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NEUROLOGICAL SURGEONS

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June 13, 2008

Kerry N. Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services,  
*Attention: CMS-1390-P*  
P.O. Box 8011, Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates: 73 Fed. Reg. 23,528; April 30, 2008 (CMS-1390-P)

Dear Mr. Weems:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing 4,000 neurosurgeons in the United States, appreciate the opportunity to comment on the above referenced proposed rule. These comments will focus on the section entitled "**Hospital Emergency Services under EMTALA.**"

The AANS and CNS welcomed the establishment of the EMTALA Technical Advisory Group (TAG) and participated in its proceedings throughout its 30-month tenure. We commend the work of the TAG, which conducted a thorough and thoughtful analysis of the EMTALA statute, regulations and interpretive guidelines and made a number of very valuable recommendations to the Secretary of the Department of Health and Human Services. We believe, if implemented, most of these recommendations will help clarify the current interpretation of certain aspects of EMTALA and help improve the delivery of emergency medical services.

Our comments are summarized as follows:

1. The AANS and CNS support most of the recommendations of the EMTALA TAG and urge CMS to implement this as soon as possible.
2. The AANS and CNS oppose the proposed recommendation apply EMTALA to inpatients.
3. The AANS and CNS support moving the on-call list requirement from the EMTALA regulations to the Medicare provider agreement regulations. We also support eliminating the language requiring hospitals to provide on-call services in a manner that "best meets the needs of the hospital's patients."
4. The AANS and CNS support the recommendations allowing for the establishment of community call plans.

**TAG Recommendations Not Addressed in this Proposed Regulation**

In the proposed rule, CMS notes that the TAG submitted 55 recommendations and that 5 of these have already been implemented by CMS. While the proposal does not specifically ask for comments on most of the remaining TAG recommendations, the AANS and CNS nevertheless wanted to take this opportunity to highlight several of the recommendations, which are of particular interest and

supported by organized neurosurgery. Since the TAG reports provide the detailed rationale for these recommendations, we will not elaborate on the reasons for our support in this document. However, the AANS and CNS would be pleased to provide CMS with additional information or answer any outstanding questions that the agency may have regarding these recommendations at a later date.

Number	Recommendation	AANS/CNS Position
1	The TAG recommends that CMS continue to not require physicians to take emergency call as a Condition of Participation in Medicare.	<b>Agree</b>
8	<p>The following statements represent the consensus of the TAG, which recommends that CMS incorporate the concepts into Interpretive Guidelines for 489.24(f), recipient hospital responsibilities:</p> <ul style="list-style-type: none"> <li>• 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 the transfer, the receiving hospital should also have available the necessary equipment, space, staff, etc. to accommodate the patient transfer.</li> <li>• The presence of a physician who has privileges at the receiving hospital but is not on the call roster or who is not on call at the time of the transfer should <i>not</i> be considered a specialized capability.</li> </ul>	<b>Agree</b>
9	The TAG recommends that 489.20(4)(2) be interpreted by CMS as meaning that all hospitals, including specialty hospitals, should maintain a call list in accordance with the statute and provider agreement. If necessary, the Interpretive Guidelines at TAG 404A should be revised to clarify this point.	<b>Agree</b>
11	<p>The following statements represent the consensus of the TAG, which recommends that CMS incorporate these comments into the Interpretive Guidelines for 489.24(j), availability of on-call physicians:</p> <ul style="list-style-type: none"> <li>• Response times should be defined in a range of minutes, not a single number of minutes.</li> <li>• Response time should refer to the initial response by the physician on call.</li> <li>• Through their medical staff bylaws, hospitals may define who may respond on behalf of the on-call physician (i.e., physician's designated representative).</li> <li>• The initial response may occur by phone (or other means).</li> <li>• Hospitals should develop policies and procedures to address the response time and appropriate exemptions.</li> <li>• A physician's failure to respond when called or failure to arrive at the hospital when requested may be a violation of EMTALA.</li> </ul>	<p><b>Agree</b></p> <p><u>Note:</u> CMS should continue to not penalize a physician for failure to respond when called or failure to arrive at a hospital when requested within the requisite amount of time when circumstances beyond the physician's control exist (e.g., beeper failure, traffic, etc.)</p>

Number	Recommendation	AANS/CNS Position
13	<p>The TAG recommends that CMS delete the following paragraph in the Interpretive Guidelines for 489-24(j), availability of on-call physicians:</p> <p>Physicians that refuse to be included on a hospital's on-call list but take calls selectively for patients with whom they or a colleague at the hospital have established a doctor-patient relationship while at the same time refusing to see other patients (including those individuals whose ability to pay is questionable) may violate EMTALA. If a hospital permits physicians to selectively take call while the hospital's coverage for that particular service is not adequate, the hospital would be in violation of its EMTALA obligation by encouraging disparate treatment.</p>	<b>Agree</b>
14	<p>The following statements represent the consensus of the TAG, which recommends that CMS incorporate these concepts into the Interpretive Guidelines for 489.24(j), availability of on-call physicians:</p> <ul style="list-style-type: none"> <li>• When a physician takes call for patients with whom he/she has a preexisting medical relationship, that is <i>not</i> considered "selective call."</li> <li>• When a physician is not on the call roster, he/she is not obligated to provide call coverage (e.g., when he/she is in the hospital seeing patients).</li> <li>• If the EMTALA-related call list is adequate and meets the requirements of the statute, physicians may see patients in the hospital as they see fit.</li> <li>• A physician on call must see patients without regard for any patient's ability to pay.</li> <li>• If a physician volunteers to see patients in the ED while not participating in the call list, the physician must agree to see patients regardless of any patient's ability to pay.</li> <li>• If a surveyor identifies a discriminatory or disparate pattern of selective referral for specialty care on the basis of patients' ability to pay, that is potentially a violation of EMTALA.</li> <li>• Hospitals should be reminded of their obligation to fulfill call coverage duties, e.g., they should not permit discrimination to occur.</li> </ul>	<b>Agree</b>
19	<p>The TAG recommends that HHS amend the Interpretive Guidelines with respect to follow-up care to clarify that once a patient has been stabilized, the hospital and physician have no further follow-up care obligation under EMTALA. The hospital must, however, comply with applicable Medicare Conditions of Participation. The TAG believes this interpretation is more consistent with the EMTALA statute and regulations, which no longer apply once the patient is stabilized, and current CMS interpretation.</p>	<b>Agree</b>

Number	Recommendation	AANS/CNS Position
27	<p>The TAG recommends HHS change the Interpretive Guidelines to state the following:</p> <p>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:</p> <ul style="list-style-type: none"> <li>o telemedicine</li> <li>o other staff physicians</li> <li>o transfer agreements designed to ensure that the patient will receive care in a timely manner</li> <li>o regional or community coverage arrangements</li> </ul>	<p><b>Agree</b></p> <p><u>Note:</u> We note that in some instances it may not be possible for the backup plan to include these options and the only option that the hospital may have is to go on "diversion status."</p>
52	<p>The TAG recognizes that professional liability is a concern for providers and that having protections would increase coverage in the ED. The TAG recommends that HHS act to support amending the EMTALA statute to include liability protection for hospitals, physicians, and other licensed independent practitioners who provide services to patients covered by EMTALA.</p>	<p><b>Agree</b></p>
53	<p>The TAG recognizes that reimbursement is a major factor that impacts hospitals' and physicians' ability to provide emergency care and recommends that HHS act to support amending the EMTALA statute to include a funding mechanism for hospitals and physicians.</p>	<p><b>Agree</b></p>

**The AANS and CNS urge CMS to adopt the above recommendations as soon as possible.**

**TAG Recommendations Included in this Proposed Regulation**

CMS does propose to adopt several of the TAG's recommendations. The AANS and CNS oppose the recommendation regarding the applicability of EMTALA requirements to hospital inpatients and support the recommendations related to physician on-call requirements.

***Applicability of EMTALA Requirements to Hospital Inpatients***

CMS is proposing to amend the EMTALA regulations to add a new provision that states when an individual covered by EMTALA is admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the individual. **The AANS and CNS believe this is an ill-conceived idea, and, based on the following reasons, we urge CMS not to finalize this proposal.**

- As noted in the proposed rule, when CMS revised the EMTALA regulations in 2003, the agency established a new policy that a hospital's EMTALA obligation ends when that hospital, in good faith, admits an individual with an unstable emergency medical condition as an inpatient to that

hospital. The AANS and CNS supported this change, noting in our comments that other patient safeguards protected inpatients, including the Medicare hospital Condition of Participation rules, state duty of care requirements and medical malpractice laws. This policy was adopted to clarify what had been confusion over whether or not EMTALA applied to inpatients and to establish a bright-line rule. To in part reverse this policy would be to once again add unnecessary confusion and burdens to the emergency medical care system.

- CMS has not adequately demonstrated the need for this new policy. This topic was discussed at length at various EMTALA TAG meetings, and we do not believe sufficient and compelling evidence was shown to merit such a sweeping change. Moreover, as identified by the American Hospital Association in their comments on this proposal, we continue to maintain that there are adequate protections in existing regulations that require hospitals to render appropriate care to inpatients making this proposed change unnecessary.
- This policy would be potentially abused and an unintended consequence may be an increase in the number of patients being “dumped” from one hospital to another. In recent years, many academic medical centers, trauma centers and large tertiary care hospitals have reported an increased number of patients being transferred to them from hospital Emergency Departments (ED) under the “specialized capabilities” transfer rules. According to a survey of neurosurgeons conducted by the AANS and CNS in late 2004, 45 percent of neurosurgeons practicing at an academic health center or Level 1 or 2 trauma center had experienced an increased number of neurosurgical emergency cases in the preceding two years and one-third of these stated that the reason for these transfers was that:

The neurosurgeons in my area who are on call instruct their hospitals to transfer emergency neurosurgical cases to my hospital claiming the patients require specialized services and my hospital is considered a “higher level care” institution and under EMTALA requirements I must treat these patients.

These hospitals are already stretched thin and are experiencing ED overcrowding, ambulance diversion, and shortages of intensive care unit (ICU) and other inpatient beds. In addition, these patients are often uninsured or underinsured and as a result of the increased number of transfers, many of these hospitals are facing significant fiscal difficulties. Expanding this EMTALA transfer option for inpatients will only exacerbate these problems.

- As the Coalition for American Trauma Care (CATC), of which the AANS and CNS are members, stated in their comments, this proposal will likely worsen patient care as it will create “disincentives for hospitals to identify early patients who need tertiary care.”
- This was one of the TAG’s most controversial recommendations and it only passed by a razor thin margin. Indeed, eight members of the TAG felt so strongly about this recommendation that they took the extraordinary step of writing a formal letter of dissent to the TAG’s chair.<sup>1</sup> This letter stated in part:

We are very concerned that this recommendation, if implemented, will adversely affect patient care and potentially increase the number of unnecessary patient transfers. All of the practicing surgical specialty physician representatives as well

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<sup>1</sup> Members signing this letter, which is contained in Report Number Seven from the EMTALA TAG, September 17-18, 2007, Appendix 4, were: James Nepola, MD, Julie M. Nelson, Rory S. Jaffe, MD, David W. Tuggle, MD, Richard Perry, MD, James L. Biddle, MD, Rachel Seifert, MD and John A. Kusske, MD.

as all of the hospital representatives of the TAG are in opposition to this recommendation.

Even the two physician members of the TAG who supported this recommendation were sufficiently concerned about the potential unintended consequences that they too felt compelled to register their concerns in their own letter,<sup>2</sup> stating in part:

We two physician members of the TAG who voted for the recommendation feel that its implementation should be carefully considered as having potential for abuse (ie. patient dumping)...We fear that the potentially unintended consequence may be the transfer of EMTALA patients for reasons other than those related to emergency care of the problem for which the patient was originally admitted when these services could have been provided at the sending hospital.

**For all the above reasons, the AANS and CNS strongly recommend that CMS not adopt this proposed policy.**

### ***Physician On-Call Requirements***

As mentioned in the proposed rule, CMS notes that the EMTALA TAG spent a great deal of its time discussing a wide variety of issues related to hospitals' and physicians' on-call obligations. We are therefore pleased that CMS has proposed two very positive changes to the rules governing the on-call requirements, which the AANS and CNS support.

#### ▪ **Relocation of Regulatory Provisions**

During its deliberations, the TAG recommended that CMS move the regulation that discusses the hospital's obligation to maintain an on-call list from the EMTALA regulations<sup>3</sup> to the regulations implementing provider agreements.<sup>4</sup> In the proposed rule, CMS states that it agrees with the TAG and therefore the agency proposes to delete the provision relating to maintaining a list of on-call physicians from §489.24(j)(1) and replace it with new §489.20(r)(2) language, which would require hospitals to maintain:

An on-call list of physicians on its medical staff available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under [EMTALA] in accordance with the resources available to the hospital.

Given the fact that the EMTALA statute contains **no** specific requirement for hospitals to maintain an on-call list, the AANS and CNS believe this is an appropriate change that would ensure that the regulatory scheme is consistent with the actual language of the statute. In addition, we are very

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<sup>2</sup> Members signing this letter, which is contained in Report Number Seven from the EMTALA TAG, September 17-18, 2007, Appendix 3, were: Mark D. Perlmutter, MD and Michael J. Rosenberg, MD.

<sup>3</sup> §489.24(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.

<sup>4</sup> §489.20(r) In the case of a hospital as defined in § 489.24(b) (including both the transferring and receiving hospitals), to maintain—

(2) 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.

supportive of the elimination of the “best meets the needs of the hospital’s patients” language. As the AANS and CNS stated in our written comments to the TAG in March 2005:

However, we continue to have some concerns that the “best meet the needs” requirement is a vague standard, which may invite a whole new body of litigation aimed at defining this requirement. The stated purpose for revising the EMTALA regulations and guidelines was to better clarify the law’s requirements to ensure hospital and physician compliance, and the TAG may therefore wish to provide further guidance on the “best meet the needs” requirement.”

The proposed revised language is far superior to the vague “best meets the needs” standard.

▪ **Shared/Community Call**

As CMS may know, there are only roughly 3,100 board certified neurosurgeons in active practice in the United States and approximately 5,000 hospitals with emergency departments. It is therefore impossible to have neurosurgical on-call coverage for every emergency department 24 hours per day, 7 days per week, 365 days per year. As a result, and in an attempt to provide the broadest on-call coverage, more than one-half of the nation’s neurosurgeons take call at more than one hospital at a time – 28 percent cover 2 hospitals; 13 percent cover 3; and 10 percent cover 4 or more.

Neurosurgery is not the only specialty with a shortage of available on-call specialists and the Institute of Medicine, in its *Future of Emergency Care* series of reports, has opined that the “shortage of available on-call specialists is a serious and complex dilemma, which appears to defy simple resolution. It reflects long term trends in professional practice and physician supply that would take years to address even if the solution were clear.”<sup>5</sup> The IOM committee studying this issue did, however, identify an approach that it believes warrants special consideration: regionalization of specialty services. The report goes on to note:

Much like the regionalization of trauma services, regionalization of certain specialty services will direct patients to the hospitals that have access to the needed specialists... The intent of regionalizing specialists is to rationalize the limited supply of specialists by facilitating agreements that would ensure coverage at the key tertiary and secondary locations based on actual need. This would replace the current haphazard approach that is based on many factors other than patient need. Without such regional arrangements, some hospitals may have an overabundance of certain specialists, while others face a constant shortage.<sup>6</sup>

While not exactly the same as regionalization, the concept of community or shared call addresses some of the same challenges that hospitals and on-call specialists face when trying to provide adequate on-call coverage.

The IOM committee also took note of the fact that current EMTALA rules may be hindering the adoption of regionalization or community call arrangements, stating that despite changes that CMS made in 2003 to clarify and improve EMTALA regulations, “uncertainty surrounding the interpretation and enforcement of EMTALA remains a damper to the development of coordinated,

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<sup>5</sup> IOM (Institute of Medicine). 2006. *Hospital-Based Emergency Care: At the Breaking Point*. Washington, DC: The National Academies Press.

<sup>6</sup> Ibid.

integrated emergency care systems.”<sup>7</sup> Thus, the IOM recommended “that the Department of Health and Human Services adopt regulatory changes to the Emergency Medical Treatment and Active Labor Act (EMTALA)... so that the original goals of the law are preserved but integrated systems may further develop.”<sup>8</sup>

The AANS and CNS are therefore extremely pleased that CMS has acknowledged that community call would “afford additional flexibility to hospitals providing on-call services and improve access to specialty physician services for individuals in an emergency department.” Specifically, CMS has proposed to define community call as a “formal on-call plan that permits a specific hospital in a region to be designated as the on-call facility for a specific time period, or for a specific service, or both.” Hospitals must include the following elements when devising a formal community call plan:

- ❖ The community call plan would include a clear delineation of on-call coverage responsibilities, that is, when each hospital participating in the plan is responsible for on-call coverage.
- ❖ The community call plan would define the specific geographic area to which the plan applies.
- ❖ The community call plan would be signed by an appropriate representative of each hospital participating in the plan.
- ❖ The community call plan would ensure that any local and regional EMS system protocol formally includes information on community on-call arrangements.
- ❖ Hospitals participating in the community call plan would engage in an analysis of the specialty on-call needs of the community for which the plan is effective.
- ❖ The community call plan would include a statement specifying that even if an individual arrives at the hospital that is not designated as the on-call hospital, that hospital still has an EMTALA obligation to provide a medical screening examination and stabilizing treatment within its capability, and hospitals participating in community call must abide by the EMTALA regulations governing appropriate transfers.
- ❖ There would be an annual reassessment of the community call plan by the participating hospitals.

Clearly the benefits of such a community on-call plan will allow physicians in a certain specialty to better provide 24/7/365 emergency call coverage for the community, without putting a continuous call obligation on any one physician or group of physicians. Neurosurgeons are currently stretched thin trying to cover multiple EDs to meet hospital and patient demands for treating emergency neurosurgical conditions, such as head trauma, spinal cord injury and stroke. We are hopeful that because CMS has embraced the concept of community call and essentially removed the EMTALA barrier to formulating such shared call plans, patient access to timely emergency neurosurgical care will be improved.

The AANS and CNS are cautiously optimistic that hospitals and neurosurgeons around the country will see the benefits of coordinating emergency neurosurgical care and will move forward to develop these collaborative arrangements. We do not believe that such plans must first be submitted to CMS and we support the agency’s goals of giving hospitals and physicians the flexibility, subject to the above requirements, to develop community call plans that best work for their local area. **The AANS and CNS believe that the requirements CMS has proposed are**

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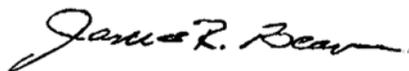
<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

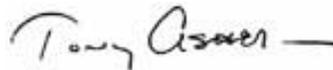
**reasonable, and we therefore support the proposed new community call section of the EMTALA regulations.**

Thank you for considering our comments.

Sincerely,



James R. Bean, MD, President  
American Association of Neurological Surgeons



Anthony L. Asher, MD, President  
Congress of Neurological Surgeons

cc: Robert E. Harbaugh, MD, Chairman, AANS/CNS Washington Committee  
John A. Kusske, MD, AANS/CNS Health Policy Liaison and Former EMTALA TAG Member

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