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Association**

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Submitted Electronically

April 29, 2014

Marilyn B. Tavenner
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 nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services's (CMS) preliminary decisions on the recommendations of the Advisory Panel on Hospital Outpatient Payment (HOP Panel) on supervision levels for select services. Based on the evidence presented at its March meeting, the HOP Panel recommended that CMS reduce the supervision level to general supervision for 18 outpatient therapeutic services. The agency made preliminary decisions to accept six of the Panel's recommendations, propose a revision for one recommendation and reject recommendations for 11 services. **The AHA supports CMS's decision to accept the HOP Panel's recommendations to change the current supervision requirements for six Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes to general supervision. However we are disappointed that CMS rejected the HOP Panel's recommendations for the eight chemotherapy CPT codes and the blood transfusion CPT code.**

The AHA supports CMS decision to accept the HOP Panel's recommendation to change the level of supervision of five services from direct to general supervision:

- HCPCS G0176, *activity therapy*;
- CPT 36593, *de clot vascular device*;
- CPT 36600, *withdrawal of arterial blood*;
- CPT 94667 *manipulation chest wall*; and
- CPT 94668 *manipulation chest wall*.



We also support CMS's decision to accept the HOP Panel's recommendation to move one code – CPT 96370, *Subcutaneous infusion, each additional hour* – from the non-surgical extended duration list to general supervision.

We agree that these services can be appropriately and safely furnished under general supervision. In particular, we are pleased that CMS recognizes that CPT code 96370, which currently is designated as an extended duration service, is appropriate for general supervision. Permitting general supervision for such subcutaneous infusions and the other five services will help preserve patient access to outpatient services in critical access hospitals (CAHs) and in small and rural prospective payment system (PPS) hospitals, where physicians, nurse practitioners and other non-physician practitioners (NPPs) are in short supply.

However, the AHA disagrees with and does not support CMS's preliminary decisions to reject the HOP Panel's recommendation to move the following eight chemotherapy services from direct to general supervision:

- CPT 96401, *Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic;*
- CPT 96402, *Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic;*
- CPT 96409, *Chemotherapy administration; intravenous, push technique, single or initial substance/drug;*
- CPT 96411, *Chemotherapy administration; intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure);*
- CPT 96413, *Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug;*
- CPT 96415, *Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure);*
- CPT 96416, *Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump; and*
- CPT 96417, *Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure).*

CMS states that the supervision standard for chemotherapy is a clinical issue and while the Panel as a whole adopted a recommendation for general supervision, the majority of the Panel's physicians voted to retain these services as direct supervision. **We are disappointed that CMS went against the HOP Panel's vote and are troubled by CMS's reasoning for doing so. In no other areas for which the HOP Panel is charged to make recommendations do certain panelists' votes count more than others.** While we agree that assigning a level of supervision to a service is a decision that must take into account clinical factors, we further note that among the criteria that the Panel is required to consider is the *clinical context* in which the service is delivered. The rural HOP Panel members, as well as other non-physician Panel members, are

certainly qualified to comment on these issues. It is inappropriate to dismiss their opinion, experience and expertise.

The clinical context in which the requirement for direct supervision for chemotherapy services is most problematic is in small hospitals, including many rural hospitals such as CAHs. In such rural areas and such facilities, there are simply not enough oncologists, other physicians or NPPs available to provide direct supervision for these services during all hours in which patients require access. However, it is more than possible to provide high-quality chemotherapy services in a safe manner without diminishing access to care in rural communities, typically by enabling a medical oncologist to work closely with the hospital or CAH to ensure that cancer patients receive optimum chemotherapy on an outpatient basis, taking into consideration the patient's condition and the resources available at the local hospital staff. Specifically, the patient's medical oncologist orders the services, which are furnished in the hospital/CAH outpatient department by licensed, skilled professionals under the overall direction of a physician or a NPP. The patient's oncologist is then responsible for assessing the patient's progress and, when necessary, changing the treatment regimen. A physician does not need to be physically present in order for hospital staff to provide safe, high-quality outpatient care. This is because non-physician hospital staff are competent, licensed health care professionals who provide services that fall within their scope of practice in accordance with state law and the provision of care is governed by clinical protocols, policies and procedures that are approved by the hospital's medical staff. In CAHs, non-physician staff are trained to provide high-quality and safe care in an environment in which there is less face-to-face contact with physicians and a greater dependence on clinical protocols, policies and procedures. Should an unforeseen situation arise, medical staff physicians can be promptly summoned by phone, radio or other means.

CMS also notes in its rationale that the American Society of Clinical Oncology/Oncology Nursing Society (ASCO/ONS) Chemotherapy Administration Safety Standards are consistent with Medicare's direct supervision standard for outpatient chemotherapy. The ASCO/ONS standards state that a licensed independent practitioner, such as a physician, nurse practitioner, clinical nurse specialist or physician assistant, should be on-site and immediately available during all chemotherapy administrations in licensed infusion centers and acute care settings. While the AHA appreciates the rigorous process used to develop these standards, in conversations with the ASCO clinical staff responsible for these standards, we learned that the needs and special limitations of rural hospitals and their communities have not been explicitly considered in the updating of this standard. In fact, the ASCO/ONS standard acknowledges that "[r]egular review of these standards will be needed as the practice of medical oncology continues to evolve rapidly."¹ The AHA agrees and will take ASCO up on its offer to provide input into the next iteration of the standard in order to address the special challenges involved in providing high quality and convenient cancer care in rural communities, in order to better accommodate the needs of cancer patients in such settings.

¹ http://www.asco.org/sites/www.asco.org/files/asco_ons_safety_standards_2013_0.pdf; Jacobson JO, Polovich M, Gilmore TR, et al: Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards: Expanding the Scope to Include Inpatient Setting.

CMS also states that, while it is proposing to maintain the direct supervision standard for chemotherapy administration, it is seeking input on whether to distinguish the supervision level between initial and subsequent administration of a given chemotherapeutic or biological agent. Depending on the public comments received, CMS may re-assess these services again at the next HOP Panel meeting. The AHA is encouraged by this request. We would expect adverse reactions to chemotherapy infusions would be far more likely to occur during a first infusion of a drug and that subsequent infusions would pose less risk of transfusion reactions. **If clinical evidence is supportive of such an approach, we urge CMS to consider developing a methodology that would assign direct supervision only during the first administration of a particular chemotherapeutic or biological agent and general supervision for all subsequent administrations of the same agent.**

Along these same lines, if CMS pursues an approach to differentiate the level of supervision depending on whether it is an initial administration of a particular agent, we recommend that CPT 96415, *Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)* be approved for general supervision. This would be consistent with the approach that CMS used in approving for general supervision other codes that involve additional infusions of the same drug, such as CPT codes 96360, 96361 and 96366.

Alternatively, or possibly in addition, we urge CMS to consider a different approach for assigning a level of supervision to these types of services. Such an approach would involve establishing a linkage between the chemotherapy infusion administration service codes and specific chemotherapeutic agent 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. While such a process would require time and significant clinical input to develop, we believe it would be a worthwhile endeavor to undertake for the purposes of allowing continued access to oncology care in CAHs and small, rural PPS hospitals.

Finally, the AHA believes that CMS's preliminary decision to change the level of supervision for CPT 36430, *Transfusion, blood or blood components*, from direct to the two-tiered "extended duration" is a step in the right direction, but does not go far enough. Instead, we urge CMS to adopt the HOP Panel's original recommendation to allow blood transfusion to be furnished under general supervision.

Blood transfusions are commonly provided, life-saving services offered in most hospital outpatient settings and CAHs; ensuring convenient access to transfusions is critical to patient care. According to the Centers for Disease Control and Prevention's "Blood Safety Basics,"² adverse reactions to blood transfusions are rare. Blood and blood products used in the United States are carefully screened for disease and donated blood is tested for blood type (ABO group) and Rh type (positive or negative) in order to ensure that patients receive blood that matches

² <http://www.cdc.gov/bloodsafety/basics.html>

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their blood type. Before transfusion, the blood is also tested for certain proteins (antibodies) that may cause problems in a person receiving a blood transfusion.

However, even if adverse reactions occur, hospitals are well-equipped to respond. For example, allergic and febrile (fever-associated) reactions from blood transfusions make up over half of all adverse reactions reported – all hospitals are well-equipped to respond to these types of reactions. Hospitals are also well-equipped to prevent the rarer, but more serious, types of reactions, such as immune reactions due to mismatch of blood type between donor and recipient. Specifically, hospitals and CAHs have initiated safe transfusion practices for type and cross matching as well as identifying correct units prior to administering to the patient in all hospital settings in which transfusion occurs. Such protocols are developed, approved and monitored by the hospital pathologist overseeing laboratory operations and by the facility's medical staff. In addition, national efforts have vastly improved transfusion safety from CMS, the National Quality Forum (NQF) and TJC have promoted the development and adoption of such practices. Patient death or disability associated with incompatible blood is one of CMS's Hospital-Acquired Conditions and is listed as one of the NQF's Serious Reportable Events and TJC's National Patient Safety Goal regarding blood transfusions includes the elimination of transfusion errors related to patient mis-identification.

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/

Linda E. Fishman

Senior Vice President, Public Policy Analysis and Development