December 22, 2010

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1504-FC
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1504-FC, Medicare Program; Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; (Vol. 75, No. 226), November 24, 2010.

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) hospital outpatient prospective payment system (OPPS) final rule with comment period. Our letter discusses the AHA’s views and concerns regarding the establishment of an independent review process that will allow for an assessment of the appropriate supervision levels for individual hospital outpatient therapeutic services. We also provide comments on CMS’ final rule payment policies for critical care services and for several new Current Procedural Terminology (CPT) codes for computed tomography (CT) services.

PROCESS FOR INDEPENDENT REVIEW OF ALTERNATE SUPERVISION LEVELS

We are pleased that, in the final rule, CMS supported several of the AHA’s recommendations for supervision of outpatient therapeutic services, including the need to establish a process for the independent consideration of the most appropriate supervision level for individual therapeutic services. CMS states that it will establish this process through the calendar year (CY) 2012 OPPS rulemaking. At this point, CMS believes the process would include a committee with representation of many types of providers, including rural providers. A set timeframe would be determined for submitting requests for the assessment of individual services. The committee would consider potential changes, establish criteria for evaluating each service, and determine a means for documenting recommended supervision levels.
The AHA supports the development of such a process and looks forward to working with CMS as it considers how the committee should be convened and operated. In our previous comments to CMS, we stated that a more comprehensive and clinically based approach is needed for assigning levels of supervision to outpatient therapeutic services and requested that the agency make a fundamental change to its supervision policy.

That said, we are very concerned with several aspects of CMS’ current vision for this process that are inconsistent with the approach that the AHA had recommended and, we believe, could impede hospitals’ ability to continue to provide certain outpatient therapeutic services. First, we were disappointed that in the final rule CMS retained its overall requirement that outpatient therapeutic services remain subject to a default level of direct supervision. By contrast, under the AHA’s approach, CMS would have adopted a default standard of general supervision for outpatient therapeutic services, with an exceptions process established to identify specific procedures that should be subject to direct supervision. We contend that general supervision better reflects the way in which on-campus outpatient therapeutic services were furnished prior to 2009, particularly in rural hospitals, and there is no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision.

In addition, the AHA does not see the need to introduce the concept of personal supervision for outpatient therapeutic services. All hospital outpatient therapeutic services are provided with the highest quality of care principles in mind. The provision of care is governed by clinical protocols, policies and procedures that are based on clinical evidence and are approved by the hospital’s medical staff. Those therapeutic services that are too complex and/or risky to perform in an outpatient setting are already done on an inpatient basis. CMS formalized this notion through the creation and maintenance of its inpatient list. Further, the higher risk and more complex services that are covered by Medicare in outpatient settings, such as certain surgeries and other invasive therapeutic procedures, are already directly performed by a physician, thus obviating the need for supervision altogether. Other services furnished in the hospital outpatient department that are not directly performed by a physician or non-physician practitioner (NPP), are furnished by other licensed, skilled professionals under the supervision of a physician or an NPP. For more than 10 years, hospitals and critical access hospitals (CAHs), both rural and urban, have successfully ensured access to high-quality and safely furnished outpatient therapeutic services utilizing general and direct supervision. In short, there is simply no evidence of safety or quality of care problems to support the need for CMS to assign outpatient therapeutic services to a level of “personal supervision” by a physician.

Therefore, before CMS embarks on a committee process involving assigning a higher level of supervision for outpatient therapeutic services beyond direct supervision, we believe that the agency should provide clinical evidence and documentation that demonstrates that there is a need for personal supervision.

The Technical Committee. The AHA also is concerned about CMS’ initial proposal of using the Federal Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) as the independent technical committee that would review requests for consideration of supervision
levels other than direct for individual services and make recommendations to CMS. While the 
APC Panel does an excellent job within the scope of its current chartered set of responsibilities, 
we do not believe that the panel, as it is currently constituted, is the right group for these other 
purposes. We disagree with CMS’ assertion that the current APC Panel members are 
“representative of various geographic areas (rural and urban).” In our review of the current 
composition of the APC Panel, we find that there is not a single representative from a rural 
hospital or CAH. Further, only eight of its 15 members are clinicians. In addition, there 
currently are no panel members from the heavily rural states located in the central part of the 
country, such as Iowa, Kansas, Missouri, Nebraska, North Dakota and South Dakota. Given the 
interest and concerns that small and rural hospitals and CAHs have shared with CMS over the 
past two years regarding supervision issues, the AHA strongly recommends that the membership 
of any panel or committee identified by CMS for the purpose of assessing the appropriate 
supervision levels for individual hospital outpatient services include more practicing clinicians 
and a better balance of geographic areas and urban/rural providers. **Unless the membership of 
the APC Panel is substantially altered to reflect such a balance, we do not believe that this 
is the right entity for the job.**

Our view of an ideal committee is described in H.R. 6376, AHA-backed legislation. H.R. 6376 
would establish an Advisory Panel on Supervision of Therapeutic Hospital Outpatient Services, 
the members of which would be appointed by the Secretary of the Department of Health and 
Human Services, based on nominations submitted by hospital, rural health and medical 
organizations representing physicians or NPPs. The advisory panel would be composed of at 
least 15 physicians and NPPs who work in hospital outpatient departments and who collectively 
represent the medical specialties that furnish outpatient therapeutic services. The legislation 
requires that not less than 50 percent of the membership of the advisory panel be physicians or 
NPPs who practice in rural areas or who furnish such services in CAHs. While H.R. 6376 has 
not yet been enacted, the AHA continues to support its provisions.

We believe that CMS has discretionary authority to convene such a panel, perhaps utilizing its 
authority to establish a technical expert panel (TEP), which CMS has employed for other 
purposes in the past. However, we acknowledge that, in the current difficult budgetary 
environment, CMS may not have the personnel and financial resources available to establish a 
new advisory committee. **If this is the case, and if the APC Panel remains the only option 
available to serve as the independent technical committee, we recommend that the APC 
Panel be expanded to include additional clinicians, particularly those who practice in small 
and rural hospitals and CAHs. Further, the charter of the APC Panel would have to be 
revised to reflect its new tasks.**

**Committee Process and Potential Evaluation Criteria.** With regard to CMS’ request for comment 
on how this committee process should work and the potential criteria for evaluating whether 
services qualify for general supervision, we look forward to discussing these issues with CMS in 
greater detail over the next several months. We also suggest that CMS hold a special open door 
call or town hall meeting with stakeholders to solicit additional input regarding these issues. We
provide a few initial ideas below but additional discussion with clinical experts and national organizations would be beneficial:

- The criteria used by the committee for evaluating services should at least include the general categories of risk, complexity, patient mix and consideration of the type(s) of professionals who actually furnish the service. Consideration also should be given to whether the service is commonly furnished in small and rural hospitals and CAHs.

- CMS should allow public stakeholders to recommend specific services and groups of outpatient therapeutic services for the committee’s consideration. Those submitting services should be asked to justify why they believe the service does not require direct supervision. Decisions and recommendations of the committee should be supported, to the extent possible, by recent clinical evidence and determined by a majority of the committee.

- CMS and its contractors should not be permitted to use for enforcement purposes the information presented by providers who are requesting consideration by the committee of a reduced level of supervision for certain services.

- Similar to the process used by the National Correct Coding Initiative, there should be an on-going opportunity to submit services for consideration into the committee process and providers should be permitted to request re-evaluation of decisions made by the committee.

- To ensure full and appropriate consideration by stakeholders, the committee’s recommendations to CMS should be subject to notice and comment through a public rulemaking process.

- As a starting point, CMS should prepare for the committee’s consideration a subset of Medicare covered outpatient therapeutic services that are paid under both the OPPS and the physician fee schedule (PFS), and for which the PFS assigns a physician relative work value (RVU) of less than 1.0. Due to the low physician work involvement inherent in these services, they are more likely to be the types of services for which general supervision would be justified. In the AHA’s analysis of these services, we found that most of the services that CMS included in the CY 2011 set of 16 “nonsurgical extended duration therapeutic services” fall into this category. We continue to believe that these services should be considered for general supervision.

- The committee should be permitted to consider certain surgical services, as well as some portion of the recovery period of certain surgical services for a reduced level of supervision. We continue to believe that there are low-risk, minor surgical procedures that could be performed safely under general supervision in a hospital outpatient department. Further, we believe that for many types of surgeries, there is a point during
the recovery period, perhaps after the patient has been cleared by the anesthesiologist, when it is safe for the level of supervision to transition from direct to general.

**CODING AND PAYMENT FOR CRITICAL CARE SERVICES**

In CY 2010 and in prior years, CMS interpreted the critical care CPT codes 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes) and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service)) to include a wide range of ancillary services such as electrocardiograms, chest X-rays and pulse oximetry.

For CY 2011, the American Medical Association’s CPT Editorial Panel is revising its guidance for the critical care codes to state specifically that, for hospital reporting purposes, critical care codes do not include the specified ancillary services. Beginning in CY 2011, hospitals that report in accordance with the CPT guidelines will begin reporting all of the ancillary services and their associated charges separately when they are provided in conjunction with critical care. However, because the CY 2011 payment rate for critical care services is based on hospital claims data from CY 2009, during which time hospitals would have reported charges for any ancillary services provided as part of the critical care services, CMS believes it is inappropriate to pay separately in CY 2011 for the ancillary services that hospitals may now report in addition to critical care services. Therefore, for CY 2011, CMS will continue to recognize the existing CPT codes for critical care services and is establishing a payment rate based on their historical data, into which the cost of the ancillary services is intrinsically packaged, and will implement claims processing edits that will conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

However, it is important to note that not all ancillary services reported on the same date of service as a critical care code are necessarily a part of a critical care service. That is, there are circumstances in which ancillary services reported on the same date of service should be considered to have been provided outside of the critical care period. For example, a patient may be seen in the emergency department and ancillary services provided, but the patient does not qualify for critical care services until later in the stay. Conversely, a patient may arrive in the emergency department requiring critical care, be stabilized, have additional ancillary services performed during an observation period, and then the patient is transferred to another facility. In these types of circumstances it would be inappropriate for CMS to package payment for the ancillary services into the critical care service payment. Rather, the ancillary services should be paid separately. **Therefore, the AHA recommends that CMS establish a modifier that will allow hospitals to identify circumstances in which ancillary services are provided to critical care patients on the same date of service as critical care services, but outside of the critical care period.** A modifier will ensure that those services are not inappropriately packaged into the critical care services payment.
Additionally, going forward, we recommend that, in order to calculate a payment rate for critical care services that appropriately accounts for the costs of packaged ancillary services, CMS establish a methodology that includes a review of multiple cost report revenue centers. For example, the critical care service provided in the emergency department would be reflected in the emergency department cost report line. However, costs for ancillary services (e.g., chest X-ray, EKG, ventilator management) would be reflected in the revenue centers for the respective departments providing the service, such as radiology, cardiology and respiratory therapy. In doing so, the AHA recommends that CMS consult with the hospital field to help ensure that such a methodology appropriately captures the full set of services that are provided for critical care services.

**Payments for New CPT Codes for Abdominal and Pelvic CT Scans**

Among the new CPT codes for CY 2011 that are available for public comment are the following combination codes:

- CPT 74176 (CT, abdomen and pelvis; without contrast material);
- CPT 74177 (CT, abdomen and pelvis; with contrast material(s)); and
- CPT 74178 (CT, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions).

Each of these new codes describes *two individual services* that are frequently performed together; that is, a patient encounter in which a CT scan of the abdomen and a CT scan of the pelvis are performed. Abdominal and pelvic CT scans are the most commonly performed CT scans, representing between 40 and 50 percent of CTs. They are performed together roughly 75 percent of the time, according to the American College of Radiology.

For 2011, CMS inexplicably assigns these new combination service codes to ambulatory payment classification (APC) groups that describe *single* services. The AHA believes that this may have been an error. **However, unless it is corrected, this decision will result in a significant underpayment for hospital CT services.** That is, CMS assigns: CPT 74176 to APC 332 (CT without contrast) paid at $193.85; CPT 74177 to APC 283 (CT with contrast) paid at $299.81 and CPT 74178 to APC 333 (CT without contrast followed by contrast) paid at $334.24. These are the same APCs into which the CPT codes for a patient encounter involving only a single CT scan of either the pelvis or the abdomen are placed in 2011. Thus, these combined services are being paid at the rate of a single service for 2011.

By contrast, under the current CY 2010 payment policy (but using 2011 rates), if a patient receives an abdominal and pelvic CT scans in a single hospital outpatient department encounter, the hospital bills two separate CPT codes that will be paid under a composite APC, either composite APC 8005 (CT and CTA without contrast) paid at $420.85 or APC 8006 (CT and CTA with contrast) paid at $628.61.
Thus, CMS’ decision to place the new CPT codes under the existing APCs for single CT services will result in hospitals receiving approximately half the payment amount that they would otherwise have received under current CY 2010 Medicare policy, causing significant and unwarranted cuts to hospitals for these commonly performed CT services.

The AHA recommends that in CY 2011, CMS establish two new APCs into which CPT codes 74176, 74177 and 74178 would be placed, depending on whether or not contrast is used in the performance of the service. We further recommend that the payment amount for each of the APCs be set at the same amount as CMS will pay for composite APCs 8005 and 8006. Alternatively, CMS could change the claims payment system logic for assigning CPT codes to composite APCs to ensure that if one of these new combination CPT codes is billed by a hospital outpatient department, the payment would be assigned to either composite APC 8005 or 8006, depending on whether contrast was used.

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