American Hospital Association

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RE: CMS May 9, 2006 Interim Report to Congress on Progress Toward Implementing the DRA Provision Affecting Specialty Hospitals

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of our 4,800 member hospitals and health care systems, and 35,000 individual members, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) interim report on the strategic plan addressing physician investment in specialty hospitals (as defined under the Medicare Modernization Act (MMA) moratorium and hereafter referred to as physician-owned, limited-service hospitals) required by Section 5006 of the Deficit Reduction Act (DRA).

The interim report contains little discussion of the primary thrust of the requested strategic plan – the monitoring and regulation of physician investments in limited-service hospitals. For the most part, the report addresses CMS' actions taken in response to earlier studies by the agency and the Medicare Payment Advisory Commission. Our comments address CMS' actions to date and those we believe that should be undertaken and reflected in the final strategic implementing plan. **Overall, the AHA urges CMS to be more actively engaged in the full-range of issues presented by physician-owned, limited-service hospitals through procedural and regulatory changes and recommendations to Congress for statutory changes.**

Medicare Payment Changes Alone are Not Sufficient

The interim report points to two major areas of payment changes under development. The first is significant changes to the inpatient prospective payment system (PPS) to reduce the variability in profitability among diagnostic-related groups (DRGs) and better reflect the severity of the patients served within a particular DRG. The second is the development of a new payment system for ambulatory surgical centers (ASCs) to reduce the incentive for ASCs to convert to limited-service hospitals in order to access better payment for outpatient surgery.

While these changes may appear to be a viable option for addressing some of the incentives driving the growth of limited-service hospitals, payment changes alone are not enough. CMS needs to address the growing problem of self-referral. The revision of Medicare inpatient payments would do nothing to address incentives for physician-owners of limited-service hospitals to increase use of inpatient and outpatient ancillary services (e.g., lab and imaging services) for which self-referral under the whole hospital exception loophole is currently permitted. And changing Medicare inpatient payments does nothing to change physician-owners' incentives to steer patients to owned facilities, select the most well-insured patients, and avoid Medicaid and uninsured patients.

With regard to the specifics of the two payment proposals, the AHA submitted a separate comment letter on the extensive changes proposed to the inpatient PPS. In summary, the AHA supports a move to cost-based DRG weights; however, it is not clear which of several ways of accomplishing this best improves payment accuracy. Therefore, the AHA recommends a one-year delay to enable further analysis and development of workable approaches. More analysis needs to be done to assess the need for, and develop approaches to, severity-adjusted payment. The AHA commits to working with CMS on these issues.

With respect to a new payment system for ASCs, the AHA has worked with CMS on early development activities and will continue to participate in those discussions. We are concerned, however, that the language describing this initiative in the interim report suggests that CMS plans to simply increase payment to ASCs to more closely approximate payment in hospital outpatient departments. ASCs and hospital outpatient departments play different roles, are subject to different regulatory standards, have different underlying costs, and serve different populations. Hospital outpatient departments should be paid higher rates than ASCs. Furthermore, raising ASC rates is unlikely to stop the conversion of ASCs to limited-service hospitals. Using the whole hospital exception to expand the range of outpatient ancillaries for which self-referral is allowed remains an attractive incentive for conversion.

Strategic Implementing Plan Should Address Appropriate Limitations on the Use of the Whole Hospital Exception

Section 5006 of the DRA directs the Secretary of the Department of Health and Human Services (HHS) to develop a strategic implementing plan on physician investments in limited-service hospitals concerning whether physician investments in such hospitals are proportional to investment returns, whether the investments are bona fide, and whether the Secretary should require annual disclosure of investment information. HHS also was directed to consider the provision of charity care by physician-owned, limited-service hospitals and the extent to which they provide services to Medicaid patients. Finally, HHS was to address the issue of appropriate enforcement in the strategic plan. The AHA offers the following comments.

- **Survey of physician-owned, limited-service hospitals and their competitors.** The interim report describes CMS' current effort to survey all physician-owned, limited-service hospitals to obtain the type of individual physician investment information currently not collected. The survey also collects information on charity care provided and levels of participation in

Medicare and Medicaid. The survey also was sent to community hospitals deemed competitors of these physician-owned, limited-service hospitals.

The Secretary's statement in the interim report that he might use the data collected to recommend a minimum charity care requirement for all hospitals misses the mark on what is needed to address the growing problem of self-referral. The lack of charity care provided by physician-owned, limited-service hospitals is symptomatic of the broader problem they pose for the community. As the AHA's recommendations for action that follow demonstrate, addressing the problem of self-referral requires addressing the ability of physicians to invest in limited-service hospitals. Any public policy questions about charity care, which is only a part of the contribution hospitals make to their communities, is within the purview of the Internal Revenue Service, which is actively engaged in examining those issues.

- **Actions that should be undertaken or recommended to Congress regarding physician investment.** HHS should never have allowed the use of the whole hospital exception by physician-owned, limited-service hospitals. Congress' intent in establishing that exception was to allow physician ownership and self-referral when the investment was in a whole hospital and the scope of services provided by the hospital was much broader than an individual department. An individual department is no different in scope than a single specialty. It was believed that a diffuse investment interest beyond the scope of practice of an individual physician would limit the effects of self-referral. The concentration of physician ownership that is occurring in single-specialty hospitals is counter to congressional intent. **The AHA continues to support a permanent ban on physician self-referral. Research has clearly shown that self-referral increases the use of services but does not reduce cost. No patient should have to question whether their physician is acting in the interest of patient care or in the physician's best financial interest. Until such a ban is put in place, the ability of physician-owned, limited service hospitals to use the whole hospital exception must be limited**.

  However, CMS has been unwilling to recommend this action to Congress – a fact reinforced by the agency's testimony at the Senate Finance Committee's hearing on May 17. At a minimum, **CMS should recommend that Congress enact increased transparency of physician investments and limitations on physician investment in limited-service hospitals if it is going to continue allowing physician-owned, limited-service hospitals to use the whole hospital exception under the Ethics in Patient Referrals Act.** Such conditions should seek to diffuse or limit the connection between a physician's financial interest in the hospital and his or her referral patterns as was originally intended. In doing so, the AHA suggests that CMS consider the following physician investment limitations, most of which are elements of the physician investment safe harbor under the federal anti-kickback law.

- Aggregate investment interests by physicians should be limited to 40 percent.*
- Individual investments by a physician in an entity should be limited to 3 percent.
- Investments must be bona fide investments (that is, the funds used to make the investment must not be loaned to the physician by the entity or another investor).*
- The investment must be available to the general public on the same terms as made available to physicians.*
- The amount of payment to a physician in return for their investment interest must be directly proportional to the amount of their capital investment.*
- The terms of the investment must not require that the physician actually make or influence referrals to be made to the entity as a condition of remaining an investor.*
- Physicians should be required to annually report their investment interests to HHS for posting on CMS' Web site.
- Physicians should be required to disclose their investment interests to their patients when scheduling an admission at the facility in which they have a financial interest.

Medicare Certification Standards and Enrollment Procedures Should be Changed

The interim report describes CMS' efforts to determine if all physician-owned hospitals meet the Medicare statutory definition of a hospital. In June 2005, CMS suspended the issuance of new Medicare provider numbers to limited-service hospitals pending its evaluation of the provider enrollment process and the need for changes. That evaluation focused very narrowly on the "primarily engaged in the delivery of inpatient services" portion of the definition, given CMS' observation that many of the surgical and orthopedic hospitals looked more like ASCs than hospitals. There also was discussion of whether all hospitals should be required to have emergency departments.

The interim report reflects the general consensus that it would be unwise to set a numeric proportionality test for inpatient versus outpatient care due to potential unintended consequences, especially for small rural hospitals. The AHA was surprised, however, at CMS' conclusion in the interim report that the hospital certification standards and enrollment procedures did not need to be changed except for a provision in the Emergency Medical Treatment and Labor Act (EMTALA) regulations. The change – regarding the duty of limited-service hospitals to accept

* This provision is similar (but not necessarily identical) to a component of the anti-kickback safe harbor for physician investment interests. Within the safe harbor context, some components only apply to passive investors and others apply to active investors or to both. We make no such distinctions. Instead, the focus is on applying the conditions to physicians in a position to make or influence referrals to the entity (sometimes referred to as "tainted investors" by OIG).

transfers even when they do not have an emergency department – was published as part of the inpatient PPS notice, and our comments on this matter are included in our inpatient PPS comment letter.

The AHA recommends that CMS adopt several changes to the Medicare conditions of participation for hospitals and the procedures for enrolling physician-owned, limited-service hospitals. They are:

- **CMS should clarify the capabilities required of a hospital with limited services regarding their ability to deal with complications that may arise, especially during or after a surgical procedure, to ensure patient safety.** For example, every hospital should have staff on the premises 24/7 who have been trained and are proficient in resuscitation and the maintenance of respiration. A variety of staff could fulfill this function.

- **Disclosure to patients at the time of admission scheduling as to the service limitations of the facility and the likelihood of transfer to another hospital in the event of complications.**

- **Every physician-owned, limited-service hospital that relies on the community's emergency services capacity should be obligated to support it.** Physician-owned, limited-service hospitals should be required to have agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient. Specifically, those agreements should be required to address:

    - *Procedures for an appropriate transfer from a limited-service hospital for patients not covered under EMTALA* (e.g., an inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital). It is not enough to dial 911.

    - *Continuity of care* (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.). Patients who suffer from complications at a limited-service hospital should never appear in a community hospital's ED as they do now with no warning call, no medical history, no operative report, no information on the anesthesia used and, often, no ability to reach the treating surgeon for consultation.

    - *Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage* (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community hospital, or the physician-owned, limited-service hospital provides financial support to the community hospital to maintain on-call coverage).

- **CMS should collect individual physician ownership information as part of the enrollment process.** CMS indicates in the interim report that it is serious about enforcing

payment restrictions for new specialty hospitals in instances where payment for self-referrals is prohibited. But CMS has no way to distinguish between claims for services resulting from prohibited self-referrals and those from physicians practicing at the facility who have no financial interest. Furthermore, all of the studies conducted on physician-owned, limited-service hospitals have suffered from the lack of any data on individual physician ownership interests. This data is critical to enable the type of referral pattern and utilization studies necessary to assess the impact of physician self-referral. Given the rapid migration of care outside the hospital setting and the degree to which physician self-referral is currently allowed, the ability to conduct such studies is essential.

- **CMS should routinely analyze the claims data from physician-owned hospitals during the first several years of their operation to determine if they are limited-service or full-service hospitals.** Hospitals that meet the CMS test of a specialty hospital as defined by the MMA and DRA (i.e., 45 percent or more of their discharges are in the cardiac, orthopedic, or surgical major diagnostic categories (MDCs)/DRGs) should be clearly categorized as a limited-service hospital. This is the only way to ensure that physician-owned, limited-service hospitals do not masquerade as full-service hospitals.

The AHA believes that the issue of physician self-referral demands a more vigorous response from CMS and the Congress. Patients have a right to expect that care decisions made are in their best interests and not the result of a conflict of interest. They also deserve to be able to rely on the ability of any entity that calls itself a hospital to be able to provide competent care and protect their safety. The AHA will continue to provide whatever help we can to CMS and to the Congress. If you have any questions on AHA's comments or recommendations, please contact Ellen Pryga, director of policy, at (202) 626-2267 or epryga@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

cc: Donald Romano, CMS