April 17, 2015

American
Clinical Laboratory
Association

VIA EMAIL

Mr. Sean Cavanaugh
Deputy Administrator and Director
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop wb-06-05
Baltimore, MD 21244

Dear Mr. Cavanaugh:

On behalf of the American Clinical Laboratory Association ("ACLA"), I am writing to express ACLA's concern about recent policies and procedures that some Medicare contractors are utilizing with respect to laboratory services, and to ask for CMS's prompt assistance for resolving these concerns. As you know, ACLA represents local, regional and national laboratories that provide a wide range of testing. As a result, almost all ACLA members are subject to these policies and their implementation.

The past few years have seen incredible advances in clinical laboratory testing. A great deal of this development has taken place in the area of new, highly sophisticated genetic testing, often referred to as molecular diagnostics, which is the basis of the "Precision Medicine" initiative that was recently highlighted in President Obama's budget proposal. (Molecular testing is testing that involves analysis of specimens to determine a patient's genetic or genomic characteristics, which allows a more personalized assessment of an individual's clinical condition or likely response to specific therapies.) As with any new area of medicine, these new types of molecular diagnostic tests have also been the subjects of increased scrutiny from payors. Other areas of testing, such as laboratory testing for drugs of abuse, have also been the subject of increased attention.

At the outset, we wish to be very clear that ACLA members do not question the importance of the Medicare Program ensuring that it only pays for medically appropriate testing. We support the adoption of appropriate policies for all of these tests, and we look forward to continuing to partner with CMS on these issues. And, we recognize that contractors have broad discretion to establish medical necessity requirements through the well-defined requirements for Local Coverage Determinations (LCDs). What contractors do not have the right to do, in our opinion, is to establish policies that create unique coding or billing requirements, or to avoid the clear procedural requirements mandated by the LCD process.

As discussed below, there are specific actions that contractors are taking that create concerns for laboratory stakeholders. As a result, we believe it would be useful if CMS clearly delineated the contractors' authority in this area to ensure that the interests of laboratories are protected. In particular, we ask CMS to look at the following areas:

1. Implement the requirements of the Protecting Access to Medicare Act ("PAMA")[1], which specifically requires that contractors follow the LCD process.

2. Establish a process to ensure stakeholder input into the new laboratory policies, and require that new policies be issued on a regular, monthly process.

3. Prohibit the use of unique coding and billing rules that apply only within that contractor jurisdiction. In particular:

    a. Limit the use of Z-codes to Molecular Diagnostic tests;

    b. Prohibit the use of Miscellaneous or "Z" codes when another more descriptive CPT code exists;

    c. Restrict the adoption of "ad hoc" panel codes, unless the panel is one recognized by the CPT Code Manual or by a HCPCS code.

Because of the complexity and granularity of the issues involved, we are requesting the assistance of CMS in resolving these issues. We are therefore requesting the opportunity to meet with you and the staff of the Hospital and Ambulatory Policy Group and the Coverage and Analysis Group, as we believe these issues fall within both Groups' jurisdictions. We welcome the opportunity to also meet with any other parts of the agency that you believe should be involved. In addition, we request that CMS convene an Open Forum Meeting with the industry where it can hear from stakeholders about the issues involved.

Set out below, we detail the background of the current issues and then we propose a set of specific actions that we request CMS take to help alleviate the concerns discussed. We recognize that many of these issues are somewhat technical, but unfortunately, there is no way to discuss these issues without getting into some detail. At the most basic level, however, the issues here surround whether contractors have the right to impose unique billing, coding and payment policies that are inconsistent with other Medicare requirements, without any input from the affected stakeholders who must bear the significant cost of implementing these requirements.

A. **Background on the Current Issues**

Many of the current issues have their genesis in actions that contractors took with regard to molecular testing. Prior to 2011, most molecular diagnostic testing services were billed using CPT codes with general "method" descriptions (also known as "stacking codes"). For example, a test that involved analysis of DNA might be billed using the codes that described only the basic steps in the process; e.g., the extraction of the DNA; amplification of the DNA, so that it can be appropriately tested; and interpretation of the results. CMS and other payors had noted that use of the stacking CPT codes failed to provide sufficient information about the specific tests that were being provided, which often made it difficult for payors to judge the medical necessity of the underlying tests. In 2012, the CPT Code Manual was revised to eliminate the old method codes and substitute new analyte-specific codes for particular genes. Today, for example, if a laboratory

[1] Pub. L. No. 113-93, 128 stat. 1040.

bills for an EGFR analysis, a common genetic test, the laboratory usually would bill CPT 81235, which specifically describes that service. Thus, there is no longer any question about what the laboratory is billing or the payor is reimbursing.

At the time that the stacking codes were in use, Palmetto GBA took the lead on many laboratory billing and coding issues. One of Palmetto's first actions was to issue a Local Coverage Determination, which set out a special set of policies for molecular diagnostic testing in a program that it referred to as the "MolDX Program."[2] As part of the MolDx program, Palmetto required laboratories submitting claims for molecular diagnostic tests to include a specialized code that would identify the underlying test. Laboratories could either use a "Z-code," which is an identifying code issued by the private entity, the McKesson Diagnostic Exchange, or a Palmetto Test Identifier ("PTI") Code, which was issued directly by Palmetto. When billing for a molecular diagnostic test, the laboratory would use the appropriate CPT code(s) and also enter the appropriate Z-code or PTI code in the "comments" field on the claim.

Even though the "stacking codes" have now been replaced by more specific codes, Palmetto continues to require laboratories to obtain Z-codes for the molecular diagnostic tests. Last year, Palmetto stopped issuing its PTI codes and after a lengthy negotiation process with McKesson, laboratories now are applying for Z-codes for the tests for which they previously had PTI codes. When Noridian took over Palmetto's former jurisdiction in J-1, it continued the use of the Z-codes there. And, Noridian just recently has announced that it will expand the requirements to another area over which it has jurisdiction. Before these requirements are further expanded, we believe it would be useful for CMS to step in to further refine when the use of these codes is appropriate.

B. A Summary of ACLA Concerns

1. The Use of Articles, rather than LCDs.

Increasingly, contractors have begun to rely on "articles," rather than the LCD process, when establishing the rules for particular tests, especially molecular diagnostic tests. The use of articles creates several concerns for laboratories. First, an article does not require input from stakeholders and does not receive advance notice and comment, as do LCDs. Further, the articles issued as part of this process are often revised on several occasions, which can make them more confusing and difficult to track. After an article is issued—without any public input—laboratories often raise questions about issues included in the article. After it receives these comments, the contractor may revise the article and re-issue it. Often, the articles are re-issued yet again as other comments come in. While the contractors are often willing to accept comment on these articles after the fact, it would certainly be preferable if laboratories were given the opportunity, such as the one afforded in the LCD process, to provide meaningful input prior to the issuance of such policies. Additionally, in situations where an LCD is released by one contractor and then copied by another contractor, there have been cases where the original LCD is revised based on stakeholder feedback, but the second contractor fails to revise its policy as well.

[2] LCD, Molecular Diagnostic Tests (MDT) (L33599).

Second, there is sometimes confusion about what rationale justifies an LCD rather than an article. For example, in some instances, the contractor will issue an article because it states that there is insufficient evidence to support the use of the test. This explanation would typically suggest a lack of medical necessity, which would require an LCD. However, in those situations, the contractor issues an article and states that no LCD is required because the service is "statutorily excluded," a rationale that does not require an LCD. This seems inappropriate to ACLA members and we think it is an area that CMS should clarify.

2. The Requirement to Use "NOC Codes."

Furthermore, these articles often include new coding and billing requirements. In some instances, they require that the test be billed using what are referred to as NOC codes or "Not Otherwise Classified" codes even though there is a more specific CPT code available that describes the specific service. NOC or Miscellaneous codes are just what they sound like: they are very general descriptions of a laboratory test that do not specify anything about the particular type of test being performed.

The policy to require the increasing use NOC codes when another more specific code is available is contrary to the most basic CPT coding requirements and certainly is contrary to CMS's efforts to obtain greater clarity and transparency concerning the testing being performed.. As the OIG said in the very first compliance guidance for laboratories:

> Laboratory compliance policies should ensure that the CPT or HCPCS code that is used to bill Medicare or Medicaid accurately describes the service that was ordered and performed. Laboratories should choose only the code that *most accurately describes the ordered and performed test.*[3]

Because of requirements to use NOC codes in a variety of situations, many laboratories note that today they have more miscellaneous codes than ever before and often more than regular CPT codes. NOC codes are problematic for most laboratories, because they are often not accepted by other payors, including other Medicare contractors. If a lab bills with a NOC code, the claim must be manually reviewed or is "pended" until the payor can investigate it. In some instances, if the claim goes over to a private payor, such as a secondary payor, they will reject the claim because it contains an NOC code. The patient then receives a notice that his or her secondary payor is refusing to pay for a service that the patient believes is covered. The patient then calls the laboratory to complain that its secondary payor is refusing to pay for the service.

Using NOC codes also allows the contractor to establish its own pricing for the test, outside the usual requirements of the Medicare Program. Currently, most clinical laboratory testing is based on a fee schedule that establishes a price for each clinical laboratory CPT Code. However, because they are general and non-specific, NOC codes are not listed on the Clinical Laboratory Fee Schedule. Therefore, the contractor sets its own price, based on its own criteria. This may be reasonable where a test is truly unique, and no specific code exists; however, for tests that already

[3] OIG Model Compliance Plan for Laboratories, 62 Fed. Reg. 9435, 9437 (Mar. 3, 1997) (emphasis added).

have a corresponding specific CPT code, it is inappropriate for the contractor to establish its own price.

Finally, and most importantly, as a result of PAMA, laboratories are about to begin a massive task of reporting their billing and pricing based on the appropriate CPT Code. Obviously that system requires that all tests be reported using the same system, and PAMA includes requirements to establish specific HCPCS codes to identify tests that do not have their own CPT codes. Given this movement towards greater and greater specificity in reporting laboratory pricing, it seems inconsistent for a contractor to establish a system that requires laboratories to bill using more general, less specific coding descriptions that apply only to that contractor.

3. New Issues Related to "Test Panels."

In addition, some contractors are establishing their own unique requirements for what they term "panels." The term "panel" usually refers to a group of tests that are commonly ordered together and are therefore described by a single CPT code. For example, Medicare recognizes certain "organ and disease panels" defined in the CPT Code Manual, (CPT 80047-80076) which establish a group of tests (*e.g.*, a lipid panel), which can be billed using a single CPT code. However, CPT defines the components of that panel and only the specified tests can be billed as part of that panel. The long-standing rule for Medicare has always been that if the tests are not part of a panel whose components are defined by a CPT code or a HCPCS code, then the laboratory is to bill the tests individually.[4] As noted above, in this way, it is clear that the tests billed reflect those that were actually ordered by the physician.

Recently, some contractors have created their own unique panels, which only apply in their jurisdiction. For example, Palmetto recently issued an article supporting its Drugs of Abuse LCD.[5] In that article, Palmetto created a new panel, which it calls "Physician-Directed Profile Testing." According to Palmetto, whenever a physician orders more than eight quantitative Drugs of Abuse tests, the testing is considered a panel and it is to be billed with an NOC code, and with a special identifier in the comment field. The testing is paid differently depending on how many tests are ordered at one time: one price for 8 – 15 tests; one for 16-34; another for more than 34. Palmetto has said it arrived at the pricing based on a confidential cost survey of laboratories that performed this type of testing.

There are numerous significant problems with this approach. First, as noted above, there is no reason to create an NOC code for the test panel, because each test can be appropriately described by the existing CPT Codes. Further, by establishing an NOC code in this case, the contractor can establish its own payment system for the tests at issue. This is inconsistent with basic payment rules related to laboratory testing, which require that tests be reimbursed based on the appropriate CPT code. Moreover, laboratories do not even know how these new prices were arrived at because the pricing is based on a survey of costs that Palmetto conducted. Thus, there is no way for laboratories even to comment on the reasonableness of Palmetto's conclusions.

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[4] *See, e.g.*, Medicare Claims Processing Manual, Ch. 17, § 90.2 ("the only acceptable Medicare definition of the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association (AMA) definition of component tests…If the laboratory has a custom panel that includes other tests… the additional tests…are billed separately.")

[5] http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Jurisdiction-11-Part-B~9SDPFR2173

Further, the Palmetto article also establishes particular requirements for how testing is to be performed. It directs laboratories to use a specific testing methodology (i.e., qualitative) for confirmatory testing, unless quantitative testing is specifically ordered by the treating physician. This distinction is not made by CMS Medicare policy or relevant guidelines, and will most likely become irrelevant in January when CMS adopts a longer-term coding solution in this area. In the interim, laboratories will need to invest significant resources to implement these policies that will only apply to Palmetto and only for the balance of 2015.

Finally, the new policy instituted by Palmetto is inconsistent with CMS's instructions in this area. At the end of last year, CMS announced it would not adopt the new 2015 Drugs of Abuse CPT Codes, because it believed they could lead to unnecessary utilization. Because this left payment in limbo for 2015, various groups, including ACLA, worked with CMS to adopt an interim solution that would apply during 2015, until CMS determined a long-term solution. As a result of that process, CMS adopted new "G-Codes" for 2015 which corresponded to the CPT codes used in 2014. CMS emphasized, "Providers are to use these G codes in the same manner in which they used the corresponding CPT codes for 2014."[6]

ACLA believes that the Palmetto approach, while well-intentioned, is still inappropriate. It is directly contrary to CMS's instructions, as none of these codes were billed or paid for based on the tiered pricing schedule that the contractor developed. Further, as noted above, it is impossible for stakeholders to determine the basis for the pricing structure that the contractor has developed. ACLA is sympathetic to the concerns that exist surrounding these codes, and we have worked (and will continue to work) with CMS to resolve these issues. But, we do not think it is appropriate for one contractor to develop its own unique approach to these issues, especially given CMS's clear instructions to bill based on prior practice.

C. Requested Actions

As discussed in more detail below, it is important for CMS to establish some parameters on contractors' action in this area. We recognize that CMS traditionally defers to the discretion of local contractors on issues of medical necessity, but in this case, the contractors are going far beyond that task. Rather, they are establishing their own unique billing and coding requirements that are inconsistent with other Medicare requirements, without the input of interested parties, in a manner that creates additional work for everyone. As a result, set out below are specific actions that we believe CMS should take that would help lead to a more fair and rational process.

1. Implement the Requirements of PAMA.

In PAMA, Congress mandated that contractors follow the requirements for LCDs when issuing coverage policies related to laboratory testing.[7] It is no secret that this provision was included largely because of Congressional concerns about the widespread use of "articles" rather than LCDs and also about the overuse of the "statutorily excluded" rationale for non-coverage. Because these policies are published as articles, laboratories are denied notice or an opportunity to provide public input on these major coding and billing policies. In the 2015 Proposed Physician

[6] CMS, Clinical Laboratory Fee Schedule (CLFS) Final Determinations at 1 (2015)(emphasis added).
[7] Protecting Access to Medicare Act, §216(g).

Fee Schedule Rule, CMS proposed implementing the PAMA requirement, although it simultaneously proposed numerous changes that would actually have relaxed many requirements of the LCD process for clinical diagnostic laboratory tests, changes to which many stakeholders objected. In the Final Rule, therefore, CMS announced that it was refraining from making any changes in the LCD requirements applicable to laboratories.

CMS should act to implement the requirements included in PAMA. It should instruct contractors that when denying coverage for specific tests, they must go through the local coverage process, as PAMA directs. It should not be sufficient for there to be a single, very general LCD that applies to all Molecular Diagnostic Testing, and then for the denial of individual tests to be handled through an "article." In addition, it should also instruct contractors that it is incorrect to use the "statutory excluded" rationale when making a determination that is clearly based on medical necessity or when a contractor believes a test usually would not be ordered for a Medicare beneficiary.

2. Establish a process to ensure stakeholder input into the new laboratory policies.

As noted above, the current process does not include public input from stakeholders, because the policies are issued as articles. Often, an article is issued, then revised, and then re-issued with a new effective date, making it very difficult for laboratories to keep up with what is required. However, were laboratories consulted first, much of the subsequent confusion could likely be avoided, and the policies that were ultimately issued would be improved.

Given the in-depth nature of the review being undertaken by contractors, we believe it would be useful to establish a process for greater input. Since it appears that Palmetto is taking the lead on major issues affecting laboratories in the future, Palmetto should establish a regular monthly meeting with laboratory stakeholders that would focus specifically on laboratory policies, through which laboratories could provide regular input and suggestions.

Further, it would be more efficient and productive for all involved if these policies were published on a regular schedule, such as once a month. Preferably, it would issue such policies after discussing them with the industry and getting input from affected parties through the stakeholder input process described above. This would allow for a more orderly process that would permit all parties to better monitor what is being proposed or implemented.

3. Prohibit the use of unique coding rules that apply only within that contractor jurisdiction

As discussed above, the coding and billing requirements are usually applicable only to a specific contractor, such as Palmetto or Noridian. No other Medicare contractor uses the Z-code system, which means that the laboratory has to establish a separate set of requirements for just those contractors. We recognize that each contractor can establish its own requirements with regard to the *medical necessity* of a test, but in this case we are looking at how that test is coded and billed for—and those are not requirements that contractors have the authority to develop. As a result, we believe that CMS should ensure the following three separate requirements are followed.

a. Limit the use of Z-codes to Molecular Diagnostic tests

The original purpose of the Z-codes was to help identify what particular *molecular diagnostic* test was being billed for, since it would not have been clear from the stacking codes alone. The need for Z-codes has diminished to a large degree because of more specific molecular diagnostic CPT codes. Even if contractors believe it is appropriate to utilize the Z-codes in the area of molecular diagnostics, these codes should not be used in other areas of laboratory testing where CPT codes exist that adequately describe the particular tests being performed. There is no reason that laboratories should need to obtain Z-codes (or other new unique types of codes developed by a single contractor), when doing other types of tests, such as drugs of abuse testing, panels, or any test for which a clear CPT code exists.

b. Prohibit the use of Miscellaneous codes when another more descriptive CPT code exists

Neither LCDs nor articles should be used to change basic, longstanding rules for coding and billing. It is particularly inappropriate for a contractor to direct a laboratory to use a NOC code over the laboratory's objection when another code exists that more appropriately identifies the tests that are being billed. These NOC codes, often called "Miscellaneous Codes," are just what that name implies: they are a non-specific, general description of a type of test. They are supposed to be used only when there is no other more specific code that identifies the test. In sum, where there is a CPT code that describes the test, the contractor should not be able to require that a NOC code be used.

c. Limit the use of "ad hoc" panel codes, unless the panel is one recognized by the CPT Code Manual or by HCPCS.

Finally, it seems inappropriate for a contractor to define new types of "panels" and establish new coding and billing requirements for such testing. For example, the Physician Directed Profile Testing Panel included in the Drugs of Abuse Article creates an entirely new "tiered" billing system, with new coding, billing and payment requirements. In fact, the long-standing policy for clinical laboratory test billing has been that unless there is a specific CPT code for a panel, a laboratory is to bill the individual codes applicable to the tests being performed. If there are three individual tests being performed, and there is no CPT code for that group of tests, then the individual tests are to be billed. Contractors have no authority to change those basic Medicare rules. Where there is a need for a specific panel of defined tests, and no CPT code exists, then CMS could issue its own HCPCS code for such a panel. ACLA would not object to that approach, and at least then, the policy would apply uniformly across the Medicare Program. Further, CMS should direct Palmetto to revoke its article establishing *ad hoc* payment levels for the Physician Directed Profile Testing that it created, based on its secret survey of laboratory costs.

d. Prohibit individual contractors from requiring specific coding rules that are inconsistent with CMS requirements.

As noted above, Palmetto is implementing coding rules that direct laboratories to use specific testing methodology for confirmatory testing, unless quantitative testing is specifically ordered by the physician. This will require laboratories either to change the way the test is performed in the Palmetto jurisdiction or to "downcode" all testing submitted to Palmetto for payment. Because these changes will likely become unnecessary as of January, 2016, it is unreasonable for Palmetto to require laboratories to makes such significant changes for one jurisdiction for such a short time period.

C. Conclusion

For all the reasons noted above, ACLA respectfully requests that CMS provide some direction to contractors on these issues. Failure to do so is unfair to laboratories, which are faced with these unique and often inconsistent billing requirements. The suggestions above will permit a more orderly, transparent, and fair process that will ultimately benefit all parties involved.

Thank you for your consideration. We look forward to speaking with you further about these issues.

Sincerely

Alan Mertz,
President

cc: Marc Hartstein
Tamara Syrek Jensen