American Hospital Association

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Mr. William Parham, III
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – B
7500 Security Boulevard, Room C4-26-05
Baltimore, MD 21244-1850

RE: CMS-10225 (OMB#: 0938-New), Medicare Program; Disclosures to Patients by Certain Hospitals and Critical Access Hospitals; Proposed Paperwork Requirement (Vol. 72, No. 81), April 27, 2007

Dear Mr. Parham:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed paperwork requirement regarding disclosures to patients by certain hospitals and critical access hospitals of physician ownership and their emergency services capacity. As indicated in our June 4 comments on the fiscal year 2008 inpatient prospective payment system (PPS) proposed rule, **the AHA supports implementation of a physician-ownership disclosure requirement but believes the emergency services disclosure requirement should be scaled back significantly.**

PHYSICIAN OWNERSHIP DISCLOSURE

The proposed rule and paperwork notice would require all physician-owned hospitals, at the beginning of an admission or outpatient visit, to disclose to patients that physicians have an ownership interest or investment in the hospital and offer to make a list of physician investors available upon request. The beginning of an admission or outpatient visit is defined to include pre-admission testing and registration. Such hospitals also would have to require, as a condition for medical staff privileges, that physician investors disclose to their patients that they have an ownership interest in the hospital when they refer patients for services.

Without a final rule, and in the absence of any draft provider implementation instructions in the clearance package, we would like to reiterate several relevant points made in our comments on the inpatient PPS proposed rule.

- **Scope of disclosure requirement** – CMS asked whether the definition of a "physician-owned hospital" should exclude physician ownership or investment interests based on the nature of the interest, the relative size of the investment, or the type of investment (e.g., publicly-traded securities and mutual funds). **We recommend that the only exception to the definition of a "physician-owned hospital" be when physician ownership is limited to holding publicly-traded securities or mutual funds that satisfy the requirements for the exception under 42 C.F.R. Sections 411.356(a) and (b). We oppose any exception based on the size of investment.** It is important for patients to know whenever their physician has an interest that could cause a conflict in making decisions about their care. The size of that interest is immaterial to the fact that the conflict may exist.

- **Definition of the beginning of an admission or outpatient visit** – The "beginning of an inpatient admission or outpatient visit" specifically includes pre-admission testing and registration. **We recommend that the definition be clarified to include scheduling as well.** Patients should receive these disclosures at the earliest opportunity so that they have an ability to act on the information if they choose.

- **Provision of a list of physician investors** – The proposal would require that physician-owned hospitals offer to provide patients with a list of physician investors upon request but does not establish any time frame for doing so. **We recommend that the list be provided to patients at the time the request is made.** We believe providers should be able to provide the list immediately upon inquiry so that patients get the information in time to consider it.

DISCLOSURE ON 24/7 PHYSICIAN AVAILABILITY AND EMERGENCY CAPACITY

As part of its *Deficit Reduction Act of 2005*-required report to Congress, CMS raised the issue of patient safety in physician-owned specialty hospitals. Recent events and media coverage also have highlighted problems. The inpatient PPS proposed rule addressed these issues in several ways. One aspect of the proposal called for a written disclosure to patients of how emergencies are handled when the hospital does not have a physician available on the premises 24 hours a day, 7 days a week.

As indicated in our June 4 comments, **the AHA believes that the proposed disclosure requirement would be applied much too broadly and, as such, would create an unnecessary burden on small, rural and critical access hospitals.** While the requirement may sound reasonable, we believe it misses the mark on the real issue to be addressed: safety concerns in physician-owned specialty hospitals.

It makes sense to apply special requirements like these to physician-owned specialty hospitals, but not all hospitals. The reason: The safety concerns raised with physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery in this country. These facilities are free-standing, generally not part of a larger system of care, most often have no transfer agreements with other hospitals or providers of care in a community, and tend to specialize in one type of care delivery, challenging their ability to treat the unexpected event or emergency.

This is not the case with full-service community hospitals. Full-service community hospitals are part of a community network of care, involving referrals from local physician practices, reliance on local trauma-support networks, participation in local emergency medical transport systems and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted, and the patient's clinical information collected at one hospital goes with the patient to the next hospital. In addition, small and rural hospitals are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals. Furthermore, the capabilities of these hospitals are well known in their communities and are looked to as a local entry point into the health care system. **Applying additional requirements for this group of hospitals is unnecessary and costly.**

The broader network of care delivery, of which full-service community hospitals are a part, is the best way to ensure that care is provided to patients at the right time in the right setting. This requirement can be used to assure that patients scheduled for admission to a physician-owned specialty hospital understand that, in the absence of being a part of the broader care network, the ability of these facilities to handle complications onsite may be limited.

The burden associated with this requirement could be further reduced by not applying the requirement to all outpatient visits. **The AHA recommends that the focus of this requirement be on inpatient admissions, and that the outpatient disclosure be limited to those outpatient visits that include surgery, other invasive procedures, the use of general anesthesia, or other high-risk treatment. Emergency department (ED) services should be specifically excluded.**

Patients being admitted to a hospital expect that the hospital can handle emergencies that arise, and patients undergoing outpatient surgery or other procedures that are invasive, involve anesthesia or are higher risk expect that related complications can be handled. A patient coming for a mammogram or going to an arthritis clinic has a different set of expectations. Therefore, we do not believe it makes sense to paper every outpatient with the disclosure notice. Furthermore, providing the notice to ED patients seems fruitless. If CMS is using this disclosure requirement to broadly expand community understanding of a hospital's limitations, we believe that goal can be accomplished through signs in hospital EDs and outpatient clinics and an annual notice in the local newspaper.

Finally, we believe that CMS' estimate of burden associated with this requirement is grossly understated, as it appears to be based solely on inpatient admissions, with no estimate for outpatient visits. While CMS estimates that approximately 2,500 hospitals would be subject to this requirement, their estimated average number of disclosures per hospital is only 1,092. Hospitals provide about 13 million outpatient visits per year. That number appears to be based on specialty hospital volume, which we do not believe reflects the wider range of outpatient services provided in hospitals, especially rural hospitals. **The AHA recommends that CMS revisit its estimate of burden for disclosures to outpatients if the requirement is applied beyond physician-owned specialty hospitals.**

If you have any questions, please feel free to contact me or Ellen Pryga, director for policy, at (202) 626-2267 or epryga@aha.org.

Sincerely,

Rick Pollack
Executive Vice President