American Hospital Association

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Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: [CMS-1321-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; INDEPENDENT LAB BILLING (71 Federal Register 48982), August 22, 2006.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on laboratory billing for the technical component (TC) of physician pathology services provided for hospital patients.

CMS proposes to amend section 415.130 in the Medicare regulations so that an independent lab may not bill the carrier for physician pathology TC services furnished to a hospital patient after December 31, 2006. CMS states that allowing independent labs to bill for these services would result in the Medicare program paying twice for the TC service – first to the hospital treating the patient through the inpatient prospective payment system (PPS) rate, and again to the independent lab that performs the TC service. **However, the AHA believes this statement is based on flawed assumptions and urges CMS to continue to pay independent labs for services to hospital inpatients in the same manner as they do today.** Given the history of the development of the inpatient and outpatient PPS systems, and CMS' guidance with respect to pathology TC services, it clear that the **TC costs are not included** in the inpatient diagnosis-related groups (DRGs) created under the inpatient PPS.

BACKGROUND

The TC of physician pathology services includes the preparation of the slide involving tissue or cells that a pathologist will interpret. These services also include a pathologist's examination of tissue removed during surgery – such as tumors, inflammatory tissue and biopsies – to determine whether disease is present and, if so, which one(s). They are necessary in order to continue to provide many kinds of surgical services in hospitals.

Many hospitals elect to use physician pathology services provided by independent labs. Some hospitals enter into these arrangements because they lack the surgical volume necessary to support an in-house pathology practice. Others choose to send out specimens because, by taking in referrals from multiple sites, an independent lab can provide more sophisticated diagnostic services for a wider range of cases than a single hospital alone can afford for its patients.

Medicare had a long-standing history of paying labs directly for both the preparation and interpretation of the patient specimen under the physician fee schedule prior to 1999. That year CMS proposed eliminating separate billing and payment for these TC services. This would have created significant hardship for both labs and the hospitals they served. At the request of stakeholders, CMS delayed implementing this policy for one year to allow sufficient time for hospitals and independent labs to negotiate arrangements. Subsequent congressional action over the last six years has allowed for the continuation of separate billing for the TC services for a large number of hospitals that had arrangements with independent labs in place prior to CMS' 1999 proposal. Under the *Medicare Modernization Act of 2003* (MMA), Congress extended the "grandfathering" of these hospital arrangements through 2006.

IMPACT OF PROPOSED POLICY ON HOSPITALS

Allowing this provision to expire will harm all hospitals included in the grandfather provision, and would be especially burdensome for small and rural hospitals. Hospitals and independent labs will have to put into place costly and administratively complex new billing systems and procedures, stretching already scarce resources and potentially forcing them to reduce the variety of services they provide.

Under current direct billing arrangements, labs submit a single global bill to Medicare for both the TCs and the physician's professional component services. Without direct billing, the labs will be required to issue two bills – one to Medicare for the professional component and another to the hospitals for the TCs, thus doubling the lab's billing costs. Hospitals will in turn be required to set up systems to receive and account for these bills, and to pay the labs once payment has been received from the hospitals' fiscal intermediaries. Although hospitals established similar accounting systems years ago for other services that were bundled into the DRGs, they have never done so for physician pathology TC services. These new and unnecessary billing systems and administrative overhead requirements will be costly and burdensome.

This burden will be particularly acute for smaller hospitals, which often serve rural areas and rely heavily on independent labs for surgical pathology services. The primary alternative to outsourcing these services – creating internal capacity to perform anatomic pathology TC services – is out of reach for most small and rural hospitals.

TC COSTS NEVER INCLUDED IN INPATIENT PPS

The AHA strongly believes that the decision to end the current billing system is based upon flawed assumptions and assertions. CMS' policy overlooks important Medicare payment history that supports continuing the current grandfather provision.

According to CMS, the primary reason for changing the direct payment policy to independent labs is that Medicare is paying twice for the same service – once to the hospital as part of the DRG payment and once to the laboratory through the Medicare physician fee schedule. However, when PPS rates were developed in 1983, **Section 2802 of the *Provider Reimbursement Manual* instructed hospitals using independent labs not to include the costs of pathology services in their base period costs**. **This applied to all hospitals – urban, suburban and rural**. When the *Medicare Intermediary Manual* was updated in 1986, section 3618 included the same exception. In 1992 when the Medicare physician fee schedule was implemented, CMS reiterated that independent labs should bill Medicare directly for both the professional and technical component of physician pathology services furnished to hospital inpatients and outpatients. Again, this applied to urban, suburban and rural areas.

In 1999, the agency proposed changes that would prevent independent labs from billing Medicare directly for TC services provided to hospital inpatients. CMS assumed that the DRGs now included TC payments because separate urban and rural DRG rates were eliminated in 1995, and urban hospitals were likely to have included these costs in their base period costs that formed the DRGs.

However, all urban hospitals did not provide in-house pathology services when the DRGs were developed 1983. CMS acknowledged this in the 1999 proposed rule. In fact, a 2003 report[1] by the Government Accountability Office, formerly the General Accounting Office, on this topic acknowledged that urban hospitals outsource *more* pathology services under arrangements with independent labs than rural hospitals. Because these costs were never included in the base rate, budget neutral reweighting of hospital DRGs will never compensate for these increased costs. In addition, CMS does not propose adding any new dollars to the inpatient PPS base rate to account for the additional TC costs that hospitals will be required to bear if the grandfather provision is allowed to expire.

There are hospitals of all sizes in all geographic locations that have, based upon Medicare's long-standing payment policy, made arrangements with independent labs to provide pathology services. These beneficial arrangements reflect the medical care decisions reached by hospitals and responsible pathologists about the best way to provide needed services to patients in each community. Maintaining the current grandfather provision is a reasonable policy approach. It would cover only those hospitals that relied on these arrangements before the proposed policy change, allowing CMS to continue to implement its desired payment changes prospectively. Most importantly for patients, it would provide much needed stability for those hospitals that rely on independent labs for critical pathology services.

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[1] "Modifying Payments for Certain Pathology Services Is Warranted." General Accounting Office, GAO-03-1056, September 2003.

We urge CMS to allow these arrangements between grandfathered hospitals and labs to continue so that quality diagnostic testing may proceed without disruption and increased costs.

The AHA appreciates the opportunity to comment. If you have questions please feel free to contact me or Roslyne Schulman, AHA senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President