

August 29, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1385-P, Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (Vol. 72, No. 133), July 12, 2007.

Dear Mr. Kuhn:

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 rule for the calendar year (CY) 2008 physician and ambulance fee schedules.

The majority of our comments address the proposed changes to regulations regarding prohibited physician self-referrals under Medicare and Medicaid. **The AHA supports CMS' efforts to modernize how federal laws manage potential physician conflicts of interest.** The physician self-referral law is one of several federal laws focused on prohibiting or limiting interactions between hospitals and physicians that might have monetary value to either party. While the intent is honorable – to avoid conflicts of interest – it is important that the net effect not impede hospitals' and physicians' ability to work together using appropriate incentives to improve quality, patient safety and community access to services. **We urge CMS to view the application of physician self-referral prohibitions not only from the perspective of controlling abusive behavior, but also from the perspective of encouraging care improvement initiatives that would benefit patients, hospitals and physicians.**



PHYSICIAN SELF-REFERRAL PROVISIONS

All health care is about teamwork. Hospital care is especially dependent on the ability of hospital leaders and physicians to work together to improve the delivery of health care to get patients the right care, at the right time, in the right setting. The need for collaboration among health care providers has never been more compelling, as collaboration, quality and efficiency are inextricably related.

Federal laws that affect hospital-physician relationships should be applied to recognize and facilitate care improvement initiatives that would benefit patients, hospitals and physicians. They should allow hospitals and physicians to come together, using incentives where appropriate, to not only reduce costs, but also improve access and the efficiency, quality and safety of hospital care. To do that, they should foster hospital-physician incentive arrangements designed to improve or maintain community access to services, or to achieve one or more of the six aims for health care delivery articulated by the Institute of Medicine (IOM) in its report, *Crossing the Quality Chasm*. The six aims are that health care be *safe, effective, patient-centered, timely, efficient and equitable*.

Specifically, the AHA believes the self-referral rules and others should foster hospital-physician incentive arrangements that are designed to:

- Achieve needed improvements in the health care delivery system, even if they do not produce an immediate cost savings.
- Sustain community access to services that are essential. With physicians less dependent on hospitals as a place to practice, new relationships, including financial relationships, should be allowed in order to maintain community access to services (such as trauma and emergency department (ED) services), support community outreach efforts, care for the uninsured and other aspects of hospital operations that require physician support.
- Promote the integration of clinical care across providers, across settings and over time. Health plans and purchasers often adopt different approaches to payment for hospitals and physicians that in turn create differing and sometimes conflicting incentives. As more purchasers move toward pay-for-performance methods, the need to align hospital and physician payment incentives becomes critical.
- Enhance institutional or practitioner productivity or achieve other efficiencies.

The AHA urges CMS to reconsider its proposed changes to meet both the goals of the self-referral laws and the equally important public policy goal of evidence-based, patient-centered and systems-oriented care delivery.

Our specific concerns and comments on this proposed rule follow three overarching themes:

1. The percentage-based compensation proposal would work against achieving clinical integration and coordination.
2. The proposals do not adequately facilitate the coordination and cooperation needed to

serve communities, especially in rural areas.

3. The proposed expansion of the exception for subsidizing obstetrical (OB) malpractice insurance is too narrow.

However, at least twice in the proposed rule CMS alludes to changes it may be making in another rule that are related to the same topics. To the extent later proposals affect AHA's views, we may provide additional concerns or comments at that time.

1.) THE PERCENTAGE-BASED COMPENSATION PROPOSAL WOULD WORK AGAINST ACHIEVING CLINICAL INTEGRATION AND COORDINATION.

The proposal to limit percentage-based compensation solely to "revenue directly resulting from personally performed physician services" is too limiting and fails to recognize the important role financial incentives play in achieving the goals that the IOM has set for all of health care. It would appear to prohibit payment arrangements based on achieving quality measures, patient satisfaction or efficiencies. It also focuses on an individual physician in a vacuum. Achieving many of the public policy goals for patient care and the delivery system change requires more than what a hospital or a physician can do alone. To be effective, the incentives must drive individuals to work together to achieve the kind of outcomes expected (e.g., achieving immunization goals across a group of children or getting beta blockers to a heart attack victim).

The AHA believes that percentage-based payments should be permitted for certain types of arrangements when: they are designed to achieve an acceptable purpose; there are mechanisms in place to protect the quality of care provided to beneficiaries and avoid inappropriate influence on physician referrals; and the incentive arrangements are transparent to patients. The types of arrangements that should be permitted include:

- sharing of cost savings from efficiencies;
- incentives to meet quality indicators – even when cost savings do not accrue to the hospital;
- incentives to clinically integrate services and coordinate care across settings;
- sharing of pay-for-performance bonuses from payers;
- service contracts to build new service capacities; and
- management contracts.

These arrangements can improve the care provided, and while they may not yield tangible savings to a *hospital*, they may yield savings to the health care system overall.

As proposed, the change in regulation is much too limiting and out of sync with the relationships that are developing and need to evolve to meet the public policy goals for health care delivery. Recognizing the challenges set out by the IOM, and responding to the use of financial incentives by the government and other payers, the financial model for integrated care delivery has come to rely on sharing revenue in appropriate ways as a mechanism to incent appropriate behavior. These efforts will be frustrated if the only factor that may be taken into account is physician-

performed services.

Unlike anti-kickback law safe harbors, which do not preclude the evolution of financial relationships, the self-referral law requires strict compliance with exceptions. CMS should be careful it does not limit appropriate innovations designed to achieve the IOM goals. An important consideration in developing the contours of this exception is to keep in mind the companion anti-kickback law, which can be the ultimate protection against abuse. **Just as CMS "stepped back" to develop rules related to information technology (IT) that recognized larger public policy goals for IT in health care, the AHA urges the same perspective regarding the use of appropriate financial incentives to achieve evidence-based, patient-centered, systems-oriented health care.**

2.) THE PROPOSALS DO NOT ADEQUATELY FACILITATE THE COORDINATION AND COOPERATION NEEDED TO SERVE COMMUNITIES, ESPECIALLY IN RURAL AREAS.

The AHA supports narrowing the in-office ancillary services exception to cover only those services "necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office." The current expansive use of the exception has led to the duplication of services and technology and, as reported by the Medicare Payment Advisory Commission, to over-utilization, higher expenses and unnecessary procedures for patients. In today's environment, overuse of the in-office ancillary exception is one of the many forces driving hospitals and physicians apart and frustrating achievement of the IOM goals.

The negative effects are particularly acute in rural communities. While narrowing the in-office exception is a good beginning, it does not adequately address the access issues created for members of rural communities. **The rules for the "rural provider" exception also should be revised.** As currently applied, it can be used without regard to whether there is unmet need in the community or there will be reduced access for the overall community to needed health care services. Anecdotally, turn-key arrangements between manufacturers and physicians and physician-only owned technology often result in the steorage of more lucrative patients away from the community hospital to physician offices or owned entities. In rural communities where the volume of needed services is not sufficient to support both hospital-based and physician practice-based duplicative services, it is always the hospital-based service that will suffer because physicians control where their patients go. The ultimate effect is to potentially jeopardize the viability of the local hospital and that community's around-the-clock access to needed health care services. It also can jeopardize access to a particular service for less lucrative patients who do not have access to physician practice-based services.

The AHA supports CMS' effort to assure that services provided "under arrangements" meet a community need, and that individual patients receive care in the setting most medically appropriate to their medical needs. Consistent with the IOM goals, only those arrangements that foster needed improvements in the delivery system, sustain community access to essential services, promote clinical integration or enhance efficiencies should be enabled. **However, the proposal for services furnished "under arrangements" may unintentionally**

eliminate hospital-physician joint ventures designed to achieve the IOM goals.

3.) THE PROPOSED EXPANSION OF THE EXCEPTION FOR SUBSIDIZING OBSTETRICAL (OB) MALPRACTICE INSURANCE IS TOO NARROW.

As suggested in the rulemaking, maintaining OB services in some communities is an increasingly difficult challenge. Multiple factors contribute, including the cost of malpractice premiums in some areas. Fewer physicians are training for the specialty, and physicians with training and experience have left the field or are considering leaving that area of practice. Permitting malpractice insurance subsidies under a broader range of circumstances may help minimize the loss of OB services in some communities.

The current preconditions for subsidizing coverage – that the physician practice is in a primary care health professional shortage area (HPSA) and that 75 percent of those served live in a primary care HPSA or be medically underserved – are too limiting. Non-HPSA areas may have a high indigent population, and an increase in primary care physicians may take an area out of the primary care HPSA designation without any increase in physicians providing OB services. The combination of the relatively low payment for OB services and the high cost of insurance premiums works against a physician agreeing to maintain 75 percent of his or her OB practice for the underserved. Another limitation of the current exception is that it only addresses shortages in connection with the medically underserved. In some communities, the shortage is much broader. In relatively affluent areas, a mismatch between increasing insurance premiums and other practice expenses with relatively low payments for OB services is leading to OB shortages for the general community. The net effect can be “OB-underserved” communities. Permitting subsidies in those communities may similarly help minimize the loss of OB services. **The AHA recommends that this exception be allowed in any area where there is a shortage of physician OB services.**

AMBULANCE – BENEFICIARY SIGNATURE

CMS also proposed revisions in the ambulance fee schedule portion of the rulemaking. While the AHA believes that CMS was attempting to minimize the burden on ambulance providers in obtaining a signature during emergency transport, the resulting proposal in actuality would increase the administrative and compliance burden. Ambulance providers face significant hardships in complying with the beneficiary signature requirements because a large portion of the beneficiaries transported are not in a condition to sign a claims authorization form. Many beneficiaries are in physical distress, unconscious or of diminished mental capacity due to age or illness – the very reason they need ambulance transportation rather than arranging their own transportation. **Thus, we urge CMS to abandon the proposed approach, and to instead eliminate the beneficiary signature requirement for ambulance services entirely.**

Guidance on what steps must be taken when a beneficiary or authorized patient representative is not available already is included in the CMS manuals. This guidance requires the ambulance

provider or supplier to document that the beneficiary was unable to sign, the reason and that no one could sign for the beneficiary. In addition, the regulations currently permit an ambulance provider to submit a claim signed by its own representative when the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf.

Under the proposed rule, a provider would only be reimbursed for a claim when the beneficiary did not sign for the service if a series of requirements are met. The proposal mirrors the existing requirements, but *adds* additional documentation requirements. Two of the requirements proposed are already always met, as the ambulance crew will always complete a trip report that lists the condition of the beneficiary, the time and date of the transport and the destination where the beneficiary was transported. A third proposed requirement that these items be maintained for four years from the date of service is also reasonable. However, we do not believe it is necessary to formally include these in the regulation as they are already required and standard practice.

The AHA would support the adoption of the amendment to 42 C.F.R. §424.36(b)(6) to include subsection (i), which requires that no authorized person was available or willing to sign the claim on the beneficiary's behalf at the time the service was provided in order for an exception to apply. This would formally adopt an exception under those circumstances that would allow ambulance providers to bill Medicare without a beneficiary's signature.

The proposed rule also would add a requirement that an employee of the receiving facility (i.e., hospital) sign a form at the *time of transport*, documenting the name of the patient and the time and date the patient was received by the facility. The AHA does not support this new requirement as it adds burden for both facilities and ambulance providers during a particularly hectic period of service delivery when all of the focus should be on the patient. Treatment and care of the beneficiary should be the overriding focus of all parties, not another form signed by already overburdened ED personnel.

The beneficiary signature is no longer necessary given that it is not required for the assignment of benefits or the authorization of records release. In addition, almost every covered ambulance transport is to or from a facility (i.e., a hospital or a skilled nursing facility). These facilities typically obtain the beneficiary's signature at the time of admission, authorizing the release of medical records for their services *or any related services*. We believe that ambulance transport to a facility, for the purpose of receiving treatment or care at that facility, constitutes a "related service."

The AHA urges CMS to withdraw the proposed beneficiary signature requirements for emergency ambulance transports and instead eliminate the beneficiary signature requirement for ambulance services entirely if the beneficiary is physically or mentally incapable of signing and no other authorized person is available or willing to sign on the beneficiary's behalf.

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If you have any questions about these comments, please feel free to contact me or Maureen Mudron, Washington counsel, at (202) 626-2301 or mmudron@aha.org regarding the physician self-referral provisions, or Danielle Lloyd, senior associate director for policy, at (202) 626-2340 or dlloyd@aha.org regarding the beneficiary signature provisions.

Sincerely,

Rick Pollack
Executive Vice President