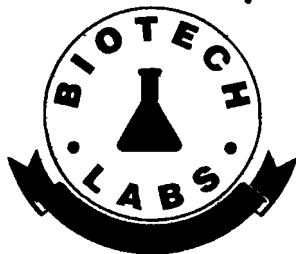


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**BIOLOGICAL TECHNOLOGY  
LABORATORY, INC.**

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no post mark

June 22, 2007

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development - C  
Attention: Bonnie L. Harkless  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Faxed to: Carolyn Lovett (202) 395-6974**

**RE: Comments on Revised CMS Advance Beneficiary Notice (ABN)**

Dear Ms. Harkless:

Our company, Biological Technology Laboratory, Inc., (BioTech Lab) is a regional laboratory serving over 300 nursing facilities as well as many physicians and out-patients. We respectfully submit the following comments relating to the Notice dated May 25, 2007 for additional public comment on the revised Advance Beneficiary Notice (ABN) (CMS-R-131). We welcome the opportunity to partner with the Centers for Medicare & Medicaid Services (CMS), other laboratories, providers, and Medicare carriers in seeking to develop and implement the most effective ABN and associated instructions for all relevant stakeholders.

Proper instructions for ABN use are essential in order to communicate the possible denial of Medicare coverage to beneficiaries in the most clear and concise fashion possible. Beneficiaries also need and deserve significant advance notice about Medicare coverage to allow them to make an informed decision about whether to

proceed with a particular course of medical care. We are pleased that CMS decided to keep a specific ABN for clinical laboratory services; however, we continue to have other specific concerns about the notice.

First, we would like to express concern with the addition of another ABN, bringing the total number of options to three. BioTech Lab often serves patients who have their blood drawn at another outpatient laboratory. It is possible another lab might use a different version of the ABN. This already has caused confusion among beneficiaries who do not understand why they are signing a new and different ABN. By adding a third, "generic" ABN, there is the possibility of even further confusion.

Second, the new ABN form does not provide sufficient space to list all of the tests that are subject to National Coverage Determinations ("NCDs") and Local Determinations ("LCDs"). The current ABN provides enough space for a laboratory to list all of the NCD or LCD tests. Having them listed allows staff to simply circle the NCD and/or LCD test when the medical necessity does not support the test being ordered. Filling in each of the tests will create an unnecessary and time-consuming step. We believe that this is an important point due to the fact that coverage determinations affect the results of an ABN.

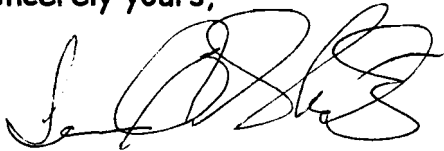
Third, we recommend that CMS maintain the heading for the NCD tests that have frequency parameters. The old ABN included the heading "Medicare does not pay for these tests as often as this (denied as too frequent)." Certain tests, such as the Hemoglobin A1C, are considered medically necessary by Medicare to be performed only once every three months. In many cases a laboratory has no way of knowing how many times the patient has received the test in the past. Since the patient may have already met the frequency parameters without our knowledge, we may not have him or her sign an ABN and will end up paying for the test. The heading for the NCD tests provides a simple explanation to the Medicare beneficiary that this test has frequency parameters that might not have been met yet but if they have, the beneficiary will be responsible for payment.

Fourth, though CMS claims that there will not be a cost associated with the new ABN, there will be a cost associated with training staff to understand and sufficiently explain the new ABN to Medicare beneficiaries. While we appreciate CMS' willingness to ensure that the concerns of the clinical laboratory community are met, we are not convinced that there will be a significant positive outcome for patients by creating a new ABN.

Finally, we believe that there should be an exception for clinical laboratories from the ABN requirement. Clinical laboratories are unique from other providers because we do not order any tests - they must be ordered by the treating physician. Therefore, the laboratory has no access to additional information at the time of service. While we appreciate CMS' recognition of this with a lab-only ABN, the fact that laboratories are not in the same category as physicians or other providers remains unaddressed.

BioTech Lab is ready to work with CMS and other stakeholders to ensure that both the clinical laboratory ABN and its associated instructions meet the needs of Medicare beneficiaries, providers, carriers, and laboratories. If you have any questions about our comments, please do not hesitate to contact me.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Tamara Schwartz', with a stylized, cursive script.

Tamara Schwartz, Executive Vice President