



## **Statement by the ACLA to the Special Open Door Forum**

### **Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project**

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I am Alan Mertz, President of the American Clinical Laboratory Association (ACLA). ACLA is an association representing clinical labs throughout the country including local, regional and national clinical laboratories.

Our history is filled with ideas that looked good on the surface, but fell by the wayside because their fatal flaws doomed them to failure. The Edsel and New Coke come to mind. The concept of competitive bidding for laboratory services is a similarly errant approach to providing highly complex medical services to Medicare beneficiaries and should be withdrawn. If implemented, the destabilizing impact on the laboratory industry will be devastating and will have a detrimental impact on the quality and access of laboratory services to the healthcare marketplaces and Medicare beneficiaries.

HHS has struggled for more than a decade to develop a demonstration project to test competitive bidding for laboratory services. The new Bidder's Package, all 75 pages, exemplifies the complexity and impossible obstacles associated with this idea. Even though the American Clinical Laboratory Association and the laboratory community have raised many questions and concerns about the demonstration project since its inclusion in 2003 legislation, those same questions and concerns not only remain but have been heightened with the release of the Bidder's Package. This is not meant as a criticism of the Centers for Medicare and Medicaid Services (CMS) or its contractor. It is a simple fact that the design is not fixable.

Medicare beneficiaries benefit from about one million clinical laboratory tests daily which are ordered by providers who serve not only office patients but nursing homes, home-care patients, rural satellite clinics, and other medical sites. The draft design does not reflect or incorporate an in-depth understanding of the complexities associated in keeping this level of service seamless and exemplary. Every effort to fix problems results in more entrenched obstacles.

In a significant, unexpected and late design change, CMS has reduced the demonstration project test menu from 1000 tests to 358 tests. This change is completely counter to the informed position put forth in August of 2005.

- In talking to many smaller laboratory owners, this project will force them to accept bids that could be well below their profit margins, which will cause many of them to close their doors.
- The test menu change creates two potentially incompatible systems for paying Medicare lab tests: competitive bidding schedule and Medicare clinical lab fee schedule for other tests. There also will be added complexity of labs and physician practices in distinguishing which tests are or are not included in the demonstration.
- Vulnerable patient populations – such as those in nursing homes and rural clinic patients – could find access to laboratory services seriously compromised.
- Some high complexity and esoteric reference labs, thousand of miles from the demonstration area, may not even know they are required bidders, thus freezing them out of any Medicare payment from that area if they do not submit a winning bid.
- Other reference labs may choose not to bid, or not be winners...thus, creating a situation where local labs cannot bid on all 358 tests, and whose beneficiaries lose access to important tests.
- Small local, independent and hospital outreach laboratories could find it impossible to deal with the complexity of the bid process, and therefore lose their Medicare reimbursement, potentially forcing them out of business altogether.

Numerous questions remain unanswered. For example, how will CMS take the various winning bids submitted for the 358 tests and develop a single, rational and fair Fee Schedule for each of those tests? What is in the “Terms and Conditions” that winning laboratories will be required to sign?

Most importantly, this is anything but a competitive bidding model. Competitive bidding, by definition, places emphasis on obtaining the best price. But competitive bidding in the private sector allows for negotiation, indication of volume, a streamlined submission and payment process, and consistent lab-to-lab referral arrangements – none of which exists with this monopsonistic approach.

Laboratory services account for only 1.6% of Medicare spending. Medicare payment amounts for clinical laboratory services have already been reduced by about 40 percent in real, inflation-adjusted terms between 1984 and 2004. This program will create a substantial and cumbersome administrative burden on CMS and the affected laboratories. No bidding model for clinical laboratory services will meet the objective to provide clinical laboratory services at fees below current Medicare reimbursement rates, while simultaneously maintaining quality and access to care.

ACLA has developed a detailed document incorporating the continuing questions and concerns which we will make available to CMS and post on our web site.

Ford and Coca-Cola faced up to a bad idea and cut their losses. CMS should do the same and report to Congress that competitive bidding for laboratory services is unworkable.