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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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August 7, 2007

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

Dear Secretary Leavitt:

I am writing with respect to implementation of the Medicare Clinical Laboratory Competitive Bidding Demonstration mandated by Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. I understand that a draft bidders' package has recently been published providing details of the design of the demonstration, the process by which CMS intends to select winning laboratories, and the tentative timeline for proceeding with the demonstration. The details of the design, the bidding process, and the calculation of the final demonstration fee schedule are profoundly important when applying competitive bidding to something as complex as providing laboratory services. Care must be taken that, even in demonstration, the concept neither compromises the availability of quality laboratory services to Medicare beneficiaries, nor adversely affects small laboratories serving vulnerable Medicare beneficiaries.

In order for the Committee on Energy and Commerce to better understand what CMS is proposing, I ask you to respond to a number of questions before CMS proceeds with its implementation.

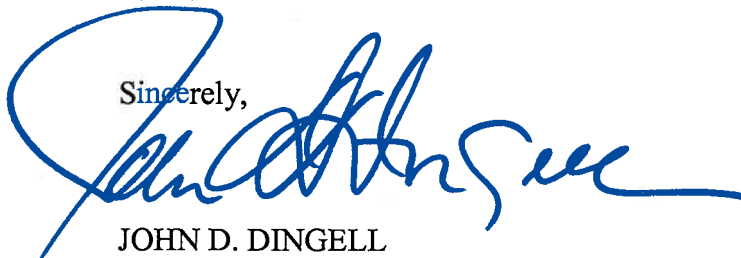
1. Please explain the analyses you have undertaken to understand the impact of this demonstration on small laboratories and the resulting impact on special patient populations in the demonstration area.
2. Please explain how CMS will ensure the timely delivery of quality laboratory services to all Medicare beneficiaries residing in the demonstration area, including those in special categories such as nursing homes, homebound, and dialysis.
3. If laboratories that provide services to vulnerable patients, such as nursing home residents and those served by home health agencies, are not selected for the demonstration, how will CMS ensure the same level of access to care to their patients? Will CMS require

selected laboratories to provide services to beneficiaries in those facilities or in locations where these laboratories had not previously provided services? If so, how will the level of service be identified to bidders in advance so that they can reflect those costs in establishing the prices they will bid?

4. How will CMS measure quality and access to laboratory services on an ongoing basis during the demonstration project? What criteria will CMS use as benchmarks to determine the success or failure of the demonstration? What measures would trigger a decision to terminate the demonstration project?
5. Please explain how CMS estimated the cost and resources required for small businesses located in the demonstration area to submit bids. Once the bidders package is final, will CMS re-estimate the actual cost of bidding, and will it consult with the laboratories themselves on the true cost of bidding?
6. What is the methodology for CMS to determine the test volumes in advance and to disclose them to bidders before the bid, given the fact that the bid design permits tests to be performed in physician office labs (POLs) and laboratories that are under the \$100,000 ceiling?
7. Please explain why CMS decided to limit the laboratory test menu for the demonstration area to 358 CPT codes, when there are approximately 1,100 tests on the Medicare clinical laboratory fee schedule.
8. Please explain why CMS decided to require "niche" laboratories that only offer a few tests to submit bid applications for the full range of tests on the demonstration test menu. If the "niche" labs are not selected as bidders, they will be precluded from providing their specialized test services to Medicare beneficiaries in the demonstration area through the life of the demonstration. How will you guarantee capacity and access to this subset of unique tests if these laboratories are not winning bidders?
9. What is CMS's plan to recalculate the demonstration prices if winning bidders drop out or are eliminated during the course of the demonstration for quality or other reasons?

I appreciate your full consideration of these critically important questions as you proceed with this demonstration. I ask that you respond by no later than Monday, August 20, 2007. If you have any questions, please contact me or have your staff contact Yvette Fontenot with the Committee on Energy and Commerce staff at (202) 226-2927.

Sincerely,



JOHN D. DINGELL
CHAIRMAN