Submitted Electronically

October 22, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS’s Preliminary Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) preliminary decision on the recommendations of the Hospital Outpatient Payment (HOP) Panel on supervision levels for select services. Based on the evidence presented at its August meeting, the HOP Panel recommended that CMS reduce the supervision level for 28 outpatient therapeutic services from direct to general supervision. In a preliminary decision, CMS accepted 15 of the Panel’s recommendations and rejected the other 13.

**HOP Panel Recommendations**
The AHA supports CMS’s decision to accept the HOP Panel’s recommendations to change the current supervision requirements for **15 Healthcare Common Procedure Coding System (HCPCS) codes from direct to general supervision**. We agree with the HOP Panel that these services can be appropriately and safely furnished under general supervision. In particular, we are pleased that CMS recognizes that Current Procedure Terminology (CPT) code 96360, *Intravenous infusion, hydration; initial*, and CPT code 96361, *Intravenous infusion, hydration; each additional hour*, which are currently designated as non-surgical extended duration therapeutic services, are appropriate for general supervision. Permitting general supervision for intravenous (IV) hydration infusions and the other services will help preserve patient access to outpatient services in critical access hospitals (CAHs) and small, rural prospective payment system (PPS) hospitals, where physicians, nurse practitioners and other non-physician practitioners (NPPs) are in short supply.
The AHA is concerned about CMS’s decision to reject the HOP Panel’s recommendation for general supervision for 13 HCPCS codes. These include services such as direct admission to observation services, several IV infusion services, several drug injections, H1N1 vaccination, strapping, application of compression systems and bladder irrigation. CMS explains that its decision is related to the fact that these services either involve assessment by a physician or a significant potential for patient complications or reactions that would require a supervising physician or appropriate NPP to be immediately available.

We respectfully disagree with the agency’s contention that stakeholders presenting to the HOP Panel provided inadequate clinical justification as to why it would be safe to furnish these services under general supervision. In fact, there is little or no research available that evaluates the clinical implications of direct versus general supervision of outpatient services, especially as it relates to specific services covered under the outpatient PPS. Evidence presented to the Panel and CMS reflects hospitals’ years of experience with furnishing these services in environments where physicians and NPPs are in scarce supply and where high-quality care is rendered by highly trained nurses and other ancillary staff. These staff members furnish services under general supervision using strict clinical protocols developed by physicians and with close communication with treating physicians and NPPs. In these rural and often frontier communities, such an approach is absolutely necessary to ensure that patients have access to a wide variety of services.

In our view, the clinical and other justifications presented by the hospital stakeholders and supported by the HOP panelists for services that CMS rejected were equally compelling as the justification for the services that CMS preliminarily approved. The difference, we believe, is attributed to the non-specific nature of several of the HCPCS codes. That is, the codes for IV infusion (CPT 96365 – 96368) and injection (CPT 96372 and CPT 96374 – 96376) services are used with a wide variety of drugs, ranging from the most benign and safe drugs to the most potentially risky and toxic pharmaceuticals. This is equally true for observation services; that is, patients are admitted to observation care with a wide range of symptoms, co-morbidities and risk factors. This wide range of drugs and conditions for which these services may be furnished to Medicare beneficiaries makes it almost impossible to formulate a justification consistent with CMS’s criteria that would apply in all cases. The billing codes do not provide enough distinction to separate those services where the clinical risk of providing the service is small and appropriate for general supervision from those where the clinical risk to the patient is sufficient to warrant the presence of more highly trained personnel.

The AHA suggests that CMS consider a different approach for assigning a level of supervision to these types of services. This approach would involve establishing a linkage between the infusion and injection administration service codes and specific drug J codes. The list of drug specific codes could be reviewed and sorted for those drugs for which clinical evidence is available to demonstrate a relatively low-risk profile and for which administration could be safely provided under general supervision. For example, IV antibiotics, such as ceftriaxone and levofloxacin, and IV anti-nausea medications, such as ondansetron (Zofran), are among the drugs that the Panel may consider for administration under general supervision. By the same token, for observation services it may be possible to create a list of
less complex diagnoses for which CMS could permit general supervision. Such a process would require time and significant clinical input to develop, and we understand that this approach would be different from that which CMS has approved for the HOP Panel through regulation. However, it would be a worthwhile endeavor to undertake for the purposes of allowing continued access to care in CAHs and small, rural PPS hospitals. We would welcome the opportunity to discuss the merits of this option with CMS staff in the near future.

HOP PANEL PROCESS
Hospitals are pleased that the HOP Panel was expanded and has started a promising process to review and recommend changes to the supervision level of certain outpatient therapeutic services. We feel that the process could be improved in a number of ways. The AHA recommends that CMS:

- Provide more precise and explicit guidance on what constitutes an appropriate presentation; the type of data or evidence that meets CMS’s criteria; and instructions on how to submit a presentation to CMS;

- More prominently post and communicate information about the HOP Panel process, especially upcoming HOP Panel meetings and the related opportunity to testify, and CMS’s preliminary decisions regarding HOP Panel recommendations and the related 30-day opportunity for public comment;

- Immediately acknowledge via an electronic response all presentations received and communicate in a timely manner the agency’s decision regarding whether the hospital will be permitted to present at the HOP Panel meeting; and

- Send the full set of materials to HOP Panel members at least seven business days before the meeting date so as to allow panelists sufficient time to adequately review the topics upon which they would be expected to discuss and vote.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President