

## **Clinical Laboratory Fee Schedule: Time for a Change?**

### *Background on Current Fee Schedule*

Clinical laboratory services have been reimbursed utilizing a fee schedule since 1984. The original fee schedule payments were based on 75 percent of the reasonable charge of clinical laboratory services that were currently being utilized by independent clinical laboratories and other providers at that time. In exchange, Congress required direct billing of those services to Medicare contractors, eliminated the requirement for beneficiaries to make a copayment when receiving services and provided for an annual Consumer Price Index (CPI) update to the fee schedule.

Shortly after the adoption of the fee schedule, Congress began to reduce reimbursement through the establishment of a National Limitation Amount (NLA) for the reimbursement of tests and through reductions in the annual CPI updates. The NLA is set at the median of all local carrier fees and was originally established at 115 percent and now stands at 74 percent. In the past fifteen years, the CPI has been frozen or reduced in all but two years. The current freeze on the CPI update won't expire until December 31, 2008. **Clinical laboratory services are currently being paid less than those same services were reimbursed five years ago (after accounting for inflation), while reimbursement under the Medicare program for other health care services continue to grow.**

When new technology is introduced, the Centers for Medicare and Medicare Services (CMS) determines whether or not that technology is clinically similar to tests reimbursed under an existing HCPCS or CPT code. If it is clinically similar, then CMS applies "cross-walking" and those services are reimbursed at rates comparable to reimbursement for existing technology even if the cost to perform those new tests is substantially higher. If CMS determines that the tests are not "clinically similar", then reimbursement is set at 100 percent of the reasonable charge for a two to three year period so that CMS contractors can gather data before establishing the payment levels for the new technology.

### *Threats to the Current Fee Schedule*

Congress has indicated that it intends to reduce spending on Medicare and Medicaid services by \$15-20 billion as part of the FY 2006 Budget Reconciliation Act. Congress also faces substantial pressure to provide an update to the physician fee schedule which would increase spending by approximately \$130 billion over ten years. If such an increase to the physician fee schedule is provided, it would have to be offset by further reductions in other services reimbursed under the Medicare program. An extension of the freeze in CPI updates would not realize savings until FY 2008 and later. In light of the limited budgetary impact of further extensions of the CPI freeze, reinstatement of a copayment or reductions in the NLA below 74 percent are real possibilities unless a concerted effort to defeat such proposals are

mounted by the clinical laboratory industry. The Clinical Laboratory Coalition is organized and intends to mount such an effort but legislative success is not guaranteed.

At the January 2005 American Clinical Laboratory Association Annual Meeting, Senator Richard Burr (R-NC), an historic friend of the clinical laboratory industry, told those assembled that it was no longer acceptable for provider groups to simply say "no" to any changes in reimbursement. He stated that Congress no longer has no patience with sectors of health care that refuse to come forward with alternatives to proposed reductions in reimbursement. He admonished the attendees to work with Congress to develop alternatives if proposed reductions in reimbursement are unacceptable.

Congress directed CMS in 1997 to develop a demonstration of competitive bidding for the clinical laboratory industry. This directive was reinforced in section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) wherein CMS was directed to implement the demonstration. CMS has selected RTI as their contractor and a Technical Experts Panel has been appointed. The demonstration is likely to focus on those services that are most frequently performed in the clinical laboratory and that represent the highest potential for savings. The conclusions drawn from that limited menu of tests will then be applied across the entire fee schedule and could represent substantial reductions in reimbursement. There is no timetable for when CMS must implement the demonstration. However, a status report is due to Congress no later than December 31, 2005.

Congress established the authority for CMS to utilize "inherent reasonableness" in 1997 to adjust reimbursement for services up or down by 15 percent. To date, CMS has not exercised that authority but has signaled an intention to do so in the near future. This authority can be applied in specific geographic areas or for specific services. CMS has signaled its intent to apply this authority to clinical laboratory services that it believes are reimbursed at substantially above the cost to perform those services or that are paid at levels that are inconsistent with other carrier areas.

The Office of Inspector General (OIG) in the Department of Health and Human Services proposed rulemaking in 2003 that would apply civil monetary penalties to providers, such as clinical laboratories, that charge the Medicare or Medicaid program "substantially in excess" of their "usual charges." This is the third attempt by the OIG to implement this authority. OIG withdrew the proposed rule after the previous attempts. This time, though, the OIG has proposed to limit reimbursement under the Medicare or Medicaid programs to 120 percent of an entity's "usual charge" with the usual charge based on what a clinical laboratory is willing to accept from other payors. The OIG has not announced when or whether it will publish a final rule.

Finally, Don Thompson, Acting Director of the Hospital and Ambulatory Policy Group of CMS recently attended at Clinical Laboratory Coalition meeting. He stated that he believed that the current fee schedule was "irrational" and, because it was "irrational", Congress was unlikely to provide any updates to the fee schedule. He challenged the clinical laboratory to work together to develop an alternative or suggested the use of "negotiated rulemaking" to develop an alternative. Negotiated rulemaking was recently used by CMS for the purpose of

developing the National Coverage Decisions for 23 clinical laboratory tests and for revising Medicare payment policies.

*Where do we go from here?*

The clinical laboratory industry must first determine if the status quo is acceptable. The status quo would be defined by declining reimbursement for clinical laboratory services, little financial incentive to introduce new technology, reduced funding available for personnel, and potential reductions in patient access to services. If it is, then discussion of changes in current reimbursement are pointless. If the status quo is unacceptable, then the industry must consider potential alternatives.

Those alternatives can be developed internally by the clinical laboratory industry and then presented to Congress for any necessary changes in current law and to CMS for purposes of implementing those revisions. Or, those alternatives can be developed in an open forum through a process, such as negotiated rulemaking, where all interested parties are represented.