

# Competitive Bidding Demonstration Site Announced and Repeal Efforts Continue

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Not long ago I was presenting a session at a regional ASCLS meeting entitled “Legislative and Regulatory Issues Impacting the Practice of Clinical Laboratory Science”. One of the participants, who also happens to be a good friend and colleague, after looking quickly at the handout said, “These look like the same issues we discussed last year.” I laughed and told him he was absolutely correct! Although there are many exciting developments in the advancement of the knowledge and technology impacting clinical laboratory science, on the legislative and regulatory side, it seems trying to enhance and protect reimbursement for clinical laboratory services is always at the top of our professional “issues” list. Without appropriate reimbursement for our services, clinical laboratories cannot provide the quality our patient public deserves!

The Medicare Clinical Laboratory Competitive Bidding Project is the current threat to assuring appropriate reimbursement for laboratory services. In my last article, I provided an update on the status of the project as well as initiatives to repeal the competitive bidding mandate. Much has happened since that writing.

The Centers for Medicare and Medicaid Services (CMS) announced that the site for the first of two competitive bidding demonstration projects, scheduled to run for three years each, would be the San Diego-Carlsbad-San Marco Metropolitan Statistical Area (MSA) in California. The Bidders Conference was originally scheduled for October 31, 2007. However, due to rampant fires producing emergency situations in that area, the conference was postponed. It has now been re-scheduled for December 5, 2007. The demonstration project requires all hospital outpatient and independent clinical laboratories in the MSA billing more

than \$100,000 annually in Medicare testing to bid if they want to continue to do such testing. Exemptions include physician office laboratories and laboratories that provide services exclusively to beneficiaries entitled to Medicare by reason of end-stage renal disease or in skilled nursing facilities. (Complete information regarding the demonstration project is available at the CMS website: [www.cms.hhs.gov](http://www.cms.hhs.gov)) The bid package is based on 303 Health Care Procedure Coding System codes which represent approximately 99% of the tests reimbursed under the Part B Clinical Laboratory Fee Schedule according to CMS volume and payment data. According to CMS, multiple winners will be selected based on their ability to offer lower prices than the current fee schedule, provide quality services, and demonstrate testing capacity, as well as other quality thresholds. Laboratories not required to bid will be paid the competitively-set price for each test code. Non-winning laboratories will be allowed to serve as reference laboratories to the winning facilities but will not be able to bill Medicare directly.

ASCLS, along with other professional organizations, is planning a pre-conference session to be held the night before the Bidders Conference, to help laboratory professionals representing their laboratories in the competitive bidding process prepare by discussing the process, answering questions, and assisting in the formulation of questions that will need to be answered by the CMS representatives.

While the competitive bidding demonstration project continues, the efforts to repeal this mandate have escalated. In the last Washington Beat, we reported HR 3453, the Community Clinical Laboratory Fairness in Competition Act of 2007, had been introduced by Representative Nydia Velazquez (NY), chair of the House Small Business Committee. This bill amends Title XVIII of the Social Security Act to repeal the Medicare competitive bidding demonstration project for clinical laboratory services. Due to the grassroots efforts of clinical laboratory professionals contacting their Congressional representatives, support for this bill is gaining momentum. Additional co-sponsors include key members of the House Energy and Commerce Health Subcommittee.

*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, Co-chair 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.*

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In addition, on September 26, 2007, Senators Ken Salazar (D-CO), Pat Roberts (R-KS), and Maria Cantwell (D-WA) introduced S.2099, the Preserving Access to Laboratory Services Act of 2007. This companion bill to HR 3453 would also repeal the Medicare competitive bidding demonstration project for laboratory services.

Clinical laboratory professionals must continue to contact their members of Congress to educate them regarding the

potential impact of competitive bidding for laboratory services on our ability to provide timely and high quality laboratory testing and diagnostic information. Please urge your congressional members to support HR 3453 and S.2099. Meanwhile, ASCLS is committed to work with our members in the San Diego MSA in an attempt to assure that should the demonstration project go forward, it will be implemented in a way that will minimize the negative impacts on laboratories and the healthcare providers and patients they serve.

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