Submitted Electronically

August 30, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

RE: CMS-1590-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Proposed Rule (Vol. 77, No. 146), July 30, 2012

Dear Ms. Tavenner:

The Florida Hospital Association (FHA), on behalf of its more than 180 hospital and health system members, as well as nearly 1,200 individual members, appreciates the opportunity to offer comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the physician fee schedule for calendar year 2013. The FHA is concerned about certain provisions of this proposed rule, including the adoption of outpatient G-codes and modifiers for therapy services, telehealth, and the revised discussion of the previously settled issue of physician signatures on laboratory requisitions.

Outpatient Therapy

As required by law, CMS proposes to collect claims-based data on patient condition and function, services delivered and outcomes achieved over an episode of physical therapy, occupational therapy, and speech language pathology services to develop an improved payment system for Medicare therapy services. While the FHA supports CMS' intent to develop a long-term replacement for the current therapy caps, this proposal is clearly too complex, too burdensome, and too costly for implementation. CMS proposes that hospitals and other therapy providers include non-payable G-codes and modifiers on claims to capture data on a beneficiary's functional limitations at the outset of the outpatient therapy episode, at specified points during treatment, and at discharge. Additionally, the therapist's projected goal for functional status would be reported on the first claim and periodically throughout the episode.

In support of the recommendations of the American Hospital Association, the FHA believes that therapists should be required to report only a patient's primary functional limitation; reporting secondary functional limitations should be optional, especially during the early years of the new requirement. Hospital outpatient therapy departments treat very complex patients with multiple

comorbidities and functional limitations. These patients often receive therapy services over an extended period of time. It would be costly, time intensive and burdensome to report numerous secondary functional limitations.

We also encourage CMS to consider eliminating its severity/complexity modifiers as it is unlikely they would yield valid, reliable and meaningful information. CMS proposes to require therapists to use a modifier to report the severity or complexity for each functional limitation (primary and secondary) using a 12-point scale. Therapists would be required to translate data from an assessment tool of their choosing to CMS's severity modifier scale. These proposed modifiers are too cumbersome and subjective. However, if CMS proceeds with this requirement, we encourage you to reduce the number of levels to a more reasonable number of five or seven.

The FHA supports requiring claims-based reporting only at the outset of a therapy episode and at discharge, and to not adopt the proposed interim reporting. If CMS proceeds with interim reporting, however, we support its proposed timeframe of at least once every 10 treatment days or at least once during each 30 calendar days, whichever time period is shorter. The 10/30 reporting timeframe is consistent with current requirements for clinician progress reports and billing requirements for hospitals.

Telehealth

The FHA supports CMS' proposal to cover alcohol and substance abuse assessment and intervention services in the list of approved Medicare telehealth services (codes GO396 and GO397) on a Category 1 basis in 2013. We also support the addition of new preventive services to those approved under Category 1 as well. These would include screening and behavioral counseling interventions to reduce alcohol misuse, screening for depression in adults, intensive behavioral therapy for cardiovascular disease, and intensive behavioral therapy for obesity.

Physician Signature on Laboratory Requisitions

The FHA is concerned that CMS has again proposed the requirement that the medical record and the laboratory requisition be signed by the physician or qualified non-physician practitioner (NPP). In a June 30, 2011 proposed rule, CMS proposed to retract a policy requiring the signature of a physician or qualified NPP on a requisition for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule. In the CY2012 PFS final rule, CMS formally stated that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test. Therefore,, we were surprised to see in the "Collection of Information Requirements" section of this proposed rule a proposal to require "both the medical record and the laboratory requisition (order)" to be signed by the physician or qualified NPP. We believe this is a simple mistake and ask the error be corrected in the final rule.

In case this is not a mistake and CMS is actually proposing this requirement again, the FHA is taking the opportunity to reiterate the points made in previous comments on the requirement. Previous justification for this change in policy was to create a less confusing process that would eliminate any uncertainty over whether a document is a requisition or an order, as signatures would be required on both. This adds to the confusion surrounding laboratory orders/requisitions, rather than reducing it. In addition, requiring physician signatures on both orders and requisitions

would add to the administrative process and could harm patients if requisitions have to be returned for signatures, delaying patient care.

According to CMS, there has been a great deal of confusion surrounding the signature requirements on an order and a requisition since the March 10, 2000 Negotiated Rulemaking, which initially addressed this issue. The Negotiated Rulemaking clearly indicated that a physician's signature was not the only permissible way to document the ordering of a test and that physician signatures would not be required on requisitions for clinical diagnostic laboratory tests. Demonstrating that the physician ordered the services can be through:

- A written document signed by the treating physician that is sent to the lab;
- A telephone call by the treating physician to the lab (in this case, both the treating physician and the lab) must document the call in their respective copies of the patient's medical record; or
- An email or other electronic communication by the treating physician to the lab.

The administrative burden that would be created as a result of this new requirement is untenable. There would be duplication of record keeping, as the physician would need to sign the requisition and the order on the chart. In most cases, the physician places an order for tests on the chart and signs the order, but it is staff that collects the laboratory specimens and, using preprinted requisition forms, sends the specimens for processing. To wait for the physician to also sign the requisition is redundant.

In addition, the proposed policy would hold hospital-based reference laboratories financially accountable for non-compliance that is outside of their control. Community physicians who order clinical diagnostic laboratory tests do not have much of an incentive to comply with signature requirements, nor do they experience direct consequences for their non-compliance. If CMS finalizes this proposal, unsigned requisitions would place the hospital laboratory in the unreasonable position of either having to delay providing the testing service in order to obtain a physician signature – an action in conflict with the laboratory standard of care – or being unable to bill for the services rendered.

Any confusion that currently exists relates to the use of the terms order and requisition interchangeably in various CMS manuals and related correspondence. As an example, current language in the Medicare Policy Manual, Chapter 15, Section 80.6.1 indicates that "no signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services." Here CMS has used the term "order" where "requisition" was clearly the intent. CMS should carefully review and resolve the inconsistencies and ambiguous language in its manuals and other communications.

Confusion about this issue could have serious adverse consequences for laboratories. CMS contractors, such as Recovery Audit Contractors and the Comprehensive Error Rate Testing Contractors, often focus on whether or not a laboratory has a valid order for services performed and billed. Often disputes with these contractors revolve around what is specifically required for a valid laboratory order. Therefore, it is vital that the requirements be clear and unambiguous. Further, they must reflect the actual practice of physicians and laboratories – otherwise the

laboratories could end up being forced to make overpayment refunds simply because of some highly technical and largely unexplained interpretation of CMS' requirements.

Again, the Florida Hospital Association appreciates the opportunity to provide these comments on behalf of our members. If you have any questions concerning our comments, please feel free to contact me at kathyr@fha.org or via phone at (407) 841-6230.

Sincerely,

Kathy Reep
Vice President/Financial Services