American Hospital Association

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Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-9-CPG
Room 5246, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Supplemental Compliance Program Guidance for Hospitals, OIG-9-CPG

Dear Mr. Morris:

On behalf of our 4,700 member hospitals and health care systems and our 31,000 individual members, the American Hospital Association (AHA) welcomes the opportunity to comment on the OIG's draft supplemental compliance program guidance (CPG) for hospitals. We appreciate the OIG's desire to keep the CPG current with the latest developments in the hospital field. The AHA and its members were actively involved in the development of the original CPG. We believe that formal compliance programs are key to minimizing billing errors as hospitals strive to comply with Medicare's complex and continually changing legal and regulatory requirements.

Hospitals across the country have established compliance programs and are actively pursuing compliance initiatives, and the AHA continues to make compliance a focus of the services it provides to members. We were glad to see the OIG acknowledge the significant investment hospitals have made in compliance efforts, and their good faith commitment to ensuring and promoting integrity. In the notice soliciting comments, OIG explained that the final CPG would "assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts." Overall, the draft supplemental CPG provides a useful update for the field on both the framework for a compliance program and areas of the law that should be given particular attention in a hospital's program. It also provides a helpful compendium of existing guidance on matters discussed in the CPG. We offer several recommendations to help improve the value of the CPG for the hospital field.

Integrate the CPG documents
It would be most helpful to have one CPG for hospitals, rather than the original CPG and a supplement. Maintaining separate documents would increase the risk of confusion and impose

an unnecessary burden on hospitals. Hospitals would have to determine what is and is not new, and whether any differences in language were intended to alter or impose new compliance obligations. Integrating the original CPG and the final supplemental guidance would provide hospitals a single and updated source to turn to for OIG's views. In addition to suggesting how to structure a compliance program, the compliance document also suggests the substantive areas that should be included. This makes it particularly important that there be a comprehensive statement of OIG's views.

Inconsistency across the agencies
On several items discussed in the supplemental CPG, the OIG takes a different view than CMS. This is particularly troublesome when the authority to interpret and implement the statute is delegated to CMS. In an addendum to this letter we discuss the specific items. It is very difficult for the field when there are differences across or within the agencies on what is or is not required under the statute or regulations. OIG should reference or defer to CMS guidance on matters within the purview of CMS.

Interpretations beyond the statute or regulations
While the OIG states in the draft that the guidance does not create any new law or legal obligations, there are several comments that appear to vary from current law. The CPG is not an appropriate vehicle to add or modify existing guidance on what is required under the law. Those specific items are also listed and discussed in our addendum.

Thank you for the opportunity to provide input as you finalize the CPG. If you have questions regarding our comments please feel free to contact Maureen D. Mudron, Washington counsel, at mmudron@aha.org or 202.626.2301.

Sincerely,

Rick Pollack
Executive Vice President

ADDENDUM
DRAFT COMPLIANCE GUIDANCE FOR HOSPITALS

Inconsistency with CMS guidance

- **Evaluation and management codes:** The OIG recommends that hospitals take steps to ensure that the evaluation and management (E/M) codes used to describe medical services provided to patients follow published CMS guidelines. The OIG then references E/M documentation guidelines for physicians, which do not apply to hospitals. Currently, CMS does not have a uniform methodology for facility E/M reporting. Instead, CMS has directed that each facility develop a system for matching the provided services or combination of services furnished to the different levels of effort represented by the existing codes. CMS has indicated it intends to develop specific guidelines for hospitals and has invited recommendations. In response, the AHA and the American Health Information Management Association convened an expert panel and submitted a proposed facility E/M model to CMS.

- **Billing for observation services:** The discussion suggests that billing for observation services is only appropriate if the hospital is entitled to a separate payment. This is contrary to CMS instructions. Although separate payments are made for observation services in connection with certain diagnoses, assuming that the coverage requirements are met, billing for observation services is appropriate regardless of whether separate payment is made. Hospitals are required to report observation charges to properly capture cost data for future payment updates.

- **EMTALA:** The discussion suggests that if a hospital is on diversionary status (i.e., lacks capacity) and a patient comes to its emergency department (ED), the hospital must provide an evaluation or treatment. However, if the hospital does not have the capacity a transfer of the patient to another hospital may be in the patient's best interests. As long as such a transfer complies with the transfer requirements of EMTALA, the hospital would have met it obligation to the patient. The discussion also suggests there is a specific requirement for training on-call physicians and ED staff. Hospitals are required to have policies and procedures in place to carry out their EMTALA responsibilities. While training will be part of the hospital's implementation of EMTALA, it is not a legal requirement as implied in the discussion.

Interpretation beyond the statute or regulations

- **False Claims Act:** The discussions of the physician self-referral and anti-kickback laws assert that the violation of either can give rise to False Claims Act liability. While we understand that to be the OIG's view, we note that the case law is in some flux in this area.

- **Fair market value:** The discussion of physician compensation under the anti-kickback law includes a statement that, when using comparables to determine fair market value, the comparison entities should not be actual or potential referral sources. When paying a physician for services, however, compensation for other physicians is the comparable. That is the rationale for using benchmark data, which is recognized in Phase II of Stark II in the "safe harbor" for fair market value.
- **Physician billing:** The physician compensation discussion under anti-kickback includes a statement that there must be safeguards in place to ensure that the physicians staffing

outpatient departments use the correct site-of-service coding. This suggests that hospitals have a responsibility to police physician billings. Since members of medical staff are usually not employees and submit their own claims, hospitals would not know and could not police the site of service code on the claim forms.

- **Manual issuances and intermediary guidance:** The discussion also suggests that CMS manuals and fiscal intermediary (FI) guidance should bind hospitals when the only binding law comes from the statute and regulations. This is an important distinction for compliance purposes since, in the OIG's view, failure to follow contractor guidance could suggest a violation of the law or could even implicate the False Claims Act. For example, the draft guidance says that there may be a risk of fraud and abuse liability when a hospital submits a claim that does not follow an FI's Local Medical Review Policy (LMRP). Specifically, the draft guidance says that such claims may be viewed as being submitted for medically unnecessary services. This view fails to recognize that one of the ways a hospital can challenge LMRPs is by submitting a claim for the service addressed in the LMRP, having the claim denied, and then appealing the denial. Similarly, providers may make claims for other items or services that may not appear to conform with CMS or contractor guidance, in order to challenge a reimbursement or coverage policy. The OIG's view wrongly suggests that this would be improper.