor of minimum call doesn't necessarily fix the problems with on-call availability. Six days of call per month for a neurosurgeon sounds fine,

[8] Hospital Based Emergency Care. At the Breaking Point. The Institute of Medicine, June 2006.
[9] Steinberg and Lapenta March 15, 2007

but if there aren't enough neurosurgeons, or any other specialists, to serve the hospitals in the community, and many are serving on-call to more than one hospital at a time, what happens then?

3 The recommendation of defining exceptions to the safe harbors, in the opinion of the On-Call Subcommittee, begs the question of how this proposal provides hospitals and physicians with greater certainty of rules and requirements.

4 The statute does not state that EMTALA mandates on-call responsibilities on physicians unless they are on their hospital's call roster, period. Trying to bootstrap this requirement by regulatory change is inappropriate. Mandating this will only make things worse, not better, in the view of the On-Call Subcommittee.

5 The On-Call Subcommittee supports this recommendation and we have stated so previously. We agree that liability protections for on-call physicians should be enacted. The concept of providing Federal Tort Claims Act protection for on-call physicians, the subcommittee, believes, should be supported by the TAG. A statement from the TAG, along these lines, could have a significant effect on the enactment of any legislation along these lines.

The On-Call Subcommittee has considered alternatives to the regulatory approach in its discussions and believes that cooperative community ventures and regionalization of emergency care will help reduce the burdens on the system:

- Hospitals should support call sharing arrangements, and joint ventures, with one another and the community physicians to develop community on-call calendars and systems for providing emergency care
- A good example of this is the system that has evolved in the state of Oklahoma.[10] Regional Transfer Centers have been established in Oklahoma City and Tulsa to provide assistance with transfers from the rest of the state. Efforts in Oklahoma have been directed at addressing a community wide approach to the public safety net for time sensitive patients. A state trauma reimbursement fund is in place which has the highest per capita funding in the U.S. They are currently working on ways to determine if the fund could be used to pay for on-call physicians. See Appendix 1, of this document, for a description of the problems that were occurring in Oklahoma regarding on-call specialist coverage and the plan that was put together to deal with the issues. During discussions with the TAG I will introduce how the system is now functioning.
- The On-Call Subcommittee also calls on hospital leadership to consider means of not duplicating services that already exist at other hospitals and to discuss what their (the hospitals) obligations are when there aren't enough providers in the community to provide these services.

[10] Personal communication from John Sacra, M.D. April 25, 2007

The On-Call Subcommittee has discussed the issue of “inappropriate transfers”, or lateral transfers to a “higher level of care.” It appears from many anecdotal reports that the incidence of these transfers is increasing. It is Subcommittee’s view that this issue may be better resolved with regionalized systems for emergency care delivery, rather than an EMTALA regulatory approach. This needs further discussion at the TAG.

APPENDIX 12

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VIA ELECTRONIC MAIL

March 15, 2007

David Siegel, M.D.
Chairman, EMTALA Technical Advisory Group

John Kusske, M.D.
Chairman, On-Call Subcommittee

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Emergency Medical Treatment and Active Labor Act ("EMTALA") and On-Call Obligations

Dear Drs. Siegel and Kusske:

In all the work that the EMTALA Technical Advisory Group ("TAG") has done, there is probably no issue more important than recommending to the Centers for Medicare and Medicaid Services ("CMS") the terms of adequate on-call coverage under EMTALA. As described on page five of the TAG's Report Number Five of its November 2-3, 2006 meetings:

> Members agreed that better definitions are needed of what constitutes an adequate and appropriate call list and what constitutes specialized capability. It was noted that in the past, hospitals were obligated to establish a call roster that mirrored the

> services it provided during normal business hours. Ms. Godfrey of Florida Hospital described a situation in which a hospital with 11 urologists on staff did not have any urologists on call and so transferred emergency patients out. She said CMS investigated the situation and determined that no EMTALA violation occurred.

CMS's approach to on-call has changed over time. When there were better guidelines in place, the on-call system seemed to function more consistently and fairly. Now, many hospitals feel that their ability to provide adequate on-call coverage is severely compromised.

Prior to the 2003 changes in the EMTALA Regulations, the Interpretative Guidelines stated that "If a hospital offers a service to the public, this service should be available through on-call coverage of the emergency department." While the Guidelines did not say "must," the principle was quite clear. (This connects to the Report's statement: "Hospitals were obligated to establish a call roster that mirrored the services it provided during normal business hours.") The Guidelines' language was changed in 2004 and now provides: "On-call coverage should be provided within reason depending upon the number of physicians in a speciality."

Prior to the 2003 changes in the EMTALA Regulations, most hospitals operated under the "three-physician" rule. This rule provided a known standard, a level playing field, and something of a safe harbor by which hospitals and physicians knew how to comply with EMTALA. When CMS revised the EMTALA Regulations in 2003, it disavowed the three physician rule and decided not to include specific requirements or a safe harbor for adequate call coverage. Instead, CMS articulated the "all relevant factors" test (i.e., the number of physicians on staff, other demands on these physicians, frequency with which the hospital's patients typically require the services of on-call physicians, and provisions made for situations when on-call coverage is not available).

In adopting the 2003 Regulations, CMS was attempting to provide more flexibility for hospitals to comply with EMTALA. The unintended consequences, however, of greater flexibility are fewer known rules and greater ambiguity and uncertainty in terms of compliance. This has created an environment where many hospital and medical staff leaders feel pitted against the rank and file staff members who reasonably want to take as little call as possible.

Studies conducted by the American College of Emergency Physicians (the "ACEP") in 2004 and 2005 reflect the growing problems in emergency departments across the country including more and more physicians wanting to take less and less call. This has resulted in a growing number of patient transfers. (See the ACEP's survey entitled "On-Call Specialist Coverage in U.S. Emergency Departments," released in April 2006.)

As described in many sources, including the Institute of Medicine's report entitled "Hospital-Based Emergency Care: At the Breaking Point," published in June 2006, specialists are facing real difficulties and troubling events. The supply of specialists has significantly decreased, as has reimbursement, while professional liability (and the cost of insurance) has risen. With satisfaction from work down and continually growing on-call demands, call has become one more way physicians feel they are being stretched beyond a point of fairness and reasonableness.

The current situation is untenable. Change is necessary. The well-meant flexibility provided in the revised Regulations and Guidelines has contributed to uncertainty and more difficult relationships between hospitals and on-call specialists. This is an area in which certainty and rules are required in order for the on-call system to work.

Hospital and medical staff leaders who wish to see more adequate on-call coverage currently lack the compliance and enforcement tools they used to have under the prior Guidelines and the three-physician rule. Something is needed now or the crumbling on-call system will collapse.

The TAG's Report Number Five invited comments as to what constitutes an adequate and appropriate call list. As it relates to the on-call schedule and related issues, we offer a number of suggestions for consideration by the TAG:

(1) Restore the prior language in the Guidelines – that a hospital which provides a service to the public should provide that service through on-call coverage. Hospitals and on-call specialists are obligated to establish a call roster that mirrors the services provided during normal business hours. This change can be made to the Guidelines, with perhaps a similar change also proposed for the Regulations.

(2) Provide certainty that is needed to restore the balance, through an on-call "safe harbor." The health care field is quite familiar with safe harbors – now is the time to provide hospitals and physicians with a safe harbor for call coverage, to provide rules, expectations and clear areas of compliance.

We suggest, as a starting point, a six days a month safe harbor. Thus, for example, if a hospital had a single specialist (i.e., a single orthopedic surgeon), and that specialist practiced exclusively at its facility, the hospital would comply with EMTALA if its on-call schedule covered that specialty six days a month. With this kind of safe harbor, hospitals could then extrapolate to areas where they had two, three or more specialists and/or their specialists practiced (and had on-call responsibilities) at multiple facilities, and could develop policies with certainty.

(3) The impact of call on hospitals varies by factors, including hospital size, whether the specialists on call divide their practices among several hospitals, geographic barriers and distance. These factors could be used as "relevant factors" to justify why a hospital is operating outside of the safe harbor.

(4) EMTALA call responsibilities should apply directly to physicians, and not simply to hospitals. Perhaps this could be done through a regulatory change, and not require revisions to the Act itself. But even if statutory change is required, recommending to CMS that the problem has become that acute is a powerful statement.

(5) To protect the physicians (and hospitals) that comply with EMTALA requirements, CMS could develop some type of "Good Samaritan" liability protection for those who provide on-call services. Another alternative would be to provide protection, for physicians and hospitals, under a system modeled after the Federal Torts Claim Act.

(6) To help further level the playing field, more specificity is needed in the area of specialty hospitals with "specialized capabilities." CMS adopted the TAG's recommendation, that specialty hospitals are hospitals with specialized capabilities. This change is an important first step, but we are concerned that the specialized capabilities reality has not changed.

No hospital wants to try to transfer a patient to a specialty hospital that has not planned for receiving, let alone treating, unresolved emergency medical condition patients. No hospital wants to put its patients at risk in that manner. The outcome could too easily be a patient whose condition only worsens while the specialty hospital struggles (and perhaps argues) with a proposed EMC patient transfer. There simply is not enough certainty for community hospitals to feel comfortable that transferred patients will be appropriately received and cared for.

There has to be further clarification on how specialty hospitals will handle "specialized capabilities" transfers. We respectfully recommend that specialty hospitals be required to meet the same on-call coverage and lists as full-service hospitals. Otherwise, patient safety and care are put into jeopardy.

Thank you for the opportunity to provide these comments and recommendations. We hope that they further stimulate the good work being done by the TAG and its On-Call and Action Subcommittees.

Sincerely,

Alan Steinberg

Susan Lapenta

AS/SL/pam

161572.4

APPENDIX 13

COMMUNITYWIDE ON-CALL SYSTEM
Dr. John Sacra
September 3, 2003

From New York City to San Diego and cities in between, the issue of diverting ambulance patients away from hospitals is increasingly an area of community concern. Diversion may be the result of overcrowded hospitals or emergency departments, or it may result from a lack of availability of critical services such as CT scanners or specialty physician coverage.

In the EMSA system which serves both Oklahoma City and Tulsa, a proactive approach to "diverts" has long been practiced. When more than one hospital diverts, the situation is carefully monitored. If the Office of the Medical Director of the Medical Control Board or the EMSA Communication Center deems that critical patient care may be jeopardized, the divert status is lifted for all hospitals, or a rotation is implemented allowing hospitals to be on divert for one hour at a time while ensuring the availability of one hospital in each geographical segment of the city. In addition, individual medics have the authority to override a hospital's divert status if the patient's condition warrants delivery at the closest facility.

Divert statistics are gathered and analyzed monthly. The analysis includes a breakdown by cause of divert, number of patients impacted, and trends. The data is shared with Emergency Department staff and the administrator for each hospital in the system. Over the past three years, this data shows alarming trends.

The number of patients diverted in the Oklahoma City area has increased from 936 in 2000 to more than 2300 patients this year. 2003 figures are annualized based on the number of diverts for first six months of this year. The total number of hours on divert has increased in Oklahoma City from more than 10,000 in 2000 to more than 30,000 last year and at its current rate will top 54,000 this year.

Over the same time period the reasons for divert have changed. In 2000 the reasons for divert in Oklahoma City could be grouped into four categories: ED overload, lack of Critical Care beds, trauma or lack of a CT scanner. Since 2001 in Oklahoma City, lack of neurosurgery coverage has nearly doubled every year for the past three. In 2001 the number was 4621, the 2002 number was 9401 and, at the current rate, there will be more than 18,000 hours of neurosurgery divert this year.

Orthopedics represents another serious situation. Last year there were 3683 hours of orthopedic divert in Oklahoma City. This year the number, at the current pace, will nearly double to more than 7200 hours. Plastic surgery divert hours are also increasing at an alarming rate. Last year in Oklahoma City there were 3225 hours of divert for the specialty. This year the number will likely exceed 6200.

In Tulsa, the number of patients diverted has grown steadily from 565 in 2000 to 838 in 2002 and more than 1200 are anticipated this year. In Tulsa, the number of hours on divert has increased from 2719 in 2000 to more than 10,000 last year and, at its current rate, will be more than 12,400 hours this year.

Tulsa is also seeing changes in the categories but the numbers are not as large, due in part because some acute care hospitals are paying specialists to be on call. In Tulsa the hours on divert for neurosurgical coverage was 7295 in 2002. At the current rate, that number will increase to 8500 this year. Emergency Department divert has increased from 1367 in 2000 to what is anticipated to be 3058 this year.

It has become increasingly difficult for community hospitals to provide on-call specialists in certain disciplines. Community hospitals have traditionally linked staff privileges with the obligation of providing on call services. With the many options available to physicians and their patients for medical care outside of the community hospital setting, some community hospitals have found it challenging to attract certain types of physicians who are willing to provide round the clock call coverage for their call rosters. Some hospitals have encouraged physicians to provide call coverage by paying the physicians, which in the past may have been a service provided to the hospital by the physicians without reimbursement. Since there are adequate numbers of physician specialists available to meet emergency needs, it is now a matter of organizing the resources so that appropriate numbers of specialists are available at the right place and right time to meet the community's needs.

There are differences in the experiences between Tulsa and Oklahoma City with each community having unique characteristics and factors impacting the problem. In Oklahoma City, certain specialists are concentrated at a few hospitals. Yet those hospitals are not designated as Centers of Excellence for the specialty. As a result, those hospitals without specialty coverage show a large number of patients diverted. In Tulsa, at least one major hospital is paying $3 million a year to cover stand-by costs for on-call coverage for a limited number of specialists. Other specialists are now demanding similar payment for stand-by costs. The result is a very fragile system where not all needed specialties are represented as part of a public health safety net.

One possible solution is for the Medical Control Board to simply designate delivery of patients to the hospitals with the appropriate specialty coverage. Without buy-in from the physicians and hospitals involved, this approach would, no doubt, be met with resistance. In addition, there are benefits to be gained by utilizing a public health approach to solving this problem, including the creation of a public health safety net which is more likely to result in funding for stand-by costs.

Over the past years the EMS system has recognized Centers of Excellence within the community and cooperated in patient delivery to the appropriate institution. For example facilities with Centers of Excellence in burns, trauma and pediatrics are now far less frequently on divert status than in years past. A similar approach is offered as one

possible solution for curbing the increase in hospital diversions for neurosurgery, plastic surgery, orthopedics, etc.

Utilizing the data available through the EMS system, a reliable prediction can be made as to the volume and types of patients requiring treatment in the community. By establishing a communitywide on-call system, the appropriate number of physician specialists would be on-call required to meet the needs of the community. Hospitals could rotate for the service or one hospital could be permanently designated such as the current instance for burns. Patients requiring delivery at the nearest hospital for stabilization would be transferred by ambulance to the facility with the appropriate specialty care. This would also apply to patients arriving by private vehicle.

By expanding the current Medical Control Board's protocol for Categorization of Hospitals and Destination Procedures to establish Centers of Excellence, Tulsa and Oklahoma City can utilize a public health approach to create a public safety net. Communities have long accepted the reality of stand-by costs associated with public safety related to law enforcement and fire. Communities choose to purchase appropriate firefighting equipment and staff fire stations with firefighters who can respond within a moment's notice. It is understood that equipment, facilities and personnel are needed 24 hours a day, seven days a week regardless of whether response is necessary.

Having physicians on stand-by and paying them for their time is essential for maintaining a public health safety net for the seriously ill or injured with time sensitive conditions. The cost of not having this safety net is just too high. Funding for these stand-by costs must be explored and could include small increases to various licenses including driver licenses and the availability of Federal matching dollars.

A communitywide on-call system would—

- Define patients with time sensitive conditions requiring specialized care
- Establish predictable community needs utilizing EMS data
- Designate the appropriate number of on-call specialists and receiving hospitals
- Develop patient identification criteria and designate on-call receiving facility with on-call appropriate specialists
- Establish a system for funding stand-by costs
- Seek Limited Liability for the on-call resources
- Continually collect data and perform CQI
- Satisfy the on-call requirements established by the Emergency Medical Treatment and Labor Act (EMTALA)
- Become a nucleus for the development of a regional call center that monitors the appropriateness of referrals.

By recognizing the potential disastrous ramifications of the escalating number of patient diversions and working to find a solution, the communities of Tulsa and Oklahoma City have an opportunity to create an efficient, effective public health model which meets the needs of patients, hospitals and physicians.

APPENDIX 14

DRAFT
PROPOSED RECOMMENDATION AND RATIONALE
FROM THE EMTALA TAG ON-CALL SUBCOMMITTEE

"Best meets the needs…"

1. **Tag A404 §489.24(j) (1) Availability of On-Call Physicians.** "Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians."
2. The On-Call Subcommittee proposes that the language "best meets the needs" be eliminated and offers that another approach be established which still holds hospitals accountable for providing a complement of on-call specialty physician services within its capabilities and resources. This should be done so that there are only regulatory consequences or civil monetary penalties applicable, but not including civil liability.

   Suggested wording: Each hospital must maintain an on-call list of physicians on its medical staff who are available to examine and stabilize the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

   In the past the On-Call Subcommittee has discussed this issue and has developed the following suggested changes to the Interpretive Guidelines. These changes are reproduced here. It is the intent of these suggested guidelines to assure that there is adequate medical staff participation in the planning of ED call schedules at each institution.

(See Interpretive Guidelines §489.24(j)(1) at Tab 5, page 23 of the CMS Resources Book Updated October 2005)

1) At page 23, third paragraph.[11] Hospitals have the ultimate responsibility for ensuring adequate on-call coverage. Hospitals participating in the Medicare Program must maintain a list of physicians' on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. Hospitals must have evidence of development, with medical staff input and involvement and Governing Body approval of a hospital plan for on-call coverage. The plan must be annually reviewed and updated, reflect the mechanisms for on call coverage for all hospital provided services and the

[11] State Operations Manual – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases (Rev. 1, 05-21-04)

effectiveness of the plan must be measured with reports to the hospital governing body of recommendations for improvement. Hospitals have an EMTALA obligation to provide on-call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual.

2) At page 25, fifth paragraph. CMS allows hospitals flexibility in the utilization of their medical personnel. Allowing exemptions to medical staff members (senior physicians) would not by itself violated EMTALA. Hospitals must identify in the facility plan for on-call coverage those services for which adequate call is not available. For each hospital provided clinical specialty either on-call coverage or a written transfer agreement must be in place to meet the needs of patients who present to the hospital for care and services. The written agreement must be collaboratively developed with another hospital in the same proximity with the receiving hospital agreeing to receive and treat all patients in the defined clinical specialty, who have had a MSE establishing a medical emergency, who have been stabilized, accepted by the receiving hospital and accompanied by copies of applicable patient records.

3) At page 25, sixth paragraph. Surveyors are to review the hospital policies or medical staff bylaws with respect to response time of the on-call physician. If a physician on the list is called by the hospital to provide emergency screening or treatment and either refuses or fails to arrive within the response time established by hospital policies or medical staff bylaws, the hospital and that physician may be in violation of EMTALA. Hospitals are responsible for ensuring that on-call physicians respond within a reasonable period of time. The expected response time should be stated in a range of minutes (e.g., 30 to 60 minutes) in the hospital's policies based upon local conditions which impact upon the physician's ability to respond to the Emergency Department. The hospital quality assessment and performance improvement programs must include review of the measurement data from the analysis of physician response times. Physician specific response times shall be used in the data utilized for recommendation and approval of reappointment of medical staff membership or privilege renewals. The initial response to the Emergency Department may be by telephone or other electronic means. Terms such as "reasonable" or "prompt" are not enforceable by the hospital and therefore inappropriate in defining physician's response time. Note the time of notification and the response (or transfer) time.

Rationale

1) It is proposed that the On-Call Subcommittee recommend to the TAG that the language "best meets the needs" be eliminated and advocates that another approach be established which continues to hold hospitals accountable for providing a complement of on-call specialty physician services within its capabilities and resources while reducing the liability risks associated with the "best meets the need" phrase.

2) This should be done, as testimony by interested groups has indicated to the TAG, in order to avoid overly broad interpretation, inconsistent enforcement, and unwarranted litigation risk.[12] The alternate approach still holds the hospital responsible for providing a complement of on-call physician specialty services within its capability and resources, but does so only with regulatory consequences or civil money penalties, not with civil liability. Others have criticized the vagueness of the phrase "best meets the needs of hospital patients" in relation to on-call physician staffing requirements .[13] The AMA's testimony urged the TAG "to further define the "best meets the needs" requirement. They commented that "This is a very broad standard that leaves room for numerous interpretations and extensive litigation."[14] Nevertheless the AMA recommends that CMS maintain a flexible environment whereby physicians and hospitals may work in a cooperative partnership to achieve an on-call list.[15]

3) The fundamental issue for CMS is whether EMTALA actually requires hospitals to force members of its medical staff to provide on-call services.[16] The relevant statute is 42 USC 1395cc(a)(1)(I)(iii) which requires hospitals "to maintain a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition." Bitterman opined in testimony before the TAG that "the statutory language should be interpreted to mean that hospital are only required to maintain a list of those physicians who have voluntarily or contractually agreed to take call, so that the ED is prospectively aware of what on-call physician resources are available for any given day. The language of the statute says 'to maintain a list of physicians who are on call'; it doesn't say that the hospital must actually provide on-call physicians." He states that "EMTALA was intended to require hospitals to provide the same services to all patients seeking emergency care, irrespective of their insurance status, it wasn't intended to require hospitals provide a certain defined level of services, for instance 24/7 physician services of particular specialties, such as neurosurgery or orthopedics…."

The American College of Emergency Physician's proposed the following:

- "*Eliminate* the 'best meets the need' language to avoid overly broad interpretation, inconsistent enforcement, and unwarranted litigation risk. Instead, *substitute* a different approach that still holds the hospital accountable for providing a reasonable complement of on-call physician specialty; services within its capability and resources, but does so only with regulatory consequences or civil money penalties, not with civil liability."[17]

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[12] Bitterman, RA. Written and oral testimony before the TAG March 30, 2005.
[13] Valadka, Alex. Comments of the American Association of Neurological Surgeons/Congress of Neurological Surgeons to the EMTALA TAG, March 30, 2005.
[14] Statement to the EMTALA TAG Re: EMTALA Regulations, March 30, 2005.
[15] Statement to the EMTALA TAG Re; EMTALA Regulations, June 15, 2005 at p. 6.
[16] Bitterman, RA Testimony to the EMTALA TAG March 30, 2005 at p 2 of written testimony.
[17] Communication from Frederick C. Blum, President ACEP to David Siegel dated November 21, 2005.

- Further the ACEP states that: “The ‘best meets the need standard’, sanctioned as official policy by CMS, makes the provision of on-call physician services too complex, too variable, and has already spurred numerous lawsuits against the hospitals for failure to provide adequate on-call coverage of sub-specialists. ACEP recommends that hospitals be required to prospectively post a list of who is on call so that the ED is aware at all times what services are immediately available and so that it can inform community EMS and when necessary make transfer arrangements with other hospitals with greater specialty capabilities.

4) Testimony has indicated that physicians have devised ways to avoid ED services either by reducing the number of days they take call, or by curtailing their hospital privileges to specifically reduce their exposure to ED patients and on-call duties. Others have relinquished all hospital privileges since they no longer need hospital based resources to practice.

5) As ACEP has stated it creates a slippery slope of near impossible compliance and unlimited, inconsistent retrospective enforcement and civil litigation. No hospital can know in advance what it must do to ensure compliance with the law. No hospital can possibly provide on-call coverage that ‘best meets the needs’ of all the hospitals ED patients, irrespective of the qualifying language in the regulations regarding ‘resources available to the hospital, including the availability of on-call physicians.’

APPENDIX 15

EMTALA Enforcement Overview

EMTALA TAG
May 4, 2007

EMTALA Enforcement

- **Some unique elements in EMTALA enforcement process**
- **Many elements are common to all CMS enforcement of requirements for non-LTC providers and suppliers**

EMTALA Enforcement

- **Will compare to deemed hospital complaint investigation and enforcement**
- **Most hospitals are deemed, i.e. certified for Medicare participation based on accreditation by The Joint Commission or AOA**

EMTALA	*Deemed Hospitals*
▪ **Complaint-driven**	▪ SA needs RO approval to investigate
▪ **SA needs RO approval to investigate**	
▪ **Primarily complaint-driven**	

FY 06 Enforcement Actions

EMTALA

- **678 EMTALA surveys**
- **38% substantiated (258)**

Deemed Hospitals

- **4,115 complaint surveys**
- **2.1% substantiated at condition-level (87)**
- **25% substantiated deficiencies at any level (1041)**

Enforcement Steps

EMTALA

- **RO reviews EMTALA allegation to decide if SA should survey**
- ***All EMTALA standards found in 42 CFR 489. 20 & 489.24 must be surveyed for compliance***

Deemed Hospitals

- **RO reviews complaint allegation to decide if SA should survey.**
- ***RO determines which Conditions of Participation (CoP) found in 42 CFR Part 482 relate to the complaint and must be surveyed***
- ***All standards related to a COP must be surveyed***

Time to Conduct Survey

EMTALA

- **SA must complete on-site investigation within 5 days of receipt of RO authorization**

Deemed Hospitals

- **SA must initiate on-site investigation within:**
- ***2 days for complaints suspected to pose immediate jeopardy***
- ***45 days for other complaints***
- **Time on-site dependent on scope of survey as well as hospital**

Survey Process

EMTALA

- **Specific complaint case investigated as part of review of compliance with all EMTALA standards**
- **Process involves medical records reviews, observation, review of policies & procedures and interviews**
  - ***Medical record sample size: 20 – 50 records***

Deemed Hospitals

- **Specific complaint case investigated as part of review of compliance with all standards for CoPs to be investigated**
- **Process involves medical records reviews, observation, review of policies & procedures and interviews**
  - ***Medical record sample size: 10% of ave. daily census, at least 30, for full survey. Scale to CoPs investigated for complaint survey***

Time to Transmit Survey Results

EMTALA

- **SA sends survey results and recommendations within 10 working days after completing on-site**
  - ***If SA finds no violations, may extend to 15 days***

Deemed Hospitals

- **If SA finds:**
  - ***Condition-level deficiencies that pose immediate jeopardy, results go to RO within 2 working days***
  - ***Non-IJ condition-level deficiencies, results go to RO within 10 working days***
  - ***Substantial compliance (no deficiencies or only standard-level deficiencies), results go to RO within 30 calendar days***

RO Next Steps

EMTALA

- **Except when delay would jeopardize health or safety, RO must request QIO review & consider QIO findings before making compliance determination.**
  - ***QIO has 5 days to complete***
  - ***QIO to assess clinical aspects of case, i.e., appropriateness of screening exam and/or transfer; whether the patient had not been stabilized, etc.***

Deemed Hospitals

- ***No comparable requirement***

RO Next Steps

EMTALA	*Deemed Hospitals*
▪ **RO compliance determination options:**	
▪ ***No violations***	
▪ ***In compliance, but previously out of compliance – no termination***	
▪ ***Violation(s) posing IJ – 23 day termination track***	
▪ ***Out of compliance but non-IJ – 90 day termination track***	
▪ **RO compliance determination options:**	
▪ **No violations or standard-level only**	
▪ **Condition-level violations posing IJ – 23 day termination track & deemed status removed**	
▪ **Condition-level violations non-IJ – deemed status removed; SA directed to survey all CoPs**	

Hospital Challenge Options

EMTALA	*Deemed Hospitals*
▪ **SOM 5460 - Prior to determining compliance RO may confer with hospital representatives**	▪ **No specific SOM provision, but practice also permitted**
▪ **SOM 5470 – Termination procedures may be stopped if the hospital provides evidence to the RO that the violation did not exist**	▪ **See SOM 2728B below**
▪ SOM 5465 – Upon request, RO to release the QIO review to the hospital	▪ **N/A**

Hospital Challenge Options

EMTALA	*Deemed Hospitals*

- **SOM 2728B allows hospital to submit a POC that records objections to a deficiency finding**
  - ***May refute accuracy of findings, but not CMS judgment of level, extent, scope or severity of deficiency***
  - ***CMS reviews documentation submitted by provider and removes deficiency if the added evidence is convincing***

- **SOM 2728B allows hospital to submit a POC that records objections to a deficiency finding**
  - ***May refute accuracy of findings, but not CMS judgment of level, extent, scope or severity of deficiency***
  - ***CMS reviews documentation submitted by provider and removes deficiency if the added evidence is convincing***

Deemed Status Removed

EMTALA

- **No comparable step; deemed status irrelevant for EMTALA investigations**

Deemed Hospitals

- **SA conducts full survey of all CoPs and submits findings & recommendations to RO**
- **RO compliance determination options:**
  - ***No violations or standard-level only***
  - ***Condition-level violations posing IJ – 23 day termination track***
  - ***Condition-level violations, non-IJ – 90 day termination track***

Next Steps – Past Violation, No Term.

EMTALA

- **Case referred to OIG for consideration of imposing civil monetary penalties**
  - ***RO requests QIO conduct 60 day review & forwards results to OIG***
- **Case may also be referred to Office of Civil Rights (OCR). OCR may take action under Hill-Burton Subpart G Community Services (42 CFR 124.603(b)(1)**

Deemed Hospitals

- **No comparable step**
- **If warranted, case may be referred to OCR**

Next Steps – IJ 23 day track

EMTALA

- **Public notice of proposed termination to be given at least 2 calendar days prior to term date**
- **Hospital submits POC – if credible, SA conducts revisit**
- **After revisit RO may determine:**
  - ***Compliance***
  - ***Violations, but non-IJ - conversion to 90 day term track – 2nd revisit required***
  - ***IJ continues – termination***

Deemed Hospitals

- **Public notice of proposed termination to be given at least 2 calendar days prior to term date**
- **Hospital submits POC – if credible, SA conducts revisit**
- **After revisit RO may determine:**
  - ***Compliance***
  - ***Violations, but non-IJ - conversion to 90 day term track***
  - ***IJ continues – termination***

Next Steps – 90 day track

EMTALA

- **Public notice of proposed termination to be given at least 2 calendar days prior to term date**
- **Hospital submits POC – if credible, SA conducts revisit(s)**
- **After revisit(s) RO may determine:**
  - ***Substantial compliance***
  - ***Violations continue - termination***

Deemed Hospitals

Public notice of proposed termination to be given at least 2 calendar days prior to term date

- **Hospital submits POC – if credible, SA conducts revisit(s)**
- **After revisit(s) RO may determine:**
  - ***Substantial compliance***
  - ***Violations continue - termination***

OIG/OCR Referral

EMTALA

- **CMS refers appropriate cases to OIG & OCR for review**
- ***Requests 60-day QIO review of clinical aspects of case and forwards to OIG***

Deemed Hospitals

- **No comparable OIG referral requirement – no CMP's for violation of hospital CoPs**
- **If warranted, referral to OCR is made.**

Reconsideration, Hearings & Appeals

- **Process same for EMTALA and all other hospital provider agreement termination actions**

- **Only initial determinations are subject to reconsideration, hearing or and appeal**
- ***Decisions whether a hospital meets Medicare requirements is an initial determination***

APPENDIX 16

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April 19, 2007

David Siegel, M.D., J.D.
Chair, EMTALA TAG
c/o Eric Ruiz
Centers for Medicare and Medicaid Services
C4-06-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Siegel:

Thank you for affording The American Health Quality Association (AHQA) an opportunity to comment on the federal regulations implementing Social Security Act Section 1967(d)(3), as amended by the MMA, known as the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act (EMTALA). We are submitting this written testimony and would like to present in person at the TAG meeting. As QIOs continue to submit comments to AHQA, we may modify these initial written comments.

Implementation of Mandatory QIO Consultation Established Under MMA.

Section 944 of the Medicare Modernization Act (MMA) amended the EMTALA statute to require CMS to obtain an assessment of each alleged violation of EMTALA, except when the health or safety of individuals would be jeopardized by the delay involved in obtaining such an assessment.

> "CONSULTATION WITH PEER REVIEW ORGANIZATIONS.—In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital's participation under this title, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of title XI) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B." [emphasis supplied]

The current regulations, however, continue to read as they did in the January 2003 revision, prior to the enactment of the Medicare Modernization Act (excerpt below):

> "42 CFR 489.24(h) *Consultation with Quality Improvement Organizations (QIOs)*—(1) *General.* Except as provided in paragraph (h)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1) of the Act, CMS requests the appropriate QIO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (h)(2)(iv) and (v) of this section."

This pre-MMA regulatory language requires that the QIO be asked for an assessment only "in cases where a medical opinion is necessary," but Congress has required that CMS make such requests in all cases where the Secretary is "considering allegations of violations of the requirements of this section".

We note that the regulation appears consistent with the law with respect to the exception in cases of jeopardy to patient health or safety, which was not changed by MMA.

> Recommendation: AHQA recommends that CMS amend the regulation to require CMS consultation with the QIO in all cases alleging a violation, consistent with the mandate of Section 944 of the MMA.

Variation in Regional Office Procedures. QIOs report a great deal of variation between CMS Regional Offices. For example, Atlanta and Chicago have very different processes. The volume is quite different (many more cases in Atlanta than in Chicago), and the quality of the file sent to the QIO varies by Regional Office (for example, appropriate forms and documentation may not reliably be included in the file from one RO compared to the next). Federal regulations do not envision significant variation in CMS documentation provided to QIO contractors, however, given the language in 42 CFR 489.24(h) stating "CMS provides to the QIO all information relevant to the case and within its possession or control. CMS, in consultation with the OIG, also provides to the QIO a list of relevant questions to which the QIO must respond in its report."

QIOs report a particularly troublesome form of variation in Regional Office the timeliness of the referral to the QIO. Some cases are many months old before they are referred for a 5-day review by the QIO. At some Regional Offices it appears that cases will accumulate for up to several months and then be transmitted in a batch with a request for an expedited review by the QIO.

> Recommendation: AHQA recommends that the TAG obtain and analyze filings provided by Regional Offices to QIOs in a randomly selected set of several cases from each Regional Office, evaluate the extent of the problems of variation in content and timeliness reported by QIOs, and if the problem of variation is confirmed, the TAG should advise CMS to develop recommended procedures to guide Regional Office personnel.

Efficiency of 60 Day Review Process. QIOs have observed after their 5 day initial medical review judgments have already been provided to CMS, the same case is brought back and they are asked to initiate a 60 day review in the same case. By the time of these 60 day reviews, the hospital involved has generally already consented to change its practices. When the QIO receives the file it must engage the hospital in an untimely process which can cost the provider and the government resources, with little or no added value.

> Recommendation: The TAG should consider opportunities to make the 60 day review process more efficient and less redundant for those involved, within the limits of the law. If the TAG can conceive of an alternative that would require a change in law, that alternative should be submitted to CMS for consideration as a recommended legislative change.

Physician Review Worksheet. QIOs observe that the EMTALA Physician Review Worksheet document, used by QIOs to formally record the reviewer's judgment, needs to be revised. The revision is needed so that a reviewer's clinical judgment can be stated in a way that is consistent with regulatory requirements. The revision process began over a year ago but has yet to be completed.

> Recommendation: We would request that the revision to the Physician Review Worksheet be completed as soon as possible.

Feedback to Contractors. QIOs have noted that they rarely receive feedback or data from CMS or the OIG regarding their view of the quality or completeness of their work. QIOs would like to have such feedback so they can make appropriate adjustments in their process if that is needed.

> Recommendation: We request that CMS and OIG routinely transmit a comment back to the QIO concerning the EMTALA reviews they conduct, including whether the QIO report was accepted and why (or why not), so the QIOs can initiate improvement efforts or clarify misunderstandings that may have arisen.

Feedback to Hospital Community. QIOs believe that it would be helpful to the hospital community to receive reports of the results of EMTALA cases that have been adjudicated, so they can know the problems that are occurring and the government's response to them, and make appropriate adjustments to their own practices.

> Recommendation: We recommend that CMS, either directly or through a modification to the QIO contract, provide the hospital community with feedback on EMTALA cases.

Requirements for Hospitals: Several QIOs have stated their concern that the current regulations appear deficient in that they do not require all hospitals to be responsible for accepting patients if they have the capacity to care for them. Currently, it appears that this obligation is only stated clearly in the regulations for hospitals with specialized capabilities (see below).

> "(f) *Recipient hospital responsibilities.* A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units,

neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual."

Recommendation: We request the TAG's expert assessment, or a legal assessment from CMS, as to whether the current regulations do in fact impose on all hospitals regulated under the EMTALA the obligation to provide services to individuals with needs that the institution has the capacity to treat.

Thank you again for your interest in the observations and recommendations of the Medicare Quality Improvement Organization community. We look forward to a dialog with you in May and subsequently, as alternatives to the current regulations are considered.

Sincerely,

Ferdinand Richards, III, M.D.
Chair, AHQA EMTALA Workgroup

David G. Schulke
Executive Vice President

cc: Tzvi Hefter, Director, Division of Acute Care, CMS

APPENDIX 17

The Institute of Medicine Committee on the Future of Emergency Care
in the U.S. Health System

Findings and Recommendations

Statement by

Harvey V. Fineberg, M.D., Ph.D.
President
Institute of Medicine
The National Academies

and

Megan McHugh, M.P.P.
Senior Program Officer
Institute of Medicine
The National Academies

for the

Emergency Medical Treatment and Active Labor Act Technical Advisory Group

Submitted for the Written Record on April 18, 2007

Dear Members of the Technical Advisory Group:

We are Dr. Harvey Fineberg, President of the Institute of Medicine (IOM), and Megan McHugh, Senior Program Officer, Board on Health Care Services at the IOM. The IOM was established in 1970 under the charter of the National Academy of Sciences to provide independent, objective, evidence-based advice to the government, health professionals, the private sector, and the public on matters relating to medicine and health care. We appreciate this opportunity to summarize the findings and recommendations from the recent IOM study on the Future of Emergency Care in the U.S. Health System.

BACKGROUND

The IOM's Committee on the Future of Emergency Care in the U.S. Health System was formed in September 2003 to examine the full scope of emergency care; explore its strengths, limitations and challenges; create a vision for the future of the system; and make recommendations to help the nation achieve that vision. Over 40 national experts from fields including emergency care, trauma, pediatrics, health care administration, public health, and health services research participated on the Committee or one of its subcommittees. The Committee produced three reports – one on prehospital emergency medical services (EMS), one on hospital-based emergency care, and one on pediatric emergency care. These reports provide complementary perspectives on the emergency care system, while the series as a whole offers a common vision for the future of emergency care in the U.S.

This study was requested by Congress and funded through a Congressional appropriation, along with additional sponsorship from the Josiah Macy Jr. Foundation, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the National Highway Traffic Safety Administration.

We will briefly summarize the Committee's findings and recommendations, giving particular attention to those that relate to the Emergency Medical Treatment and Active Labor Act (EMTALA).

GENERAL FINDINGS

Emergency and trauma care are critically important to the health and well-being of the U.S. population. The emergency care system handles an extraordinary range of patients, from febrile infants, to business executives, to elderly patients who have fallen. It provides not only urgent life-saving care but also primary care services to the millions of people who otherwise lack access to other health care services. In 2003, nearly 114 million visits were made to hospital emergency departments (EDs)—more than 1 for every 3 people in the United States. More than 16 million of those patients arrived at the ED by ambulance.

The emergency care system in the United States has made important strides over the past 40 years: emergency 9-1-1 service now links virtually all ill and injured people to an emergency medical response; prehospital emergency medical services (EMS) teams arrive to transport patients to definitive care; and scientific advances in resuscitation, diagnostic testing, trauma, and emergency medical care yield outcomes unheard of just two decades ago. Yet just beneath the surface, a growing crisis in emergency care is emerging; one that threatens access to quality

care for all. Emergency departments across the country are overcrowded. Ambulances are turned away, and patients, once they are admitted, may wait in hallways for hours or even days before inpatient beds open up for them. Often the specialists that patients need to see are not available. And the system that transports patients to the hospitals is fragmented and inconsistent in the level of quality it provides.

EMTALA

EMTALA was passed in 1986 to prevent hospitals from refusing to serve uninsured patients and "dumping" them on other hospitals. EMTALA established a mandate for hospitals and physicians who provide emergency and trauma care to provide a medical screening exam to all patients and properly stabilize patients or transfer them to an appropriate facility if an emergency medical condition exists. This requirement applies regardless of patients' ability to pay. EMTALA serves an invaluable purpose by protecting patients from potential abuses. As written and frequently interpreted, however, it can contribute to the shortage of specialists willing to treat patients in the ED and impede the development of regional emergency care systems.

Addressing the Availability of On-Call Specialists

EDs have become one of the nation's principal sources of care for patients with limited access to other providers, including the 45 million uninsured Americans. Indeed, EMTALA prevents hospitals from restricting access for uninsured patients by requiring hospitals to provide a medical screening examination to all patients and to stabilize or transfer patients as needed. With limited access to community-based primary and specialty care, many turn to the emergency system when in medical need, often for conditions that have worsened because of a lack of regular primary care. Much of that care is uncompensated.

Surveys of hospital administrators, ED staff, and specialists indicate that uncompensated care is one of the key factors affecting the availability of emergency and trauma specialists in the ED. In a 2000 California Medical Association survey on reimbursement for on-call emergency services, nearly 80 percent of the respondents reported difficulty obtaining payment for their services. Forty percent of the respondents who took voluntary call stated that lack of payment had forced them to reduce call, while 20 percent said they would be unable to continue voluntary call under the present circumstances.

The responsibility of hospitals to ensure the availability of on-call staff was revisited by the Centers for Medicare and Medicaid Services (CMS) in guidance published in September 2003. Prior to the 2003 amendment, there was considerable confusion surrounding hospitals' on-call list responsibilities. Afraid of violating EMTALA, many hospitals adopted a "rule of three" policy, which states that if a hospital has more than three physicians in a specialty, it must provide continuous ED coverage for that specialty. Struggling to maintain their on-call lists, some hospitals required specialists to be on call 24 hours a day, 7 days a week.

Complaints by on-call physicians and hospitals led to a clarification of the policy in 2003. CMS stated that EMTALA does not require hospitals to follow the "rule of three" and changed its statutory language as follows: "Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital,

including the availability of on-call physicians" (42 Code of Federal Regulations §489.24). CMS also clarified that physicians could be on call at more than one hospital simultaneously (though hospitals must have procedures in place for when a physician is on call at another hospital and is unable to respond) and that surgeons could perform elective surgery while on call.

The impact of the EMTALA amendment on the supply of and access to on-call specialists is not clear. Many believe that access to on-call specialists has worsened as a result. Others argue that the amendment has been beneficial. Had CMS not loosened on-call requirements, they argue, more specialists might have refused to take call in the ED altogether.

As an alternative to the current policy, some have advanced the idea of a more direct approach in which CMS would hold specialists rather than hospitals accountable for providing on-call services. One variation of this approach would be to require specialists to take call as a condition for Medicare participation. While the directness of this approach has some appeal, it fails to address some of the underlying problems, such as the declining numbers of specialists, and indeed could exacerbate that decline.

The Committee recognized that the uncompensated care associated with EMTALA contributes to the shortage of emergency and trauma specialists willing to take call in the ED. However, the supply of specialists, quality-of-life issues, and liability concerns also contribute to the shortage. The Committee concluded that it is of crucial importance to the nation to more clearly understand the true impact of all of these factors on the supply of specialty services and **recommended that Congress appoint a commission to examine the factors responsible for the declining availability of providers in high-risk emergency and trauma care specialties and recommend actions to address those factors.**

Fostering Regional Emergency Care Systems

There is substantial evidence that regionalization of services to direct critically ill and injured patients to designated hospitals with greater experience and resources improves outcomes and reduces costs across a range of high-risk conditions and procedures. Unfortunately, only a handful of systems around the country coordinate transport effectively at the regional level.

Ensuring that each patient is directed to the most appropriate setting, including a level I trauma center when necessary, requires that many elements within the regional system—community hospitals, trauma centers, and particularly prehospital EMS—coordinate the regional flow of patients effectively. Therefore, the Committee concluded that the challenges that exist in the system today could best be addressed by building a nationwide network of regionalized, coordinated, and accountable emergency care systems. The system should be regionalized in the sense that neighboring hospitals, EMS, and other agencies work together as a unit to provide emergency care to everyone in that region. A patient should be taken to the optimal facility within the region based on his or her condition and the distances involved. In case of a stroke, for example, a patient might be better served by going to a hospital that is slightly farther away but that specializes in caring for stroke patients.

However, EMTALA was written to provide individual patient protections—it focuses on the obligations of an individual hospital to an individual patient. The statute is not clearly adaptable

to a highly integrated regional emergency care system in which the optimal care of patients may diverge from conventional patterns of emergency treatment and transport.

Until recently, EMTALA appeared to hinder the regional coordination of services in several specific ways—for example, requiring a hospital-owned ambulance to transport a patient to the parent hospital even if it is not the optimal destination for that patient; requiring a hospital to interrupt the transfer to administer a medical screening exam for a patient being transferred from ground transport to helicopter if the hospital's helipad was used; and limiting the ability of hospitals to direct nonemergent patients who enter the ED to an appropriate and readily available ambulatory care setting. Interim guidance published by CMS in 2003, however, appeared to mitigate these problems. This guidance established, for example, that a patient visiting an off-campus hospital site that does not normally provide emergency care does not create an EMTALA obligation, that a hospital-owned ambulance need not return the patient to the parent hospital if it is operating under the authority of a communitywide EMS protocol, and that hospitals are not obligated to provide treatment for clearly nonemergency situations as determined by qualified medical personnel. Further, hospitals involved in disasters need not adhere strictly to EMTALA if operating under a community disaster plan. Despite these changes, however, uncertainty surrounding the interpretation and enforcement of EMTALA remains a damper on the development of coordinated, regional emergency care systems.

While the recent CMS guidance and deliberations of the EMTALA advisory group are positive steps, they have largely focused on incremental modifications. The Committee envisioned a more fundamental rethinking of EMTALA that would support and facilitate the development of regionalized emergency systems rather than simply addressing each obstacle on a piecemeal basis. They envisioned a new EMTALA that would continue to protect patients from discrimination in treatment while enabling and encourage communities to test innovations in the design of emergency care systems, such as direct transport of patients to non–acute care facilities—dialysis centers and ambulatory care clinics, for example—when appropriate.

The Committee concluded that appropriate modifications to EMTALA could be made that would preserve its original purpose and reduce its adverse impact on the development of regional systems. **The Committee recommended that the Department of Health and Human Services adopt regulatory changes to the Emergency Medical Treatment and Active Labor Act so that the original goals of the laws are preserved, but integrated systems may further develop.**

CLOSING

The Committee concluded that the nation's emergency care system is in serious peril and that swift action is needed. The way that hospitals and EMS agencies deliver emergency care is largely shaped by the legal and regulatory environment, and the IOM appreciates the work of the technical advisory group to evaluate and make recommendations on EMTALA's regulations and implementation.

Thank you for the opportunity to provide testimony. We would be happy to provide the technical advisory group with further information on our study if needed.