



FEB 27 2008

Mr. Alan Mertz  
President  
American Clinical Laboratory Association  
1250 H Street, NW  
Washington, DC 20005

Dear Mr. Mertz:

Thank you for your letter to Secretary Leavitt regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration that was mandated in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Centers for Medicare & Medicaid Services (CMS) has worked to design and implement a demonstration that is consistent with the law.

The demonstration is designed to establish a competitive market-driven fee schedule to test whether Medicare costs can be reduced while maintaining Medicare beneficiary access to quality clinical laboratory services. We believe that we have addressed the important issues of fairness to small businesses and access to laboratory services by beneficiaries with end stage renal disease (ESRD), residing in nursing homes, and receiving home health services. Under the demonstration, non-winning laboratories may continue to provide reference testing to beneficiaries residing in the demonstration area. We also believe that it is appropriate to continue to carry out the requirements of the law to operate the competitive bidding demonstration in order to obtain the benefits of market-based prices for the Medicare program.

Under the demonstration, small clinical laboratories with annual Medicare Part B payments under \$100,000 for test codes included in the demonstration provided to beneficiaries enrolled in traditional fee-for-service (FFS) Medicare and residing in the San Diego-Carlsbad-San Marcos metropolitan statistical area may continue to be paid for clinical laboratory services provided to those beneficiaries without participating in the bidding process. These small business laboratories will be paid the same rate under the competitively set fee schedule as other laboratories performing the same laboratory test, thus assuring that they have continuing Medicare business in the area. Moreover, these small laboratories have the option to bid, thereby providing an opportunity for small laboratories wanting to grow their business under the demonstration to eliminate the revenue cap by bidding and winning.

CMS also took into account the concerns of the laboratory industry regarding what tests would be included in the demonstration. During the first Open Door Forum on March 3, 2004, the laboratory community asked CMS to include the entire Clinical Laboratory Fee Schedule (CLFS) in the demonstration. After careful analyses of Medicare Part B claims, CMS concluded that it could effectively meet that goal by requiring bid prices for 303 of the 1,100 test codes that make up the

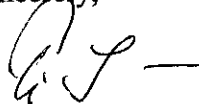
CLFS. The 303 test codes included in the demonstration constitute 99 percent of the test codes billed to Medicare and paid to independent laboratories under the Part B CLFS based on volume and revenue. The list of test codes included in the demonstration is data driven, reflects virtually all laboratory tests furnished to the Medicare population, and does not require clinical laboratories to develop bid prices for tests rarely performed for Medicare beneficiaries.

In analyzing claims data and the market structure of the potential demonstration areas, we identified a few laboratories that bill only a few codes paid under the Medicare Part B CLFS. Small business laboratories that are not required to bid and bill only a few codes paid under the Medicare Part B CLFS will continue to provide laboratory services to Medicare beneficiaries in the competitive bidding area. Using the 303 test code list, we found almost no niche laboratories that bill only a few codes and are required bidders under the demonstration. Rather, non-required bidder niche laboratories actually have two billing options. First, to continue to provide laboratory services to Medicare beneficiaries in the competitive bidding area by billing Medicare directly for the few test codes performed. Second, to continue to provide laboratory services to Medicare beneficiaries in the competitive bidding area by contracting with laboratories participating in the demonstration, thereby indirectly receiving payment from Medicare for services provided. Furthermore, non-winning laboratory firms will be able to provide and bill for services to beneficiaries in Medicare Advantage plans, to Medicare beneficiaries residing outside the demonstration area, and to non-Medicare patients. This minimizes the likelihood that competitive bidding for Medicare FFS business will put any individual laboratory firm out of business, or deny a beneficiary access to esoteric tests.

We believe these modifications to the original demonstration design address the important issues of fairness to small businesses, niche laboratories, and access to laboratory services by beneficiaries with ESRD, residing in nursing homes, or receiving home health services—the major design elements on which the laboratory community has offered constructive suggestions. Therefore, we see no basis for delaying implementation of this important demonstration and believe that it is appropriate to continue to carry out the requirements of the law.

Thank you for your interest in our demonstration programs.

Sincerely,



Timothy P. Love  
Director  
Office of Research, Development, and Information