

CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

May 14, 2008

Anthony Culotta
Director, Medicare Enrollment and Appeals Group
Centers for Medicare and Medicaid Services
Mail Stop C2-12-16
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Culotta:

The Clinical Laboratory Coalition (CLC) – a coalition of organizations committed to quality clinical laboratory testing and representing the many sectors of the laboratory industry and the professionals who serve the public in the health care field – is writing in response to the March 5, 2008 announcement that all providers will be required to use the new Advanced Beneficiary Notice of Noncoverage (ABN) form (CMS-R-131) as of September 1, 2008. For the reasons stated below, we ask that the deadline when all providers must begin to use the revised ABN be extended to one year after the final instructions to contractors are issued by a Program Transmittal and update to the CMS Medicare Manuals.

First, to implement a new ABN effectively, physicians and their staffs will need to be educated on the form's new requirements. Laboratories will need to explain to physicians and their staffs how to get pricing information, how the new ABN has changed from the existing laboratory-specific ABN, and how to fill out the new ABN. Successfully completing the educational effort is of critical importance to laboratories since they are often the rendering provider and are forced to rely on the ordering physician to obtain a complete and valid ABN for laboratory services. This educational effort cannot really even begin until the final instructions are issued for the new ABN. Furthermore, it is unrealistic to assume that physician practices will immediately begin to use the new form or that they will understand they cannot continue to use the old form after September 1.

Second, laboratories will need to work with physicians and third-party vendors to program their computer systems to accommodate the new ABN form. These system changes are significant, extensive and time-consuming to implement. Laboratories perform hundreds of tests and, for implementation of the new form, will be required to input new information about pricing and coding for all of these tests. In addition, the programming will have to be changed to print out the information in a completely different format from that used today.

CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

Finally, laboratories will need to train their own employees to execute the new form, to explain the revised form to Medicare beneficiaries and to provide their staffs with answers to questions from beneficiaries.

In summary, we ask that laboratories and other providers have at least one year to transition to the use of the revised ABN following the issuance of final instructions to the contractors. One year will allow physician practices and laboratories to understand the new requirements and fully comply with the revised ABN.

Sincerely,

American Association of Bioanalysts
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Clinical Laboratory Management Association
College of American Pathologists
LabCorp
National Independent Laboratory Association
Quest Diagnostics Incorporated