CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

January 3, 2010

Donald M. Berwick, MD, MPP
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 400 member hospitals and health systems, the California Hospital Association (CHA) 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 CHA'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.

Independent Review of Alternate Supervision Levels
CHA is pleased that, in the final rule, CMS supports 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 and we look forward to participating in that process. At this point, CMS states that the process will include a committee with representation of many types of providers, including rural providers. A set timeframe will be determined for submitting requests for the assessment of individual services. In addition, the committee will consider criteria for evaluating each service, and determine a means for documenting recommended supervision levels.

CHA supports the development of such a process and looks forward to working with CMS as it considers various components in establishing and operationalizing the committee. Several comments have called for a more comprehensive and clinically based approach for assigning levels of supervision to outpatient therapeutic services, and we support this approach.

That said, CHA is concerned with several aspects of CMS' current vision for this process. 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. 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. CMS has not demonstrated evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision to warrant such requirements.

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. Therapeutic services that are too complex and/or risky to perform in an outpatient setting are already performed on an inpatient basis. CMS formalized this policy 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, CHA believes that the agency should provide clinical evidence and documentation that demonstrates there is a need for personal supervision.

Technical Committee

CHA 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. Currently, the panel lacks representation from a rural or CAH, and only eight of its 15 members are clinicians. Given the interest and concerns that small and rural hospitals and CAHs have shared with CMS over the past two years regarding supervision issues, CHA 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 includes a majority of practicing clinicians from both urban and rural areas, including those practicing in medically underserved and professional shortage areas. Further, representation from small and rural hospitals and CAHs is of critical importance. **To not disrupt the important work of the current APC Panel, CHA strongly recommends the creation of a separate entity established with the explicit purpose of making these recommendations.**

Our view of an ideal committee is described in H.R. 6376 introduced earlier this year and supported by the American Hospital Association (AHA), as well as CHA. H.R. 6376 would establish an Advisory Panel on Supervision of Therapeutic Hospital Outpatient Services comprised of members 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 comprised 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 would require 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.

CHA believes that CMS has discretionary authority to convene such a panel, perhaps utilizing its authority to establish a technical expert panel, 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. Our initial thoughts are provided below:

- **Establish Clear Criteria:** The criteria used by the committee for evaluating services should at a minimum 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.

- **Solicit Stakeholder Input:** CMS should allow all 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. In addition, 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.

- **Establish Transparent Process:** Decisions and recommendations of the committee should be supported, to the extent possible, by recent clinical evidence and data analysis, and determined by a majority of the committee.

- **Avoid Unintended Consequences:** 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.

- **Evaluate Decisions:** Similar to the process used by the National Correct Coding Initiative, there should be an ongoing 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.

Other Considerations:

- 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 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. A recent AHA analysis of these services found that most of the services CMS included in the CY 2011 set of 16 "nonsurgical extended duration therapeutic services" fall into this category. CHA continues to believe 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. CHA believes 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.

CHA appreciates the opportunity to comment, and we look forward to working with CMS to further clarify this process. If you have any questions, please do not hesitate to contact me at akeefe@calhosptial.org or (202) 488-4688.

Sincerely,

Alyssa Keefe
Vice President, Federal Regulatory Affairs