American Hospital Association

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August 26, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1413-P, Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule (Vol. 74, No. 132), July 13, 2009

Dear Ms. Frizzera:

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) physician fee schedule (PFS) proposed rule for calendar year (CY) 2010. Our comments below refer to the "Clinical Laboratory Fee Schedule (CLFS), Signature on Requisition" section of the proposed rule.

In the proposed rule, CMS indicates that it is restating and seeking public comment on its policies regulating physician signatures for diagnostic laboratory tests to resolve any confusion that has emerged since the Clinical Laboratory Negotiated Rulemaking Final Rule (66 *Federal Register* 58787) was issued. CMS describes two policies that it claims are long-standing. First, the proposed rule states that a physician signature is *not* required on a *requisition* for clinical laboratory diagnostic tests paid on the basis of the CFLS, if it is evident that the physician ordered the services in accordance with the existing regulatory requirements relating to documentation and recordkeeping pursuant to 42 CFR 410.32(d)(2) and (3). Second, that a written *order* for diagnostic tests, including those paid under the CLFS and those that are not paid under the CLFS must be signed by the ordering physician or non-physician practitioner (NPP).

<u>CMS' "Clarification" Creates New and Confusing Policies for Laboratories</u>

In this attempt to clarify its physician signature policy, CMS introduces new issues that will result in a more complicated policy and will cause even more confusion for hospital laboratories.

Confusion about these issues has important consequences because of the focus that Recovery Audit Contractors (RACs) and the Comprehensive Error Rate Testing (CERT) program place on whether a laboratory billed Medicare for a valid "order." To avoid disputes with Medicare contractors, it is therefore critically important that Medicare policy not only reflect the "real-world" practice of physicians and laboratories, but that it be clear.

One area in which CMS creates a new policy relates to signature requirements for laboratory services paid under the CLFS versus those paid under the PFS (such as physician pathology services). That is, CMS states that its policy of not requiring physician signatures on requisitions for laboratory services only applies to laboratory services paid under the CLFS, and not to those paid under the PFS. However, the preamble to this proposed rule contains several examples of documents in which CMS has stated that signatures are not required on orders for physician pathology services, including Transmittal 1787, Change Request 2410 (January 24, 2003) and Transmittal 94, Change Request 6100 (August 29, 2008).

It is critical that Medicare policy for laboratory requisitions be consistent, without regard to whether the services are paid via CLFS or PFS. This would be less confusing and burdensome for laboratories and physicians. Physicians are unlikely to know under which fee schedule a particular test is paid, and a single requisition could conceivably include tests paid in both ways.

For laboratories, this new policy will lead to delays in providing services as they attempt to locate physicians to obtain the necessary signatures. Further, CMS provides no clinical or policy rationale for why such a distinction is necessary. CMS should clarify that its longstanding policy has been that physician signatures are not required on any requisition for laboratory services, regardless of how the services are paid**.**

A second area in which CMS has introduced new policy is in the distinction that it makes between a *requisition*, which CMS states does not require a signature, and an *order*, for which CMS requires a signature. In fact, as CMS states in the proposed rule, these terms have been used interchangeably in its documents. For example, in a 2002 Transmittal CMS stated that "No signature is required for the *ordering* of such [clinical diagnostic laboratory] services or for physician pathology services." Thus, we do not believe that CMS previously had a policy that explicitly required laboratory *orders* to be signed by physicians.

Simplifying Laboratory Policy Will Avoid Confusion and Ensure Timely Provision of Services

Hospital laboratories receive "requests for laboratory services" and do not distinguish between whether these are technically "requisitions" or "orders," as CMS proposes to define the terms. Further, hospital laboratories cannot ensure that requests for laboratory services that come from outside the hospital are signed by physicians prior to furnishing the laboratory service. Once a laboratory receives a written request, regardless of whether it is signed by the ordering physician or not, the laboratory is obligated to perform the test immediately. Immediate testing is in the patient's best interest and ultimately is a quality of care issue, as laboratory specimens tend to degrade over time.

Requiring physician signatures on requests for laboratory services places the hospital laboratory in the unreasonable position of either having to delay providing the service to obtain a physician signature or being unable to bill for the services rendered.

Therefore, as there is no practical distinction between a requisition and an order for a laboratory service, the AHA recommends that CMS establish a single policy for requesting all clinical diagnostic laboratory tests, including those paid under the CLFS and the PFS. Doing so will eliminate confusion about Medicare policy, ensure timely provision of laboratory testing and minimize unnecessary disputes between hospital laboratories and Medicare contractors, such as those who operate the CERT program and the RACs. Finally, we believe that CMS should make it clear that a signature is not required on any request for laboratory services, including clinical diagnostic tests or physician pathology services, paid on the basis of the CLFS or the PFS.

If you have any questions, please contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org

Sincerely,

Rick Pollack
Executive Vice President