American
Clinical Laboratory
Association

December 2, 2011

Dr. Elaine Jeter, Medical Director
Mr. Michael Barlow, Vice President
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P.O. Box 100190, AG 300
Columbia, South Carolina 29202-3190

RE: Palmetto GBA Draft Local Coverage Determination (LCD) for Molecular Diagnostic Tests (MDT) (DL 32288)

Dear Dr. Jeter and Mr. Barlow:

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 J1 Medicare Administrative Contractor'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 "Palmetto Laboratory and Molecular Diagnostic Services Program" as a whole (also known as "MolDx"), which is referenced in the Draft LCD. As we understand it, this program would include a process for creating a "registry" of existing molecular diagnostic tests (the Z-Code process that Palmetto contemplates being administered on its behalf by McKesson), a process for determining the clinical utility of new molecular diagnostic tests, and payment and pricing determinations. Palmetto has released several documents relating to the MolDx program, including a December 2010 article,[2] FAQs,[3] a timeline,[4] test registry

[1] Draft Local Coverage Determination ("LCD") for Molecular Diagnostic Tests (MDT) (DL32288). ACLA is submitting comments on the Draft Local Coverage Determination ("LCD") for Non-Standardized Organ or Disease-Oriented Panels (DL32286) under separate cover.

[2] Palmetto Laboratory and Molecular Diagnostic Services Program (Dec. 14, 2010), *available at* *http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~Lab~88WHVW2123?open&navmenu=Articles||||* (last visited Dec. 2, 2011).

[3] MolDx Program Frequently Asked Questions (Nov. 2, 2011), *available at* http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx~FAQs~8N3ELL4072?open&navmenu=Articles|||| (last visited Dec. 2, 2011).

[4] MolDx Timelines (Nov. 2, 2011), *available at* http://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/Jurisdiction%201%20Part%20B~Articles~MolDx~General~Molecular%20Diagnostic%20Services%20Program%20(MolDx)%20Timelines?open&Expand=1 (last visited Dec. 2, 2011).

directions,[5] a coverage determination process,[6] and an article about expansion of the MolDx program.[7] Additionally, Palmetto representatives have made various oral representations about the MolDx program, most significantly at a meeting of the California Clinical Laboratory Association in Lake Tahoe on November 2, 2011 ("CCLA meeting"). Therefore, ACLA's comments are not limited to the four corners of the Draft LCD; rather, we address all written and oral representations about the MolDx program to date, as the Draft LCD is but one small part of the overall program. Additionally, while we are submitting our comments herein, we believe that 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.

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. After Palmetto issued the December 2010 article about its plans for the MolDx program, 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.

ACLA therefore was surprised by the recent succession of announcements and documents from Palmetto that seem 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 MolDx program. It is highly unusual for CMS to establish a new comprehensive process through a contractor that affects all aspects of

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[5] MolDx Test Registry Process (Nov. 15, 2011), *available at* http://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/Jurisdiction%201%20Part%20B~Articles~MolDx~General~Molecular%20Diagnostic%20Services%20Program%20(MolDx)%20Test%20Registry%20Process?open&Expand=1 (last visited Dec. 2, 2011).

[6] MolDx Coverage Determination Process (Nov. 2, 2011), *available at* http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx~General~8N3ELJ8758?open&navmenu=Articles|||| (last visited Dec. 2, 2011).

[7] CMS Directs Expansion of the MolDX Program (Nov. 2, 2011), *available at* http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx~General~8N3EA28253?open&navmenu=Articles|||| (last visited Dec. 2, 2011).

laboratory coding, coverage, billing, and payment without providing a meaningful opportunity for comment. Nevertheless, in this situation, it appears that most aspects of the MolDx program have been designed by Palmetto, in collaboration with McKesson, but without any involvement of or input from laboratories. Although comments are permitted on the Draft LCD, Palmetto has been quite clear that it will not accept formal comments on many of the significant aspects of the program – almost all 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 MolDx program. Depending on the actual scope of the MolDx 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 meet all of the program's deadlines. 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 MolDx program, its complexity and the lack of clear answers to many questions risk nullifying any potential gains from the program.

In addition to what we anticipate will be Palmetto's own difficulty meeting proposed timelines, most laboratories' IT departments are focused on programming required for the implementation of the X12 Version 5010 standard for electronic transactions and for the implementation of ICD-10. These both are gargantuan programming tasks, and ACLA laboratories estimate that their IT departments would need at least one year of lead time to program billing systems to apply the Z-Codes properly. More than that, an IT department cannot begin to program a laboratory's system accurately with so many unanswered questions and variables.

We note, also, that Palmetto's MolDx 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 MolDx 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 MolDx program before implementing the program. The MolDx 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 MolDx 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 MolDx program in general. We begin by discussing our strong objection to the McKesson Z-Code process. We then address 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. McKesson Z-Code Process

ACLA's understanding is that existing tests would not need to go through the coverage decision request process immediately, but rather that laboratories would apply for and obtain a unique code from McKesson to place in the comment field of a claim. ACLA strenuously objects to Palmetto's subcontract with McKesson to assign a McKesson Z-Code™ ("Z-Code") to each molecular diagnostic test "to identify the billed test, determine reasonable and necessary services and apply appropriate reimbursement." In the context in which they would be used, the Z-Codes act as a local contractor code set, which is forbidden by Federal law. Additionally, as a condition of receiving reimbursement for Medicare claims through Palmetto, ACLA members would be forced to enter into a non-negotiable commercial licensing agreement with a third party, McKesson, that is fraught with the potential for unauthorized use of individual laboratories' proprietary information and inures to McKesson's sole benefit with little or no benefit to laboratories or the government.

The actual Z-Code process that went live on November 15, 2011 bears no resemblance to the purely administrative and ministerial function that McKesson was to play, as described to ACLA by Palmetto earlier. Palmetto appears to have engaged McKesson not merely to assign unique codes, as asserted by Palmetto, but also to gather information to be used in clinical validity and clinical utility evaluation processes for molecular diagnostic tests.[8] Further, in order to obtain a Z-Code, certain information is required that has no bearing on the identification of a

[8] We note there also are serious questions about who is required to obtain a Z-Code. For example, while, with respect to this Draft LCD and the MolDx program, Palmetto has jurisdiction only over laboratories located in Jurisdiction 1 ("J1") for Medicare Part B (California, Nevada, and Hawaii), Palmetto representatives also have said that a reference laboratory located outside of J1 would have to obtain a Z-Code for a molecular diagnostic test if a laboratory inside J1 purchases the service and bills Palmetto. Most laboratories located outside the jurisdiction will be surprised to learn that they will be required to obtain a new type of code from McKesson and enter into a licensing agreement, even if they do not bill Palmetto for their services.

particular test. For example, McKesson requires information concerning a laboratory's turnaround time for a particular test. This information is not necessary for Palmetto or for any other Medicare contractor to know what it is paying for.

1. Local Contractor Code Set

Palmetto's attempt to duplicate the function of the AMA's Current Procedural Terminology ("CPT") Coding System and assign its own codes, through McKesson, to molecular diagnostic tests violates the requirements of the Health Insurance Portability and Accountability Act, Pub. L. 104-191 ("HIPAA"). Palmetto representatives have claimed that the code is not being used as a "billing code," but rather a mere description or comment. But as of March 1, 2012, a Z-Code – purportedly a descriptor of the laboratory service – would be required in order for a laboratory to receive reimbursement, just as a CPT code is required in order to receive reimbursement. In this case, it is a difference without a distinction and a violation of well-established Federal law.

HIPAA requires the use of national, uniform code sets for financial and administrative transactions, including those for health claims.[9] A "code set" is defined as "any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes."[10]

Subpart J of the HIPAA Transactions and Code Sets ("TCS") regulations provides that when conducting a covered transaction, a HIPAA-covered entity must use the applicable medical data code sets described in 45 C.F.R. § 162.1002 (as set forth in the adopted implementation specification) that are valid at the time the health care is furnished. Subpart J adopts the Current Procedural Terminology, Fourth Edition (CPT-4) code set, as maintained and distributed by the AMA, as the standard medical code set for physician services and other health care services, including clinical laboratory tests.[11] Except as otherwise provided in the TCS regulations, if a covered entity or a covered entity's business associate conducts a transaction with another covered entity that is required to comply with a transaction standard adopted under the TCS regulations, using electronic media, the covered entity or business associate must conduct the transaction as a standard transaction.[12] At a minimum, Palmetto is a business associate of CMS, although it also may be a covered entity. CMS, with whom Palmetto acts as a business associate, itself is a covered entity, as are laboratories. Accordingly, all three are required to conduct financial transactions using transaction standards and national code sets. A health plan (including CMS and its business associates) may not delay or reject a transaction or attempt to adversely affect the other entity or the transaction because the transaction is a standard transaction.[13] A health plan must accept and promptly process any standard transaction that contains codes that are valid as provided in Subpart J of the TCS regulations.[14]

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[9] 42 U.S.C. § 1320D-2(c).
[10] 42 U.S.C. § 1320D(1).
[11] 45 C.F.R. § 162.1002(e)(4).
[12] 45 C.F.R. § 160.923.
[13] 45 C.F.R. § 162.925(a)(2).
[14] 45 C.F.R. § 162.925(c)(1).

As of March 1, 2012, an electronic claim submitted by a laboratory to Palmetto that contains specific, valid CPT codes (including "stacking" codes), but that does not contain a Z-Code, will be in compliance with the version 5010 837 claim transaction implementation guide as a standard transaction (assuming the laboratory otherwise follows the implementation guide). Palmetto would be required to accept and promptly process such a transaction: to reject it for lack of a Z-Code, which is not an adopted code under the TCS regulations, would be a violation of the TCS regulations.

Medicare contractors do not have the authority to adopt a different code set or to assign a different code for a test when there is an existing code for the service. HIPAA eliminated the use of local codes by Medicare contractors, and services and procedures are to be coded uniformly regardless of where they are performed or what entity is billing.[15] When CMS selects a code set that it will use for health care transactions, there is a well-established administrative process that includes notice and an opportunity for comment, and stakeholders are permitted to give input as to the impact of the proposed code set.[16] Palmetto has not followed this process in implementing this new code set.

Even if the use of Z-Codes as proposed by Palmetto was legally permissible under the TCS regulations, their use would create operational difficulties in both claims and remittance transactions that make the proposal unworkable.

When constructing claims in the version 5010 837 professional claim format, there are a couple of locations where a Z-Code could be placed. However, these locations are structured for free-form text, making it difficult to communicate more than one thought per field. Currently, it is not uncommon for providers to report each CPT code with multiple units of service. Each CPT code may be represented by multiple Z-Codes, and each Z-Code may be associated with multiple CPT codes. Providers would need guidance on how to structure the reporting of the multiple Z-Codes and how to match them to the CPT units of service associated with each Z-Code. Free-form fields are difficult to automate, do not contain the normal designators that help to divide the data for use, and are limited in size.

Laboratories also would find it difficult to reconcile payments with the reported codes. If multiple Z-Codes are linked to a CPT code and the claim contains multiple units of service for the CPT code and the reimbursement is different for each Z-Code, applying the payments will be problematic. There is no guarantee that all units of service will be paid. If all units of service are not paid, the laboratory may need to call the payor to identify the proper application of the payment. This manual payment reconciliation process would be inconsistent with the goal of administrative simplification and would be burdensome for both laboratories and payors.

[15] *See* 45 C.F.R. § 162.1000 *et seq*.
[16] 45 C.F.R. § 162.910.

2. Licensing Agreement

As a condition of receiving reimbursement for a molecular diagnostic test from the Medicare program through Palmetto, upon implementation of the MolDx program, a laboratory must have a Z-Code in the claim's comment field. To obtain a Z-Code for a molecular diagnostic test, a laboratory would be required to enter into a licensing agreement with McKesson for use of its Z-Codes.[17] The agreement that McKesson has put forward is a one-sided document in which all the terms favor McKesson alone. The licensing agreement's most serious flaw is that it would place no restriction on how McKesson could use information gathered through the Z-Code assignment process. (We discuss this in detail in Section B.4, below).

Unlike other private contracts between commercial entities, this agreement appears to be non-negotiable. There would be no opportunity for a laboratory to offer counterproposals to the more objectionable terms described below or to amend the licensing agreement in any way. When executed, such non-negotiable, one-sided contracts often are considered by courts to be "adhesion contracts," worthy of strict judicial scrutiny of their terms and void as against public policy.[18]

As an example of the one-sided nature of the present agreement, McKesson would be able to change the Terms of Use of the licensing agreement at any time without prior notice to a licensee. The agreement reads: "McKesson reserves the right to revise these Terms of Use at any time in its sole discretion. Such modifications to these Terms of Use, or any rights under it waived, will be by written document only and accepted by Licensee's authorized representative."[19] It is unconscionable to require a licensee to agree in advance to accept changes it cannot foresee. Also placing laboratories at a distinct disadvantage is the fact that McKesson "does not warrant that the Z-Codes will remain unchanged." This it proclaims in all capital letters. It is unreasonable to require laboratories to agree to such a clause in the licensing agreement, since Medicare reimbursement for molecular diagnostic tests necessarily would rely on the stability of the Z-Code system.

Also in McKesson's sole discretion would be the right to suspend a licensee's "access to and use of the Z-Codes" at any time if "the performance, integrity, or security of the Z-Codes are in danger of being compromised as a result of such access."[20] Laboratories cannot agree to give McKesson sole discretion to determine that their use of Z-Codes should be terminated. This could place a laboratory in jeopardy of losing *all* Medicare reimbursement for molecular

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[17] Terms of Use for McKesson Z-Codes, *available at* http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Z-Codes_licensing_terms.pdf/$File/Z-Codes_licensing_terms.pdf (last visited Dec. 2, 2012).

[18] An "adhesion contract" has been described by the Supreme Court of California as "a standardized contract prepared entirely by one party to the transaction for the acceptance of the other; such a contract, due to the disparity in bargaining power between the draftsman and the second party, must be accepted or rejected by the second party on a 'take it or leave it' basis, without opportunity for bargaining and under such conditions that the 'adherer' cannot obtain the desired product or service save by acquiescing in the form agreement." *Steven v. Fidelity and Casualty Co. of New York*, 58 Cal.2d 862, 882 (1962).

[19] Terms of Use for McKesson Z-Codes at Sec. 15.

[20] *Id*. at Sec. 9.

diagnostic tests in Palmetto's jurisdiction, since all molecular diagnostic tests now would require the use of a Z-Code.

The licensing agreement would require laboratories to release McKesson from almost all liability and indemnify it for its actions. The licensing agreement states (again, in all capital letters) that McKesson disclaims all liability for any claim, loss, or damage of any kind whatsoever in connection with or as a result of a licensee's "use of, reference to, or reliance on the Z-Codes…or any other matter relating to the Z-Codes."[21] Laboratories would have to rely on McKesson's consistent administration of the Z-Code process for reimbursement from the Medicare program in Palmetto's jurisdiction, and it is unfair to condition that reliance on a blanket release from any liability in connection with the Z-Code process. In addition, laboratories would be required to "defend, indemnify, and hold harmless McKesson from and against all claims arising from or in any way related to Licensee's use of the Z-Codes…"[22] It is unreasonable to expect laboratories willingly to forfeit all legal remedies against McKesson in advance.

The licensing agreement would require a licensee to warrant that it would "abide by all applicable laws, ordinances, rules and regulations with respect to its use of the Z-Codes." Yet the agreement gives no information about what the licensee is agreeing to abide by. Laboratories cannot agree to abide by a set of rules of which they have no knowledge. Even after entering into a licensing agreement, laboratories would be unable to craft policies and procedures to ensure compliance by all of its end users.

Perhaps most troubling about the licensing agreement (discussed in more detail in Section B.4, below) is this clause: "Licensee acknowledges that the Z-Codes and any derivative works, including all applicable rights to patents, copyrights, trademarks, and trade secrets inherent therein and appurtenant to, are the sole and exclusive property of McKesson…Licensee agrees (a) that all rights, title, and interest in the Z-Codes will be deemed to vest and remain vested in McKesson…"[23] This strongly suggests that McKesson may use information it obtains in the course of assigning Z-Codes in any way it chooses and that McKesson has the sole right to determine how to use the information in its other "derivative products."

The McKesson licensing agreement stands in contrast with the AMA's License for Use of the CPT codes.[24] The AMA agreement is simpler, far more balanced, and does not require a licensee to relinquish all claims or to indemnify the AMA or CMS as a condition of use. Moreover, the AMA grants a license for the use of ubiquitous codes – which can be used by any laboratory – whereas the McKesson license is for the use of codes assigned specifically to a laboratory's unique tests and based on information provided by the laboratory about its tests. Despite this, the McKesson license is far more restrictive regarding the use of the codes than the AMA's license is.

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[21] *Id*. at Sec. 7.
[22] *Id*. at Sec. 8.
[23] *Id*. at Sec. 4.
[24] License for Use of Physician's Current Procedural Terminology, Fourth Edition ("CPT"), *available at* http://www.palmettogba.com/viewamalicense (last visited Dec. 2, 2011).

The McKesson licensing agreement demonstrates why laboratories should have been involved in the process and permitted to work with Palmetto to develop an implementation plan. ACLA thought it had been involved in the process until Palmetto released a wholly new version of the MolDx plan, just a month or two after meeting with ACLA on other aspects of the plan. Moreover, Palmetto outlined the Z-Code plan at the CCLA meeting. At no time did Palmetto reference or describe this onerous and one-sided licensing agreement, most likely because it knew that laboratories would object strenuously. It is inconceivable that Palmetto would develop a plan with McKesson, on the side, and expect laboratories to accede without objection or comment.

Because the Z-Code would be mandatory as a condition of payment and McKesson would be the only entity that could provide the code, what is needed is a new agreement between McKesson and laboratories that is pre-negotiated and approved by the laboratories that would be bound by such an agreement. (That is assuming that other concerns about McKesson's involvement in the MolDx program could be resolved.)

3. Z-Code Application

Until recently, Palmetto representatives consistently represented McKesson's role in assigning Z-Codes as essentially a cataloguing role: that is, a laboratory would submit an application that describes a molecular diagnostic test, and McKesson would assign a unique Z-Code. Even the instructions for completing the application describe the process benignly as "completing and submitting an application," which will result in registration and assignment of a unique Z-Code. However, in reality, McKesson's Z-Code application requires far more detailed information than is truly needed merely to assign a unique code to a particular molecular diagnostic test. The Z-Code Application calls for no fewer than **thirty two distinct pieces of information** about a test, some of which are impossible to provide in the format requested and most of which are not necessary just to assign a code.

Some information requested is "required," and some information is "optional." ACLA has no way to know whether information that is "optional" today may be required later on. McKesson's refusal to warrant that the Z-Codes will remain unchanged makes ACLA unwilling to assume that this information (or additional information) will not, in the future, be required. Furthermore, some information "will be exposed for public view," although it unclear how, to whom, and why that public exposure is necessary for McKesson to assign a Z-Code or for Palmetto to determine what it is paying for. Also, the Z-Code Application Guide does not state what a laboratory should do if any piece of information in the application changes after a Z-Code has been assigned.

a. Application Contents

The following information, requested in the Z-Code application, goes far beyond the ostensible purpose of assigning Z-Codes, in some cases requests proprietary information, and is problematic to ACLA for the enumerated reasons.

- Medical/Lab Director Information: This information is not relevant to a description of a molecular diagnostic test.

- Credential Information: Information about a laboratory's Medicare number, CLIA number and expiration date, NPI number, State license number, and State license expiration date is not relevant to a description of a molecular diagnostic test. While this information may be relevant in claims submission and processing, Palmetto has said that the purpose of the Z-Codes is to "identif[y] each molecular diagnostic test and enable[] a one-to-one mapping of a test to a code."[25] Collection of this information belies Palmetto's claim that the Z-Codes do not constitute a prohibited local contractor code set.

- Price: McKesson asks for the list price available to the general public. While this information currently is optional, ACLA is concerned that it will not remain so. This information is unrelated to describing a test, and it should not be included in the requested information.

- Turnaround Time: This information is not relevant to a description of a molecular diagnostic test. Furthermore, this information may change frequently, and Palmetto has not provided any information about a laboratory's obligation to amend a Z-Code application in the event that this information changes.

- Procedure Coding Information Fields: McKesson requests information about CPT codes and HCPCS codes. ACLA does not object to Palmetto having this information, but its inclusion begs the question of why a Palmetto-specific Z-Code would be necessary when a test is otherwise described by national code set elements.

- Specimen, Handling, and Patient Instructions: This information is not relevant to a description of a molecular diagnostic test.

- Kit Information: The application requests information about whether the test is done using an FDA-approved kit. This suggests that if a laboratory is furnishing a test using an FDA-approved test, it still must get a Z-Code to furnish the test and that every laboratory using the same FDA-approved kit for cystic fibrosis, for example, would have to obtain its own Z-Code, even though the kit is approved or cleared by the FDA. It is difficult to see why Palmetto would want each laboratory to obtain a Z-Code, and the rule seems intended simply to help McKesson build a broad database for its own commercial products with information required to be supplied by laboratories. McKesson then could sell this information to commercial payors and explain exactly how each laboratory performs a given test. (Our comments expand upon this in Section B.4, below.)

[25] Z-Code Application Guide, *available at* http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Z-Code_Application_Guide.pdf/$File/Z-Code_Application_Guide.pdf (last visited Dec. 2, 2011).

b. Clinical Validity and Clinical Utility Information

The Z-Code application asks for information that typically is used in making clinical validity and/or clinical utility judgments. In light of the fact that Palmetto represented that McKesson would play no part in making these judgments in the context of the MolDx program, it is curious that McKesson now is asking for such information. It raises serious questions about McKesson's true involvement in clinical validity and clinical utility determinations. ACLA sees no reason why McKesson should have the information when it is, allegedly, not involved in this part of the MolDx program.

For example, the application asks for information about a test's analytical sensitivity, analytical specificity, and positive and/or negative predictive value. These are not simple measurements. These are very sophisticated scientific judgments, and they do not lend themselves to a "fill in the blank" application such as the Z-Code application. For some tests, analytical specificity simply is not available, although it is "required" in the application.

The last piece of information asked for in the application is something called "clinical net reclassification index." During a recent conference call with some of the most experienced laboratory scientists in the nation, it came to light that not one of them knew what this term means. This again suggests that it would have been far more reasonable to involve the laboratory industry in developing the MolDx program, rather than develop a set of ambiguous standards and undefined terms that the industry is unable to interpret.

Finally, ACLA notes that the National Institutes of Health ("NIH") recently developed its own registry of genetic tests. That process went through rounds of notice and comment rulemaking and included extensive comments from the laboratory industry, in part because even an organization as sophisticated as NIH understood that the development of such a registry was difficult and would involve numerous technical and scientific questions. Moreover, even the NIH has made public assurances that its genetic test registry would not include cost or time information, which are based on numerous factors and subject to change, and most importantly, are not relevant to that registry or to Palmetto's proposed registry. ACLA is troubled by the fact that Palmetto did not feel that such input was necessary for its registry, even from the industry that would be responsible for completing registry applications.

c. No Appeal Rights

A claim for molecular diagnostic testing services submitted to Palmetto without a Z-Code will receive a front-end rejection. However, there is no assurance that laboratories will always be able to get a Z-Code, given the amount of information required by McKesson in the application process. The Z-Code application process is so problematic that McKesson likely will reject a number of applications for Z-Codes as "incomplete," and there is no apparent process for review of such a determination by McKesson. Further, a claim that receives a front-end rejection is not appealable.

It will be difficult, if not impossible, for some laboratories to complete the Z-Code application to McKesson's satisfaction, since several of pieces of information it requests cannot

be dropped into a spreadsheet easily (see Section B.3.b, above). Presumably, if McKesson decides that an application is incomplete, it will notify a laboratory of the missing information, but the laboratory may not be able to provide the information in an acceptable format. Neither McKesson nor Palmetto has set forth a process to solve a dispute if McKesson were to determine that a laboratory's application is incomplete but a laboratory claims it cannot submit information in the form and format requested by McKesson.

A laboratory could face two equally bad choices: hold claims indefinitely, hoping that the Z-Code process will change, or submit claims without a Z-Code and receive front-end rejections. A provider whose claim is rejected, rather than denied, does not have a right to appeal the rejection through the appeal process set forth at 42 C.F.R. Part 405, Subpart I.[26] Thus, what otherwise would be a valid and complete claim would be rejected with no recourse.

4. Potential for Unrestrained Commercial Use of Information Gathered through Z-Code Process

Perhaps the most troubling aspect of Palmetto's arrangement with McKesson is the potential for McKesson to use detailed proprietary information gathered from laboratories in any way it chooses and even to the detriment of the laboratories that would provide the information. The Medicare Contractor Beneficiary and Provider Communications Manual is unambiguous on this point:

> Contractors may not use their position as a Medicare contractor for purposes of furthering their private business interests or gain. They may not use any material or information obtained from the Secretary or developed in performing their functions under their agreement with CMS to promote their private business interests.[27]

As Palmetto is aware, McKesson markets its Diagnostics Exchange Registry Module to commercial payors and other health care entities.[28] Trade press reported earlier this year that "McKesson began offering its MDx/genetic testing products about three years ago as a 'soft launch' and since then has been building the business. [McKesson's Vice President for Decision Management] declined to disclose revenue figures for the molecular and genetic testing management business, but said that it is 'a significant area of investment for McKesson'… McKesson also is moving to create a centralized repository of information about molecular and genetic tests on the market."[29] Palmetto, essentially, would be using government funds to pay McKesson to build a database of molecular diagnostic test information from which McKesson

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[26] "Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier" are not considered "initial determinations" that are appealable. *See* 42 C.F.R. § 405.926(s).

[27] Medicare Contractor Beneficiary and Provider Communications Manual, Ch. 1, Sec. 20.

[28] Palmetto's Molecular Diagnostic Services Program (MolDx) Test Registry Process document references the module and says that tests will be added to the registry.

[29] McKesson Aims to Help Health Plans Navigate MDx, Genetic Testing Space, Genome Web Daily News (July 8, 2011), *available at* http://www.genomeweb.com/dxpgx/mckesson-aims-help-health-plans-navigate-mdx-genetic-testing-space.

would stand to profit handsomely and much of which could be used to the disadvantage of laboratories.

This vast amount of information would be of great use not only to McKesson's Diagnostics Exchange Registry Module, but also to others McKesson subsidiaries. In December 2010, McKesson announced that it had acquired U.S. Oncology, one of the nation's largest networks of oncologists.[30] U.S. Oncology earlier in the year announced a joint venture with a molecular diagnostics facility and laboratory facility affiliated with the Baylor Health Care System that it expected to have an annual payroll of $67 million.[31] As it stands, nothing would stop McKesson from taking information gathered on Palmetto's behalf and using it to put U.S. Oncology's business at a competitive advantage over the very laboratories that would be forced to share the information. Also, McKesson would have a significant advantage, and even be conflicted, when applying for a Z-Code for its own laboratory.

In fact, it would appear that McKesson's involvement with U.S. Oncology and its new molecular diagnostics laboratory presents such a significant conflict of interest that McKesson should have been disqualified from acting as a contractor for the MolDx program in the first instance. It is unclear whether McKesson disclosed this issue or whether Palmetto inquired about it. ACLA requests that CMS make available any correspondence and/or information about discussions between CMS, Palmetto, and McKesson with regard to this apparent conflict of interest.

As we discussed above, the licensing agreement for McKesson's Z-Codes, which laboratories would be forced to sign as a condition of receiving Medicare reimbursement through Palmetto for molecular diagnostic tests, places **no restrictions on McKesson's use of information gleaned through the Z-Code process**. It is essential that Palmetto restrict the amount of information and McKesson's use of information contained in Z-Code applications, permitting McKesson to access only the information needed to assign Z-Codes and to use it for no other purpose. McKesson should not be permitted to use the information for any commercial purpose unrelated to Palmetto's MolDx program. Palmetto should conduct periodic audits of McKesson's Z-Code operations to ensure that McKesson is adhering to these restrictions, and McKesson should be liable to laboratories for any misuse of the information it gathers. However, whatever is done in this regard must be developed with the industry and as part of a broader discussion of the MolDx program.

ACLA has serious concerns about the appropriateness of McKesson's involvement in this program. At the very least, if the MolDx program is to proceed and if McKesson is to remain a subcontractor to Palmetto for purposes of the program, Palmetto must renegotiate its contract with McKesson to limit McKesson's role and to restrict McKesson's use of the information it gathers from laboratories.

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[30] McKesson Completes Acquisition of U.S. Oncology, December 30, 2010, *available at* http://www.mckesson.com/en_us/McKesson.com/About%2BUs/Newsroom/Press%2BReleases%2BArchives/2010/McKesson%2BCompletes%2BAcquisition%2Bof%2BUS%2BOncology.html.

[31] Baylor, U.S. Oncology to Hire 900, Dallas Business Journal (Jan. 24, 2010), *available at* http://www.bizjournals.com/dallas/stories/2010/01/25/story7.html?page=all.

C. Draft LCD

We now address one of the written items Palmetto has issued as part of the MolDx program: the 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.[32]

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. The draft 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:
>
> 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).[33]

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 if it, indeed, applied to any molecular test that

[32] We also note that the Draft LCD and the MolDx program appear to be designed to limit the ability of laboratories to appeal successfully to Administrative Law Judges upon denial of coverage for molecular diagnostic tests.
[33] Draft LCD at 2 (emphasis added).

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 FAQs document posted on Palmetto's website further obscure the scope of the Draft LCD. The fourth FAQ is: "What types of molecular assays are subject to the MolDx program?" This answer, also, is so broad as to cause great concern: "Assays that include gene tests, infectious disease probes, tumor markers, pharmacogenomic assays, predictive and risk assessment assays and other molecular tests, with or without an existing CPT or HCPCS code that does not specify ONE test per unique CPT/HCPCS code. Multi-variant molecular testing is a subset of MDT." Like the Draft LCD, the FAQs do not limit the scope of the policy to new tests.

The December 2010 article describes the scope of the MolDx 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)."[34]

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. Additionally, although some published materials acknowledge that laboratories may continue to use NOC codes and stacking codes after March 2012, so long as a claim has a Z-Code, the Draft LCD does not reference the phased-in approach, as it should.

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.[35] 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

[34] Palmetto Laboratory and Molecular Diagnostic Services Program (Dec. 14, 2010).
[35] *See* Principles of CPT Coding, 2nd Ed., American Medical Association (2001).

> the testing procedure. "Unlisted procedure" codes ending with 99 should be used only when the analyte or method is not listed.[36]

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. 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.

D. 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 December 2010 article is very prescriptive about what must be included in the dossier submitted with an application.[37] 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*."[38]

Palmetto's FAQs differ from what is in the December 2010 article. FAQ #9 says, "In addition to the published requirements, the following published documentation may be considered in evaluating clinical utility: Retrospective studies, White-papers written by national societies and recognized experts, Virtual or theoretical models that have been vetted in the scientific literature, Abstracts." Palmetto representatives' oral representations have been different still. At the CCLA meeting, Dr. Jeter said that Palmetto 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.

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[36] *Id*, at 305.
[37] *See* Palmetto Laboratory and Molecular Diagnostic Services Program (Dec. 14, 2010).
[38] *Id*. (emphasis added).

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.

2. Treatment of Proprietary Information

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 MolDx program, such as outside consultants or experts, will safeguard laboratories' information.

Although a Palmetto FAQ states that "the expert reviewers [on the Technology Assessment ("TA") panel] 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 D.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. (We have set forth our concerns about McKesson's use of laboratories' proprietary information in Section B.4, above.)

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 McKesson and any members of a Technical Assessment 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, McKesson, 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 their involvement in the coverage decision process, and ACLA believes it is wholly unfair to establish such a 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.[39]

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?** FAQ # 11 states 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.

[39] 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 MolDx 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 MolDx program must be more transparent and standardized, and the panelists must be accountable both to the integrity of the MolDx 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 December 2010 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 D.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. Decision and Publication

Palmetto's MolDx Coverage Determination Process[40] includes several self-imposed deadlines:

- Within 30 days of a request for a coverage determination, Palmetto would be required to notify the requestor that the request is valid and complete or that it is incomplete.

- Within 90 days of receipt of notification of a valid and complete request, Palmetto would be required to notify the requestor either of a coverage determination, a suspension, or non-coverage. (This was described differently at the CCLA meeting; there, Palmetto representatives said that the TA panelist would have 90 days to do a technical assessment.)

- In the event of an "assessment backlog" (which, to our knowledge, has not been defined), Palmetto would have one 60 day extension.

- Within 30 days of receiving a summary of a technical assessment from a TA panelist, Palmetto would post the assessment on the McKesson Diagnostics Exchange site for comment and permit a 45 day comment period.[41] (This is not included in any of Palmetto's written documents; a Palmetto representative discussed these deadlines at the CCLA meeting.)

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[40] Molecular Diagnostic Services Program (MolDx) Coverage Determination Process, *available at* http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx~General~8N3ELJ8758?open&navmenu=Articles||||.

[41] Just as ACLA is concerned about McKesson's involvement in the Z-Code process and its unlimited use of information obtained therein, ACLA also objects to technology assessments being posted on McKesson's site, not on Palmetto's, and about McKesson's use of information in a technology assessment for its own commercial purposes. Further, Palmetto may wish to consider whether there is a need for comments from the public or whether comments should be limited to those from the requestor.

- Based on other deadlines, within 15 days of the close of the comment period, Palmetto would be required to notify the requestor of the decision.

- In the event of a non-coverage decision, a laboratory would be required to wait 180 days before resubmitting an application.

ACLA appreciates that Palmetto endeavors to return a coverage decision in a reasonable amount of time. Based on the fact that Palmetto contemplates one person being responsible for rendering coverage decisions for all tests, ACLA anticipates that Palmetto will not meet these deadlines in many cases, especially given the fact that Palmetto itself says it expects that there are at least 1,500 tests that would have to be reviewed under its new policy – a figure that ACLA believes is low. It is not clear what recourse a laboratory would have when Palmetto misses one of the above-described deadlines. Additionally, it would not be possible for a requestor to know whether some deadlines had been missed, e.g., whether Palmetto posted a technology assessment online within 30 days of receiving it from a TA panelist.

ACLA is baffled by the requirement that a laboratory that receives a non-coverage decision would be required to wait 180 days to resubmit an application. Insufficient scientific data are not the sole reason for a non-coverage decision, and an applicant should be permitted to resubmit an application immediately if it has additional information or believes it has a strong case that a test should be covered. Given the resources a laboratory must put into assembling a dossier, it is unlikely that Palmetto would receive any "nuisance" applications.

6. 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.

E. Payment

Both the dossier for a new molecular diagnostic test and the Z-Code application ask 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.

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

As we stated previously in these comments, ACLA is under the impression that existing tests are not subject to the Draft LCD and that laboratories may continue to use NOC codes and stacking codes, so long as a test has a Z-Code in a claim's comment field. The Draft LCD does not plainly state this, as it should, but this information appears elsewhere in written materials about the MolDx program.[42] What will be the eventual treatment of these existing tests, and whether, when, and how Palmetto will make coverage decisions about existing tests is anything but clear.

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, will those existing tests be subject to any or all of the same process as new tests? Will Palmetto impose the same deadlines on itself? Will those tests be subject to the same TA process? Will they be subject to the same notice and comment period?

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 MolDx program. Virtually any change to a test potentially could be a change in information, requiring that it be submitted to McKesson for a Z-Code or resubmitted for a different Z-Code. 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 McKesson or Palmetto, apply for a new Z-Code, or go through the coverage decision process after making a change.

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[42] MolDx Test Registry Process (Nov. 15, 2011), *available at* http://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/Jurisdiction%201%20Part%20B~Articles~MolDx~General~Molecular%20Diagnostic%20Services%20Program%20(MolDx)%20Test%20Registry%20Process?open&Expand=1.

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. At the CCLA meeting, a Palmetto representative 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. The same representative also said 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.

G. Conclusion

ACLA members have significant questions about the new MolDx program. 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 are particularly concerned with the role played by McKesson in this process, given the fact that there are no apparent limits on its use of the information it collects and given its position as a private contractor with interests directly in conflict with the laboratories from whom it would obtain the information. We also are very concerned that Palmetto is attempting to implement the use of a local contractor code set in a manner that is prohibited under current Federal law.

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

cc: Marilyn B. Tavenner, Principal Deputy Administrator and COO, CMS
Jon Blum, Deputy Administrator and Dir. of the Center for Medicare, CMS
Robert Tagalicod, Dir. of the Office of E-Health Standards and Services, CMS