

February 13, 2008

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the American Clinical Laboratory Association (ACLA), I am writing to urge you to suspend immediately for a period of at least 180 days any activity by the Department to implement the Medicare clinical laboratory competitive bidding demonstration project. Unless a more rational approach to designing this project is developed, Medicare beneficiaries living in the demonstration area will almost certainly be denied access to laboratory testing services, especially innovative new tests that save lives and dollars.

Unfortunately, there continue to be serious flaws and uncertainties in the competitive bidding demonstration project, even though we are just days away from the date when bids are due. Despite the industry's attempts to bring these concerns to the attention of CMS, they remain uncorrected and could have far-reaching implications for laboratories, physicians and patients.

Under the existing design of the project, any laboratory whose annual revenues from Medicare are more than nominal (\$100,000) must proffer a bid on each of 303 laboratory test codes, even if the laboratory is a specialized laboratory that performs and bills only a few of those test codes. Failing to bid or failing to win the bid means that the laboratory can no longer bill Medicare directly for the three year life of the demonstration. If the laboratory had less than \$100,000, it is still affected because if its revenues exceed this cap at any point during the life of the demonstration—a reasonable goal for any growing business—then it is once again excluded from Medicare participation. Finally, once the demonstration begins, the proposed rules of the project would prohibit any new laboratory--- including those offering esoteric tests the codes for which are included on the demonstration menu--- to serve beneficiaries in the demonstration area for the duration of the demonstration.

These aspects of the design of the demonstration have serious and potentially life threatening implications for Medicare beneficiaries located in the demonstration area. Small laboratories primarily, but not exclusively, serving niche markets like nursing homes and home health agencies will likely be unable to proffer a winning bid, because they offer a limited test menu that does not include all, or even most, of the 303 test codes included in the demonstration..

Of even more importance is the circumstance of the esoteric laboratory---often the sole offerer of certain cutting edge molecular and other test services used to identify, diagnose or design the course of treatment of cancers, HIV-AIDS, and other critical conditions. These laboratories bill for these tests using as few as ten of the codes of the demonstration list. Nonetheless, they are deemed required bidders and *must bid on all 303 test codes*. Further, and inexplicably, they must provide winning bids on those codes in order to participate, an almost impossible challenge since they have no experience with the vast majority of these tests nor relationships with laboratories that do perform them. Moreover, under the terms of the demonstration, a participating lab must perform at least 70% of the offered tests on site, rather than on a contract basis. This means that these smaller esoteric laboratories are likely to be wholly unable to participate, because they only do a few tests themselves, and if they contract with another laboratory to supply the rest, they will violate the "70% rule" when they try to bill for them. If these innovative laboratories are unable to participate in the demonstration area, Medicare beneficiaries will be denied access to critical, often life saving technologies.

As president of ACLA, over the past four years, I, our member laboratories and representatives of the entire laboratory industry have met with CMS officials, attended conferences and meetings where the demonstration was discussed and communicated our concerns both in writing and orally. Unfortunately, those concerns have not been addressed and, unless activity on the demonstration is suspended until they are resolved, Medicare beneficiaries will be hurt.

Sincerely,

A handwritten signature in cursive script that reads "Alan Mertz". The signature is written in black ink and is positioned above the printed name and title.

Alan Mertz
President