Laboratory Reimbursement—Competitive Bidding and After

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Will 2008 be considered a watershed year for clinical laboratory Medicare reimbursement? Early in the year laboratories faced a dismal reimbursement future with a competitive bidding demonstration project scheduled to begin in San Diego in July, along with a soon-to-be announced second site. Fast forward to August and Congress has repealed CMS's authority to implement the demonstration, legislation has been introduced to re-engineer the laboratory fee schedule, and laboratories are poised to receive a 4.5% update beginning January 1, 2009. Let's look at how these paradigm changes occurred and the potential impact in the future.

The 2003 Medicare Modernization Act, best known for implementing a prescription drug benefit for seniors, also included a provision for a competitive bidding demonstration project for Medicare Part B clinical laboratory services to occur in two areas. Despite ongoing opposition from the entire clinical laboratory industry, the Centers for Medicare Services (CMS) has proposed competitive bidding for laboratory services multiple times in the past. The industry remains concerned that when a limited number of laboratories are selected to provide all testing in an area, primarily based on cost, significant incentives exist to bid below cost such that quality of testing may be compromised and beneficiary access is reduced. Competitive bidding came closer to fruition this time than previously—San Diego was named the first site and bids were submitted. The process was delayed shortly before winners were to be announced in April when a preliminary injunction was granted in response to a lawsuit against CMS, filed by affected San Diego laboratories.

In the meantime, the Clinical Laboratory Coalition (CLC) was working with Congress to repeal the authority of CMS to implement the demonstration. Bills were introduced in the House and Senate but had gone nowhere. The legislative vehicle emerged with the need to enact Medicare legislation by July 1 or physicians would see a greater than 10% cut in Medicare reimbursement. The CLC was successful in having competitive bidding repeal language included in both House and Senate bills. The House passed HR 6331 by a veto-proof margin of 355-59, but the Senate was unable to agree on a bill. With the July 4 recess rapidly approaching, the Senate attempted to vote on the House bill but failed by two votes to bring the bill forward for discussion. Following intense media attention and lobbying during the recess, as well as a Senate appearance by Senator Edward Kennedy who was under treatment for a brain tumor, the Senate succeeded in passing HR6331 upon return. However, the victory was short-lived when President Bush vetoed the legislation. The President primarily opposed the legislation because funding came from cuts to the Medicare Advantage program. Both the House and Senate were able to override the veto so that competitive bidding for laboratory services was repealed and the physician fee cut avoided. Laboratories will forego 0.5% of the 2009 consumer price index (CPI) increase in order to offset the $600 million savings scored for the demonstration project. While the physician community was obviously influential in passage of the legislation, the impact of clinical laboratory professionals' contact with their members of Congress was significant. Many ASCLS members were involved in efforts to educate their members regarding the negative impact of competitive bidding on beneficiaries, showing that support was crucial to the successful repeal.

Even though the industry has once again averted the competitive bidding threat, the Medicare laboratory fee schedule remains based on 1984 reimbursement, which bears little resemblance to the cost of performing testing in 2008. Congress realizes the fee schedule is "broken" and is not likely to update a fee schedule that clearly does not reflect today's cost. Yet clinical laboratory data influences 70% of patient care decisions. How long can an industry making such a valuable contribution to healthcare continue to oppose governmental attempts to impose copayment and competitive bidding without offering an alternative for a more rational reimbursement system?

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated by Paula Garrott and Judy Davis, Co-chairs of the ASCLS Government Affairs Committee; and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS, (301) 657-2768 ext. 3022, (301) 657-2909 (fax); or mail to ASCLS, 6701 Democracy Boulevard, Suite 300, Bethesda MD 20817, attn: Washington Beat.

ASCLS and the Clinical Laboratory Management Association (CLMA) have long asserted the fee schedule should be changed so that it more closely reflects the cost of performing testing and has a mechanism for regular updates, as other fee schedules do. The Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008 (HR 6761) was introduced July 31 by Representatives Bart Stupak (D-Michigan) and Michael Burgess (R-Texas). The legislation would invoke a consensus-driven negotiated rulemaking process, similar to that used to develop the laboratory national coverage guidelines and involving all stakeholders, to modernize the fee schedule. A report is to be submitted within two years. Reimbursement would be based on resources required, value of testing, and geographic cost variations. The fee schedule changes would be phased-in and the new reimbursement system will not require beneficiary copayment. The two organizations earlier supported a study of laboratory reimbursement by the Institute of Medicine, which released a 2000 report recommending a single rational national fee schedule with a mechanism for periodic updates, developed through a data-driven consensus process and adjusted as needed for geographic location.

HR 6761 is not expected to advance during the current Congress; however, if laboratory reimbursement is to reflect current costs and is to be updated on a regular basis, the issue needs to be on the table. Without a major change in the method of reimbursement, laboratories can expect to be subject to continued cuts whenever funding is needed for other programs. The laboratory industry should celebrate its recent success with competitive bidding and embrace the challenges of revamping the reimbursement system.