AMA
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ASSOCIATION

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Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to Physician Self-Referral Rules; File Code CMS-1504-P; 75 *Fed. Reg.* 46,169 (August 3, 2010).

Dear Dr. Berwick:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding physician ownership of hospitals and supervision requirements for outpatient therapeutic services. Our detailed comments are set forth below.

PHYSICIAN-OWNED HOSPITALS "UNDER DEVELOPMENT"

Sections 6001 and 10601 of the "Patient Protection and Affordable Care Act (ACA)," as amended by section 1106 of the "Health Care and Education Affordability Reconciliation Act," ban new physician-owned hospitals in Medicare, but current hospitals may continue operating under a limited grandfather provision. The provision requires that current hospitals have a provider agreement in effect as of December 31, 2010. This latter requirement conflicts with another requirement providing that the baseline percentage ownership in a hospital cannot exceed such percentage as of the date of enactment of the law (March 23, 2010). **The AMA urges CMS to reconcile these dates. Specifically, CMS should apply the March 23 date only to hospitals that have Medicare provider agreements already in place, while hospitals that are under development or expansion, for which Medicare certification is needed, would have until December 31, 2010, to complete these requirements, including establishment of a ownership percentage baseline.**

In enacting this provision, Congress intended to allow hospitals undergoing expansion or development to complete their work and obtain a Medicare provider agreement by December 31, 2010. This is critical because many projects under development include situations where physicians are rescuing and rehabilitating bankrupt inner city and rural facilities and substantial investments have been made in about 60 different projects around the country. CMS's decisions on the regulations will have significant consequences for the future viability of these projects and communities, including access to medical services provided to these communities.

The December 31, 2010, deadline, however, conflicts with the requirement that projects under development cannot exceed the percentage of physician ownership in place on March 23, 2010. The AMA believes this is an error in drafting as the legislation went through successive iterations of rewriting. This view is reinforced by the fact that Congress corrected the same problem as it related to the baseline number of beds, operating rooms, and procedure rooms in the "Reconciliation Act." In that case, Congress set the baseline date as the date of receipt of the Medicare agreement. Clearly, this is strong evidence of Congress' intent to allow projects time to complete construction and Medicare review.

If CMS does not reconcile these dates, it creates debilitating marketplace confusion and uncertainty, making it impossible to advise physicians and other investors on how to proceed, especially because penalties for a mistake are significant. In the proposed rule, however, instead of reconciling these dates and providing clarity on the matter, CMS proposes that the physician ownership must be in place on March 23, 2010. This effectively nullifies the December 31 date because as of March 23 there is no "hospital" to be owned. There is simply a construction project, not yet licensed as a hospital. Also, the physician corporation might not have purchased the project that will become a hospital by that date, even though the original intent was for physicians to own the hospital. Other common "market place" factors also may prevent the baseline of physician owners to be in place as of March 23. For example, a physician-owned project may not fully settle the exact mix of physician investors until late in the development process. This is a very common occurrence and reflects the need for projects to be flexible as they develop, which is why Congress provided the December 31 date, i.e., to allow projects under development to be completed in accordance with market place standards, including flexibility which promotes the success of a project. This, in turn, affects the medical services that are available to patients.

CMS' proposal would virtually halt all projects, making it impossible for these projects to obtain a Medicare provider agreement by the December 31 deadline, which undermines the statutory purpose of allowing "under development" projects until December 31 to complete the project. This outcome can be avoided. **CMS should reconcile the legislative drafting error by allowing "under development" projects until December 31, 2010 to obtain physician ownership and Medicare certification. This would meet the ultimate goal of the statutory language, while avoiding penalizing hospitals under development or undergoing expansion/renovation that Congress clearly wanted to protect.**

DEFINITION OF PROCEDURE ROOMS

The AMA agrees with CMS' proposed definition of "procedure rooms" as including only those rooms where endoscopy, catheterizations, angiographies, and angiograms are performed. The statute makes specific references to these services, underscoring Congress' intent to ensure that this definition specifically mirrors that statutory language.

PREVENTING CONFLICTS OF INTEREST

The AMA believes that the procedures set forth in the proposed rule for assuring that patients are informed about the ownership interests of referring and treating physicians are adequate and not overly burdensome. The requirements placed on hospitals to disclose that they have physician investors also seem reasonable. While there may be other methods to convey the same information, the proposed rule is practical and consistent with the general office practices of physicians and hospitals.

TREATING PHYSICIAN

To incorporate certain ACA requirements, CMS proposes that a hospital must require each referring physician owner or investor to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment in the hospital (and, if applicable, the treating physicians' ownership or investment interest in the hospital) to all patients the physician refers to the hospital at the time the referral is made. CMS comments in the proposed rule that it does not plan to define "treating physicians" and recognizes that a patient may have multiple conditions for which there are a variety of physician specialists who are responsible for different aspects of a patient's care. CMS further discusses that it will consider treating physicians to be those physicians who are responsible for any aspect of a patient's care or treatment.

The AMA believes that while a referring physician generally may know the other physicians who may be involved in treatment of the patient, this cannot always be predicted. Another physician owner may need to be called in and there would have been no early opportunity to inform the patient. The referring physician may then be in technical violation of the rules. **The AMA recommends that CMS take an alternative approach by which the referring physician would provide the patient with a list of all physician owners who are still actively practicing at the hospital.** This would obviate the need to specify the treating physician in advance when, in fact, there may be no way of knowing who that will be until the patient is in the hospital.

HOSPITAL DISCLOSURE OF PHYSICIAN OWNERSHIP

The AMA urges CMS to simply require the hospital to note on one location in its website that it has physician owners who actively practice at the facility. Since Web sites are not consistent in their design or content across all hospitals, CMS should be general, not

specific. For example, CMS could require these hospitals to disclose physician ownership in one location commonly visited by potential patients. This could be the homepage, the "About Us" section or a section listing the physicians affiliated with the hospital. The notice should be clearly visible to the typical reader.

"Public advertising" should constitute any paid media the hospital uses to attract potential patients. This would include print, radio, TV, Web sites, or social media. Payment for the ad should be the determining factor. If the hospital uses unpaid media for advertising to patients, the media should be treated as comparable to a Web site and the notice handled in an equivalent manner. A hospital should not have to be required to disclose in a newspaper story about the hospital or in an interview of one of the staff.

CHANGE IN PHYSICIAN OWNERSHIP

CMS discusses in the proposed rule that "if a hospital had physician ownership or investment as of March 23, 2010, it may reduce the number of physician owners or investors, provided that the percentage of the total value of physician ownership or investment interests, in the aggregate, remains the same." **We urge CMS to clarify that the hospital can reduce or increase the number of physician owners as long as the percentage of the total value of physician ownership remains unchanged.** Nothing in the statute precludes the addition of new physician owners as long as the percent of ownership remains constant.

CONVERSION FROM AMBULATORY SERVICE CENTER (ASC)

CMS does not offer in the proposed rule any guidance as to what constitutes a "conversion" from an ASC. We urge CMS to provide further guidance on this matter, so as to avoid uncertainty and confusion.

NECESSITY OF CHANGES TO PROVIDER AGREEMENT REGULATIONS

The AMA believes that any changes to the current provider agreement regulations are unnecessary. The amendments and additions made to the whole hospital and rural provider exceptions are sufficient to provide guidance. Additional rulemaking would only be redundant and add layer upon layer of bureaucracy.

IMPACT ON BENEFICIARIES

CMS discusses in the proposed rule its view that the provision governing physician ownership of hospitals will positively impact Medicare beneficiaries and help minimize anticompetitive behavior affecting patient decisions about where to receive health care services, while possibly enhancing quality of care.

We disagree with CMS' assessment. Limiting the viability of physician-owned hospitals will only reduce access to high quality health care for patients and have a destructive effect on the

economy in communities these hospitals serve. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. Several studies have shown high levels of quality care and patient satisfaction in physician-owned hospitals. In addition, government studies have found fewer complications, like infections and hip fractures, in physician-owned hospitals. Studies have also shown that these hospitals provide more net community benefits through uncompensated care and taxes than not-for-profit competitors as a share of total revenues. Further, the Center for Studying Health System Change released a study that found physician-owned hospitals do not adversely affect general hospitals' ability to care for patients. These hospitals provide: tens of thousands of jobs nationally; a local economic engine through property taxes and higher-wage jobs; and patient access to the best quality health care available.

Accordingly, the AMA urges CMS to remove from the final rule its discussion concerning the "anticompetitive" nature of physician-owned hospitals. Multiple studies and the facts do not bear out this conclusion.

ENFORCEMENT

The AMA urges CMS to conduct open door forum calls and other outreach efforts to help educate hospitals and their physician owners and investors to understand the changes they will need to make, answer their questions, and receive feedback on the regulations and their enforcement.

SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES

In several recent rules, CMS has proposed changes and clarifications to the supervision requirements for outpatient therapeutic services. In the current proposed rule for 2011, CMS has identified a "limited set of services with a significant monitoring component that can extend for a sizable period of time, that are not surgical, and that typically have a low risk of complication after assessment at the beginning of the service" where direct supervision would be required at initiation of the service but would drop to general supervision for the monitoring period. The list of services being considered for the exception includes observation care and infusions other than those that involve chemotherapy and other complex drugs.

The AMA is concerned about the impact of requiring direct supervision in rural settings, where the scarcity of physicians makes it extremely difficult to keep a physician at the hospital at all times. These concerns are not limited solely to critical access hospitals. Accordingly, the AMA recommends that "general supervision," rather than "direct supervision," be established as the requirement for Medicare payment for most, but not all, outpatient therapeutic services. Key stakeholders such as the national medical specialty societies and representatives of rural communities should be included in a clinical advisory process to identify the outpatient therapeutic services for which "direct supervision" would be required.

The AMA appreciates this opportunity to provide our views on these critical issues, and we stand ready to work with CMS to achieve resolution in each of the foregoing matters.

Sincerely,

Michael D. Maves, MD, MBA