American
Clinical Laboratory
Association

January 16, 2012

Dr. Elaine Jeter, Medical Director
Palmetto GBA (J11 MAC)
P.O. Box 100190
Columbia, South Carolina 29202

RE: Palmetto GBA Draft Local Coverage Determination (LCD) for Molecular Diagnostic Tests (MDT) (DL 32394)

Dear Dr. Jeter:

The American Clinical Laboratory Association ("ACLA") hereby submits comments on Palmetto GBA's ("Palmetto's") Draft Local Coverage Determination ("LCD") for Molecular Diagnostic Tests.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services each year, many of them in the J11 Medicare Administrative Contractor's ("MAC's") jurisdiction, ACLA member companies would be impacted directly by the Draft LCD, if implemented.

At the outset, we note that ACLA's comments necessarily address both the Draft LCD and the "Local Coverage Article for Palmetto GBA Laboratory and Molecular Diagnostic Services Program," which is referenced in the Draft LCD.[2] As we understand it, this program would create a process for determining the clinical utility of new molecular diagnostic tests and payment and pricing determinations for the new tests. In the context of the nearly identical Draft LCD Palmetto issued in the J1 MAC region and the similar program surrounding it (the "MolDx program"), Palmetto representatives have made various oral representations about its decision-making processes and procedures. Therefore, ACLA's comments are not limited to the four corners of the Draft LCD for the J11 MAC region; rather, we address the written and oral representations about the programs to date, as the Draft LCDs are but one small part of the overall scheme.

Considering that Palmetto and ACLA have been engaged in extensive discussions about the MolDx program Palmetto proposes for the J1 MAC region, which has many features in common with this program, we are disappointed that Palmetto has not withdrawn this Draft LCD proactively. As this letter explains, many of the same problems arise from the programs in each

[1] Draft Local Coverage Determination for Molecular Diagnostic Tests (MDT) (DL32394). ACLA is submitting comments on the Draft Local Coverage Determination for Non-Standardized Organ or Disease-Oriented Panels (DL32396) under separate cover.

[2] Local Coverage Article for Palmetto GBA Laboratory and Molecular Diagnostic Services Program (A51401) (September 15, 2011), *available at*: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=51401&ver=4&ContrId=177&LCDId=32393&ContrVer=1&name=234*1&IsPopup=y& (last visited Jan. 16, 2012).

of the MAC regions. It would be a reasonable course of action to for Palmetto to withdraw this Draft LCD until it has had a chance to address the many issues presented by both programs.

Short of withdrawing this Draft LCD, Palmetto should consolidate all proposed policies and processes into one document and republish the resulting document as a Draft LCD. Significant differences exist between Palmetto's written documents and oral representations, and a consolidated Draft LCD would help Palmetto identify and eliminate the inconsistencies and may help clarify the issues for laboratories.

This program does not appear to be as extensive as the MolDx program that Palmetto plans for the J1 MAC region, but ACLA stands firm in its objections to replication of aspects of the J1 MAC region program in the J11 MAC region. The program in the J11 MAC region does not appear to require that laboratories obtain a McKesson Z-Code™ ("Z-Code") for each molecular diagnostic test and submit such a code with each claim in order to receive reimbursement from the Medicare program.[3] As we stated in our December 2, 2011 comment letter on the Draft LCD issued for the J1 MAC region, ACLA strenuously objects to several aspects of the Z-Code program: that it aims to implement an illegal local contractor code set, that it includes a non-negotiable and one-sided licensing agreement that laboratories would be forced to enter into with McKesson, and that it is fraught with the potential for McKesson's unauthorized use of information it gathers as it distributes Z-Codes. If Palmetto were to implement the Z-Code process in the J11 MAC region, ACLA would have the same objections to it as we set forth in our December 2, 2011 letter regarding the MolDx program.

A. Overview

ACLA agrees with the Centers for Medicare and Medicaid Services ("CMS") and Palmetto that the Medicare program, through its administrative contractors, is entitled to know what items and services it is paying for on behalf of Medicare beneficiaries and also that those items and services are reasonable and necessary. This is why ACLA has engaged in a collaborative process with CMS and with Palmetto for several years to establish a program that works for the Medicare program and for laboratories. ACLA met with Palmetto representatives in South Carolina early in 2011 to discuss how Palmetto would like to receive information about molecular diagnostic tests. As part of that discussion, ACLA members offered to provide Palmetto with their test catalogues, but Palmetto representatives said they were not yet ready to receive them. At another meeting in late August 2011, ACLA and Palmetto continued their discussion about the MolDx program and about how laboratories could help provide the information that Palmetto needs in a way that would make sense for all stakeholders. Additionally, ACLA members met with Palmetto in Lake Tahoe, California in November 2011 to discuss the MolDx program.

[3] We are confused by Palmetto's insistence that it needs Z-Codes in the J1 region "in order to know what it is paying for," and yet it does not need them in the J11 region to know the same thing. We note also that although the Z-Code requirement does not appear to be part of the program in the J11 MAC region, many laboratories submitting claims in the J11 MAC region also submit claims in the J1 MAC region and will be affected by it nonetheless.

ACLA therefore was surprised that Palmetto has seemed to disregard ACLA's willingness to provide input and the previous collaborative process it had engaged in with Palmetto. The resulting program is not one that serves both Palmetto's goals and laboratories' needs, and we have serious concerns about the substance, scope, implementation, and timing of the program. Although comments are permitted on the Draft LCD, Palmetto has been quite clear that it will not accept or respond to formal comments on many of the significant aspects of the program – many of which are not included in the text of the Draft LCD. Failing to provide laboratories with opportunity for comment is unfortunate, as it is laboratories that are the most directly impacted by the program, and it is laboratories that could provide the most useful guidance to Palmetto.

Further, ACLA believes that Palmetto vastly underestimates its workload with respect to the program. Depending on the eventual scope of the program, which we address below, Palmetto may be in a position where it must review more than 1,500 tests in a very tight timeframe. Based on what ACLA members have been told – that one person will make all coverage decisions – we are skeptical that Palmetto will be able to keep up with the overwhelming workload. Furthermore, what ACLA has been told all along is that a main purpose of the program would be to streamline the process to make it smoother and to allow a laboratory to get a coverage decision more quickly. Despite all of the work that Palmetto has put into designing the program, its complexity and the lack of clear answers to many questions risk nullifying any potential gains from the program.

We note, also, that Palmetto's program is not the "last word" in the area of billing for molecular diagnostic tests. The American Medical Association ("AMA") has developed over 100 new codes applicable to these same tests for 2012 and currently is developing more codes for 2013. CMS also is studying how to implement these new AMA codes, how to price them, and what fee schedule to use in that process. CMS has hired its own contractor to assist it in making these determinations. This means that whatever Palmetto does would be temporary, and laboratories likely would have to reprogram their systems again for 2013, once CMS decides how it plans to implement the new AMA codes. In short, the Palmetto program would require a tremendous expenditure of time and effort, even though it would be effective for a year or two at most.

Beyond ACLA's very specific and concrete concerns about the program, we feel that the totality of written and oral representations about the program has led to conflicting answers and unanswered questions. At any given time, the operative document, process or standard is unclear, and we are uncertain when those things might change, be superseded, or be contradicted. In short, it appears that Palmetto's leaders have not given adequate thought to the processes and practicalities of all aspects of the program before implementing the program. The program is being launched prematurely, if it ought to be implemented at all in its contemplated form.

ACLA believes strongly that Palmetto should cancel or delay the implementation of the program until it has given full consideration to the many questions left unanswered and until it has the capacity to implement the program efficiently and completely. ACLA is fully prepared to continue its collaborative relationship with Palmetto and CMS and to assist in the

development of policies and procedures that work for the Medicare program and the clinical laboratory industry alike.

Following are ACLA's comments on the Draft LCD in particular and on the laboratory and molecular diagnostics program in general. We begin by addressing the scope of the Draft LCD, the many questions left unanswered by the coverage decision process, issues related to payment for molecular diagnostic tests, and the procedure if a test is not covered by the Draft LCD.

B. Draft LCD

The scope of the Draft LCD is murky, many of its terms and descriptions are unclear, and written information conflicts with oral representations made by Palmetto about the tests to which the draft would apply. The Draft LCD appears to cover a wide swath of molecular diagnostic tests, and it creates more questions than it answers about the reach of the policy. It also includes misleading comments implying that laboratories have used inappropriate CPT coding for some procedures that may be covered by the Draft LCD, even though the coding is permissible.

1. Scope of the Draft LCD

One of the most troubling aspects of the Draft LCD is that it does not specify that its "non-coverage" policy would apply only to "new" molecular diagnostic tests for the time being, as conveyed to us orally by Palmetto representatives and as referenced in other written guidance from Palmetto. It is essential that the Draft LCD makes clear that only "new" tests would be subject to the Draft LCD, under Palmetto's stated "phased-in" approach.

The text of the Draft LCD is unclear as to what kinds of tests it would cover. It reads:

> This policy confirms "non-coverage" for all molecular diagnostic tests that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD) or coverage article published by Palmetto GBA. For the purposes of this policy, Palmetto GBA defines MDT as a single test (oftentimes with multiple components) that delivers one result and involves nucleic acids (DNA/RNA), proteins, enzymes, and/or other metabolite detection…In addition to this definition, this non-coverage policy applies to all tests that:
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> 1. Are Non-FDA cleared laboratory developed tests (LDTs), *or*
> 2. Are performed or marketed by a sole source, hospital, or reference laboratory, *or*
> 3. Have not received a specific AMA CPT code, *or*
> 4. Have not obtained an NCD or a coverage determination from Palmetto GBA (LCD or article).[4]

[4] Draft LCD at 2 (emphasis added).

As written, the Draft LCD would apply to a test that meets *any one* of the numbered criteria. This is in conflict with Palmetto representatives' oral representations about the scope of the Draft LCD, specifically, that it would apply only to a test that meets *all* of the numbered criteria. Additionally, its reach would be breathtaking indeed if it applied to any molecular test that merely "involves" nucleic acids, proteins, enzymes, and/or other metabolite detection. It is not clear whether Palmetto would consider the AMA's Tier 2 tests, which do not have analyte-specific codes but are specifically described, to be tests that "have not received a specific AMA CPT code." It also is unclear whether the Draft LCD would cover an LDT that *has* been cleared by the FDA, regardless of whether or not it has a CPT code.

The September 2011 article describes the scope of the program in yet a different way: "This program will affect diagnostic services that meet the following criteria: Require/use more than one CPT code to identify the service; Use the methodology-based 'stacking CPT codes' (83890-83914), microarray CPT codes (88384-88386) and cytogenetic CPT codes (88230-88291)."[5]

If this Draft LCD is operationalized, the language in it must be revised and tightened so that it reaches only those tests Palmetto truly intends for it to cover, and so that laboratories and other stakeholders are fully aware of what tests are and are not subject to it.

2. Appropriate Assignment of AMA CPT Codes for Pathology and Laboratory Services

The Draft LCD contains language implying that inappropriate CPT coding has been used to represent the procedures it covers ("[Molecular Diagnostic Tests] have been incorrectly reported for reimbursement with the following codes: method-based or stacking codes…"). The AMA has provided coding guidelines that are unique to pathology and laboratory services and allow for methodology-based codes.[6] The methodology-based codes are to be used prior to selection of a "Not Otherwise Classified" ("NOC") code as indicated in this excerpt:

> When searching for the appropriate code(s) for a laboratory test, look first for a code that describes the specific analyte (substance analyzed). If no analyte-specific code is found, search for a code that describes the methodology used in the testing procedure. "Unlisted procedure" codes ending with 99 should be used only when the analyte or method is not listed.[7]

ACLA recommends that the reference to inappropriate selection of CPT codes be removed from the Draft LCD, as it does not accurately reflect current AMA CPT guidelines and is misleading.

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[5] Although it does not apply specifically to the J11 program, the document entitled "MolDx Exempt Tests" and posted on the Palmetto J1 MAC website adds to the confusion, because some tests could simultaneously need a Technology Assessment for a coverage determination and *not* need a Technology Assessment for a coverage determination. *See* "MolDx Exempt Tests," *available at*: http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx~General~8PKRDE7744?open&navmenu=||.

[6] *See* Principles of CPT Coding, 2nd Ed., American Medical Association (2001).

[7] *Id*. at 305.

The statement also has the potential of drawing unwarranted audits by Recovery Audit Contractors ("RACs") or other program integrity contractors if they have been given reason to believe that tests may have been miscoded when in fact, they were coded in conformance with accepted AMA guidelines.

C. Coverage Decisions for Tests Covered by the Draft LCD

1. Contents of the Dossier

There is a conflict in the written information about what must be included in a dossier for a new test and in oral representations about the required information. It is critical to address the discrepancies before permitting this LCD to take effect.

Palmetto's September 2011 article is very prescriptive about what must be included in the dossier submitted with an application.[8] Specifically, to show clinical utility, the dossier must include only published articles, including two "well-designed, controlled, published articles in peer-reviewed journals" that include "sufficient numbers of subjects to establish clinical significance and includes Medicare population in study group" and that demonstrate "change in physician treatment behavior based on the assay results and/or improved patient outcomes." "Published" is defined as only "articles cited in *Pubmed*. The article continues: "Technical assessments and 'white' papers by recognized experts, published opinions and treatment guidelines (College of American Pathology, American Society of Clinical Oncologist, American Society of Hematology, etc.) are considered in the coverage evaluation but are not binding to the contractor. *Abstracts, oral presentations and testimonials will not be considered*."[9]

Other statements from Palmetto representatives differ from what appears in the September 2011 article. At various times, Palmetto representatives said they also would consider retrospective studies, white-papers written by national societies and recognized experts, virtual or theoretical models that have been vetted in the scientific literature, and abstracts. Palmetto representatives also have said they would consider "anything [laboratories] want to submit" that supports a test's clinical utility. The question of what type of information would be considered was precisely the issue that ACLA and Palmetto discussed in August 2011. We appreciate the fact that Palmetto appears to be showing more flexibility in this area, but again, it needs to issue clear and lasting written guidance as to what it intends, and such guidance should be available sufficiently in advance so that laboratories can prepare fully.

It is important that Palmetto specify exactly what information it expects to see in a dossier and what information it would consider. A laboratory that does not submit correct, complete information would lose valuable time in the decision process and would not be able to submit claims. There must be a clear, defined set of written standards and rules that apply to this process.

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[8] *See* Local Coverage Article for Palmetto GBA Laboratory and Molecular Diagnostic Services Program (A51401) (September 15, 2011).
[9] *Id.* (emphasis added).

2. Treatment of Proprietary Information

In the J1 MAC region, Palmetto will use outside experts who serve on a "Technology Assessment" ("TA") panel to review the dossiers of documents provided to Palmetto by laboratories in order to receive coverage decisions. Given the large number of molecular diagnostic tests that Palmetto expects to review and the overlap in new tests for which laboratories would need to submit dossiers for coverage decisions in both the J1 MAC region and the J11 MAC region, it is a reasonable assumption for us to make that Palmetto plans to utilize a TA panel in the J11 MAC region, as well. Palmetto has not given full consideration to, or articulated how, it or other entities involved in the review process would safeguard proprietary information received with an application for a coverage decision. Presumably, as a Medicare contractor performing functions under a Part B contract, Palmetto itself is subject to information security requirements referenced in 42 U.S.C. § 1395kk-1(e). However, Palmetto has not explained how others involved in the program, such as outside consultants or experts, will safeguard laboratories' information.

Although Palmetto has claimed that the expert reviewers on the TA panel would sign confidentiality agreements and can only assess data assigned to them by Palmetto GBA, there is no information about how Palmetto would screen reviewers for conflicts of interest or ensure that reviewers do not, in the first place, have access to information from which they could later benefit. The contours of TA program (discussed in Section C.3, below) are so amorphous that it is not clear that members of a TA panel would have to abide by the same information security requirements that Palmetto must follow.

It is essential that information submitted as part of the coverage decision process be exempt from disclosures to competitors and others under Freedom of Information Act ("FOIA") requests. Palmetto is required to abide by 45 C.F.R. § 5.65, the Department of Health and Human Services' FOIA exemption for trade secrets and confidential commercial or financial information. It is HHS's policy – and consequently, must be Palmetto's practice – not to disclose records containing information that is commercial or financial, is obtained from a person, corporation, or organization, and is privileged or confidential. A substantial portion of the information that must be submitted in the Palmetto coverage decision process would meet this test. Palmetto should state explicitly that this information will be FOIA-exempt.

Palmetto must articulate a clearly-defined process by which a laboratory could designate information as proprietary and pursuant to which all contractors, including members of a TA panel, would be obligated to protect a laboratory's proprietary information. This defined process must answer questions including:

- How would a laboratory designate information as proprietary?
- Would proprietary information be submitted separately from non-proprietary information?
- How would Palmetto and each member of the TA panel be required to safeguard proprietary information?

- What would be the procedure and ramifications if Palmetto or a subcontractor failed to safeguard proprietary information and a breach occurred?

- How would Palmetto ensure that those reviewing proprietary information do not have conflicts of interest?

3. Technical Assessment Panel

Palmetto has announced that it will establish a TA panel, one member of which will review each submission made by a laboratory for a coverage decision for a new test. Palmetto has not identified who would serve on the panel or how they would be chosen, although we understand that some panel members would come from private industry (and, therefore, potentially from competitors). There has been only a general description of the TA panel and its members' involvement in the coverage decision process, and ACLA believes it is wholly unfair to establish the panel with such opacity. ACLA also believes that the way Palmetto has established and intends to use the TA panel would not comply with the Federal Advisory Committee Act, Pub. L. 92-463 and thus may not even be lawful.[10]

Following are ACLA's questions about TA panel members – questions that must be answered for the coverage decision process to have legitimacy:

- **Who would the panel members be?** Palmetto has said that "subject matter experts from academia and industry will perform technical assessments," but this provides virtually no information about the panel's make-up.

- **How would panel members be chosen, by whom, and what would their qualifications be?** Panel members should be chosen impartially based upon their intimate knowledge of different types of molecular diagnostic tests, but there is no assurance that they would be chosen objectively or that they would be qualified to conduct technology assessments.

- **How could a panel member be removed and by whom?** ACLA is aware of no criteria for relieving a panel member from his or her duties or who could do so.

- **Who would have the ability to challenge the selection of a panelist and/or the panelist's work in the TA process?** Although Palmetto has said that panelists would not have final decision-making authority, their recommendations undoubtedly would carry a tremendous amount of weight. In light of this, it is essential that a panelist's TA advice may be challenged and reviewed.

- **How would panelists be instructed in their work?** Stakeholders should be aware of what criteria panelists would be instructed to use when conducting technology assessments.

[10] In part, the Federal Advisory Committee Act requires agencies to follow an established and transparent process for process for establishing, operating, overseeing, and terminating Federal advisory committees.

- **Would panelists be compensated for their time, travel, and other expenses, and if so, how much?** Transparency in the process demands that stakeholders know whether and on what basis panelists would earn money for participating and on what basis they would be compensated for their work and reimbursed for their travel and other expenses.

- **How would panelists' conflicts of interest be disclosed and policed?** The same "subject matter experts from academia and industry" who would conduct technology assessments very well also could be employed, directly or as independent contractors, by competitors of the laboratories requesting coverage decisions from Palmetto. Palmetto has shared no information about whether and how TA panelists would be required to disclose potential conflicts of interest and how Palmetto would police those inevitable conflicts when they arise.

- **What kind of technology assessment advice would a panelist give to Palmetto?** Palmetto has shared no information about the form or content of technology assessment advice that panelists would provide to Palmetto. Given the outsized importance of the panelists' advice, especially in the initial stages of the program, and the fact that the advice could lead to non-coverage or to delays in coverage, a transparent process is essential so that laboratories know what kind of information would be conveyed to the ultimate decision-maker.

Palmetto may not have given full consideration to the foregoing questions yet. However, this step in the process is too important to be as informal as it currently appears to be. TA panelists' participation in the program must be more transparent and standardized, and the panelists must be accountable both to the integrity of the program and to stakeholders.

4. Clinical Utility Decisions

Palmetto plans to render a subjective clinical utility decision about each molecular diagnostic test that goes through the coverage decision request process. However, the criteria Palmetto intends to use to determine a test's clinical utility are not well-defined. The September 2011 article calls for published materials to be submitted in a dossier that "demonstrate[] change in physician treatment behavior based on the assay results and/or improved patient outcomes." However, Palmetto has not made clear whether a laboratory must show that a physician's behavior changed as a result of having access to a test, ordering a test, or using a test, and it does not specify how many physicians should have changed their behavior and to what end. Furthermore, the level of clinical utility required to justify the use of a test is highly dependent upon the way the test's results will be used.

In any event, as Palmetto no doubt is aware, it is very complicated and difficult to show a laboratory test's clinical utility, and it typically cannot be shown without a long-term longitudinal study. It is rare for a laboratory to conduct prospective randomized clinical trials to show that a molecular diagnostic test has clinical utility; this information usually is deduced from other available evidence. (ACLA also is unaware of other instances in which the Medicare

program has required evidence of an item's or service's clinical utility as a condition of coverage.)

As discussed above in Section C.1, it is not clear what sort of documentation Palmetto will accept as evidence of a test's clinical utility. Despite our uncertainty about exactly what Palmetto will accept in the dossier, we are certain that coverage of new molecular diagnostic tests could be delayed by years if Palmetto accepts only published studies from peer-reviewed journals of prospective randomized clinical trials or if it refuses to accept other evidence of clinical utility in the absence of such published studies. And, if Palmetto eventually requires such published studies to be included in dossiers for existing tests, the same delay will occur, as laboratories have not conducted those kinds of prospective randomized clinical trials for the vast majority of existing molecular diagnostic tests. This could have serious implications for access to care for Medicare beneficiaries in states in Palmetto's jurisdiction.

5. Non-Coverage Decisions

The coverage decision process, in general, is rather opaque, but the decision not to cover a test – and to declare that a test is "investigational" and that reimbursement will be denied – should be transparent. An applicant should be given a specific reason why a non-coverage decision was made. The explanation ought to be in writing, and there should be an objective basis for the decision. Palmetto also periodically should publish statistics about how many applications it received, how many it processed, whether and how often it met its own procedural deadlines, and the eventual disposition of the applications it received. In the same way that Palmetto intends to act as a check on payment for tests that are not reasonable and necessary, a transparent process and transparent results will act as a check on Palmetto in its administration of the MolDx program.

D. Payment

The dossier for a new molecular diagnostic test asks for information about what reimbursement laboratories receive from other payors for a test. It is not reasonable for Palmetto to ask for that information and expect laboratories willingly to share it, especially if the laboratory is not permitted to aggregate payment information from several payors. Palmetto has not explained how a laboratory's private contract with another payor is related to what the Medicare program will pay for a test. In many instances, payor contracts may prohibit such disclosures on a payor-specific basis.

Palmetto representatives have made various statements about "value-added" reimbursement, although they have not been clear. One representative hinted that Palmetto may pay less for a test if it believes that the test adds little value to a patient's health care, but the contractor has not articulated the standards it will apply to such a decision. This is yet another area where clear standards and rules would benefit the program overall.

E. Procedure if a Test is Not Covered by the Draft LCD

How Palmetto will treat existing tests and whether, when, and how Palmetto will make coverage decisions about existing tests is difficult to understand, based on written materials and Palmetto representatives' oral representations.

1. Process and Dossiers for Existing Tests

Palmetto has stated that it wants laboratories to begin to assemble dossiers for existing tests so they are ready "when Palmetto asks for them." Some laboratories have hundreds of molecular diagnostic tests, and it is a waste of resources to begin assembling dossiers, especially if Palmetto may never ask for them or if the process changes before they are needed. Palmetto, instead, should ask for the dossiers when it is ready to process and evaluate them and when it has the capacity to do so, and it should ask for them in a methodical manner that does not overtax any one laboratory at a time. It is not clear that Palmetto has thought through what it will do with dossiers for existing tests if it ever asks for them. For instance, it is not clear whether those existing tests would be subject to any or all of the same process as new tests and whether they would be subject to the same TA process.

2. Alterations to Existing Tests

An important but as yet unanswered question is whether, when a laboratory makes a change to an existing molecular diagnostic test, the test becomes a "new" test for purposes of the program. For example, a laboratory may change a test such that it looks at 42 genes instead of only 40 genes. This would not change the stacking codes it uses or the intended use of the test. It is not clear whether a laboratory would be obligated to notify Palmetto or go through the coverage decision process after making a change.

3. Inadequate and Conflicting Assurances about Existing Tests

ACLA is concerned about the potential for retroactive payment decisions made about existing tests based on an evaluation procedure that Palmetto has not developed or articulated yet. Palmetto representatives have stated that Palmetto may choose to stop paying for an existing test after a laboratory submits a dossier for the test, although the procedure for evaluating existing tests has not been articulated yet, and that Palmetto has the legal authority to reopen claims it paid previously but that it was "unlikely to do so." ACLA's members need assurance from Palmetto that a future coverage decision will not be applied retroactively, especially because the process for existing tests has not been determined and remains amorphous. ACLA also is concerned that a RAC could attempt to use a decision by Palmetto to stop paying for an existing test as a basis for a retroactive recovery action.

F. Conclusion

ACLA members have significant questions about Palmetto's Laboratory and Molecular Diagnostic Services program in the J11 MAC region. Our primary concern is that we are being

asked to comment on and prepare to implement a program whose terms are unclear and constantly shifting. We urge Palmetto to cancel or delay the implementation of this program until the numerous legal issues raised by the program have been resolved and until the laboratory industry has had an opportunity to work with Palmetto on the important details and the timing of its implementation, to the extent that the program is permissible under Federal law.

Thank you for your consideration of ACLA's comments. We look forward to continuing our collaborative relationship with CMS and Palmetto.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association