CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

Ms. Arrah Tabe-Bedward
Director, Division of Appeals Policy
Medicare Enrollment and Appeals Group
Center for Beneficiary Choices
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Tabe-Bedward:

The members of the Clinical Laboratory Coalition (CLC), a coalition of organizations representing the many sectors of the clinical laboratory community, are writing to comment on the draft instructions for preparing the revised form CMS-R-131, Advanced Beneficiary Notice of Noncoverage (ABN.)

Before providing our comments on the revised instructions, we would like to seek clarification on whether relevant requirements of the Medicare Claims Processing Manual regarding the ABN will still apply when the revised form is implemented. Those provisions include detailed requirements on delivery of ABNs, define exceptions to prohibition on routine ABNs, describe authorized representatives, discuss use in emergency situations and otherwise provide necessary clarification and certainty to validating ABNs. Will these provisions remain in effect going forward?

We would also like to reiterate our position that the effective date of compliance with the requirements of the new ABN form and instructions should be no sooner than one year from the date the final instructions are published.

Comments on Draft Instructions

Section 50.6.2.F **Customization**: The third sentence should begin "Blanks (G) and (I) must be completed…." just to clarify that blank (H) is a field that is available to the "notifier" for annotations and other information.

Section 50.6.2.G **Modification**: What constitutes a modification or customization that goes beyond the instructions and must be approved by the appropriate CMS regional office? Any modification in Blank (D)? If a national or multi-regional

laboratory wants to modify its basic ABN must it seek approval from all CMS regional offices?

Section 50.6.3 (A) **Header**: The instructions for the existing ABN state that the "ABN's header should have the identifying information of the billing entity….A laboratory should put its own identifying information in the header where a client physician is delivering the ABN form to a beneficiary on behalf of the laboratory." We strongly urge that this instruction be retained for two reasons. First, the laboratory is the entity that will be billing the beneficiary in the event Medicare will not pay for the test, and to avoid confusion, the beneficiary should have a copy of a signed ABN identifying the laboratory with its contact information. Second, it would be unduly burdensome for the laboratory to prepare customized ABNs with provider client information for all of its clients.

Section 50.6.3 (C) **Identification Number**: The instructions for the existing ABN call for the physician or supplier to enter the patient's Medicare HICN; however, the ABN would not be invalid "solely for the lack of a Medicare HICN unless the beneficiary recipient of an ABN alleges that the ABN was signed by someone else of the same name…." We do not understand why the revised instructions would prohibit the use of the Medicare HICN on the ABN. It is used for ordering, billing and claims processing and is one of the requirements for identifying a Medicare beneficiary.

Section 50.6.3 (E) **Reason Medicare May Not Pay**: There may be more than one reason why Medicare might not pay for a particular test, i.e., it might not pay for the condition indicated or it might not pay because of frequency limitations. A laboratory should be able to apply more than one possible reason when Medicare will not pay for a test. Under existing instructions, laboratories may obtain routine ABNs where Medicare has established a statutory or regulatory frequency or condition limitation on coverage or where a local coverage decision has established a frequency or coverage limitation

Section 50.6.3 (F) **Estimated Cost**: Many in the laboratory community have expressed opposition to requiring cost estimates to validate ABNs. We find the options CMS is proposing in this section of the instructions will be very confusing to beneficiaries and are highly unlikely to permit them to make informed decisions. Asking a beneficiary to sign a "routine" ABN for a blood glucose test based on frequency limitations and providing an estimate that the beneficiary may be liable for between $1 and $199 provides no real information to the beneficiary. If laboratories choose to pre-print a menu of tests in Blank (D) and include a cost estimate for each test, what range would be considered to maintain a valid ABN? If laboratories were to print their list prices for each test, if that list price changed incrementally annually, would the ABN need to be reprinted each year to reflect those changes?

Section 50.6.3 (G) **Options**: Option 2 permits the beneficiary to choose to get the test but instruct that Medicare not be billed. What if the beneficiary subsequently changes his or her mind and asks that Medicare be billed? Must the laboratory obtain another ABN from the beneficiary?

In Option 3, the word "not" should be bold-faced. If the beneficiary is unable to sign an ABN, because of an emergency or in duress, will Medicare pay for the test?

We appreciate the opportunity to provide comments on the draft instructions.

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
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