Advancing Excellence

"Competitive Bidding for Clinical Lab Service: Where's it Heading and What Small Business Can Expect"

Statement to House Committee on Small Business

By

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The College of American Pathologists is pleased to have this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provisions related to a demonstration project for clinical laboratory services, under Section 302(e), Competitive Acquisition of Certain Items and Services.

The College of American Pathologists (CAP) is a national medical specialty society representing over 16,000 pathologists who practice anatomic pathology and laboratory medicine in the United States and Canada. The College's Commission on Laboratory Accreditation is responsible for the accreditation of over 6,000 laboratories worldwide. Many of our members provide medical director services for clinical laboratory testing in multiple settings including hospitals, independent labs and related health care settings.

The College has long advocated that competitive bidding, as a payment method for clinical laboratory services is fraught with adverse consequences. A 2000 Institute of Medicine (IOM) report on Medicare laboratory payment, mandated by Congress, did not recommend competitive bidding as a basis for payment of clinical laboratory services and reached the conclusion that the disadvantages of competitive bidding outweigh the advantages. It further stated that the impact of competitive bidding could disproportionately disadvantage certain essential segments of the laboratory industry.

CAP is particularly concerned with the potential of competitive bidding to negatively impact small regional health centers and small independent laboratories. The demonstration is currently set up so that "winning" bidders have exclusive rights to the entire Medicare market within a competitive bidding area (CBA) and "non-winning" bidders will not be allowed to bill for clinical laboratory services provided to Medicare beneficiaries within the CBA. This use of an "exclusive" model, runs counter to the competitive nature of U.S. markets today and can lead to predatory pricing whereby large laboratories use "low-bids" as a mechanism to reduce their competition, most notably smaller regional health centers and independent laboratories who do not have the same scale efficiencies to compete effectively.

CMS states in their "bidder's package" that they are exempting small laboratories. However, the College does not believe these provisions are adequate and are inconsistent with the definition of small business standards that is set by the Small Business Administration. Specifically, CMS is defining "small" labs as those with less than $100,000 in annual Medicare payments from clinical laboratory services within a CBA. The Small Business Administration, on the other hand, defines "small" medical labs as those with $11.5 million or less in total revenues. Even if one were to assume that nearly half of a laboratory's revenue came from Medicare, that would reduce the small business definition to about $5.5 million, which is considerably above the $100,000 revenue threshold that CMS has set.

CMS has stated in public forums that a Technical Expert Panel (TEP) has evaluated and provided input into the structure of the competitive bidding demonstration. While the names of the TEP are available on the CMS website, there are no minutes or summary of the discussions or issues discussed by the TEP. Further, it is our understanding that the TEP only met twice and one of those meetings was by conference call. The College is deeply concerned that the demonstration project is moving forward without adequately addressing issues regarding beneficiary access and quality of care that have been raised by both the Institute of Medicine and the clinical laboratory community.

Most notably, there has been no analysis provided on the potential adverse impact that competitive bidding would have on access to care for Medicare beneficiaries, including nursing home residents. Small community based hospital laboratories and small regional independent laboratories are often a key component for ensuring Medicare beneficiaries access to high-quality clinical laboratory services. Physicians often refer to clinical laboratories in their communities because they are readily available for consultations about testing results and other matters related to collecting patient specimens and quick turnaround time. Yet, these small labs are the ones that are most likely to lose under the current bidding structure.

CMS has stated that they will continue to monitor access to care, once the demonstration project is underway. What happens if CMS discovers midway through the demonstration project that the one or two winning laboratories are not sufficient to provide adequate access to Medicare beneficiaries? Even worse, what if CMS discovers that one of the bidding laboratories falls out of compliance with CLIA because they under-estimated their ability to continue to provide high-quality services at such a low price. CMS has stated that they would have to exclude that laboratory from the CBA immediately. The real problem becomes that the "non-winning" laboratories would have already exited the market at this point, and thus would not be available to restore access to high-quality care. This is a situation that could potentially occur and needs to be considered and adequately addressed earlier, rather than later in the process.

In closing, the College strongly believes that given the concerns outlined above, Congress should repeal the current demonstration project until a full evaluation of these issues is undertaken in a transparent and open manner. This process must clearly document how all of these issues will be adequately addressed so as to ensure that Medicare beneficiaries continue to receive high-quality access to clinical laboratory services.