



September 17, 2010

Mr. Michael Barlow
Vice President, Medicare Operations
Palmetto GBA
4249 Easter Way
Columbus, OH 43219

Dear Mr. Barlow:

On behalf of the members of the American Clinical Laboratory Association (ACLA), I am writing to seek a meeting with you and the Palmetto GBA J-1 contractor medical directors to discuss our concerns about Palmetto's recently announced plans to launch the CMS Laboratory and Molecular Diagnostic Services Program and to ask that you suspend the December 1, 2010, implementation of the program. ACLA is an association of national, regional, local and small esoteric laboratories many of which provide services to Medicare beneficiaries and are located within the jurisdictions of Palmetto GBA.

While our members have a number of issues regarding the substance of the program, their immediate concern is the significant software changes and resources that the program will require, changes that will force them to table ongoing efforts to adopt and test X12 Version 5010 and ICD-10-CM for HIPAA transactions by January 1, 2012 and October 1, 2013 respectively.

The laboratory community has many questions concerning this proposal that must be answered prior to implementation. For example, does Palmetto intend for this policy to apply to any test that is billed with more than one CPT code or only genetic / molecular tests? If the latter, will Palmetto publish a list of affected tests? Additionally, with regard to new tests, it is not clear to us under what authority you are requiring submission of literature to support new testing when that testing is FDA approved and can be billed using existing CPT codes. These are only two of many questions that our members have.

I appreciate your consideration of this request. JoAnne Glisson, ACLA's Senior VP, will contact your office to follow up with you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Mertz', is centered below the word 'Sincerely,'.

Alan Mertz
President

CC: Dr. Elaine Jeter