BY ELECTRONIC DELIVERY

August 29, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Payment Policies under the CY 2015 Physician Fee Schedule and Clinical Laboratory Fee Schedule

Dear Administrator Tavenner:

The Coalition for 21st Century Medicine (C21) submits these comments to the 2015 Physician Fee Schedule proposed rulemaking to provide information helpful to the Agency's implementation of the clinical diagnostic laboratory test coverage provisions contained in the recently enacted Protecting Access to Medicare Act of 2014 (PAMA).[1]

In particular, Section 216 of PAMA, entitled *Improving Medicare Policies for Clinical Diagnostic Laboratory Tests*, requires that coverage policies for clinical diagnostic laboratory tests be made by the Local Coverage Determination (LCD) process.[2] C21 strongly supports PAMA's goals of increased transparency, involvement of stakeholder input, and expedited beneficiary access to covered tests.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. Given the C21's mission to facilitate development and commercialization of innovative diagnostic tests

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[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule; 79 Fed. Reg. 40318 (July 11, 2014).
[2] Section 1834A(g) of the Social Security Act.

to inform important patient management decisions, we have a keen interest in the transparency and consistency of the agency's policies for laboratory tests, which are increasingly vital to patient-tailored and effective medical practice.

Overview

C21 appreciates the continued efforts of the Centers for Medicare & Medicaid Services (CMS), and in particular the Coverage and Analysis Group (CAG), to support the development of appropriate coverage policies for advanced diagnostic laboratory tests. These policies are critically important to promote a revolution in genomic and proteomic medicine. CMS acknowledges in the proposed rule that "*the current LCD process can be lengthy for some of these innovative tests, which are technically complex*."[3] Efforts to streamline this process are therefore important.

Our coalition has worked closely with several Medicare Administrative Contractors (MACs) over the past 8 years, and many of our members have participated with Palmetto GBA in the development of the MolDX program.[4] Other members have worked with other MACs such as Novitas, which has also developed a program to review advanced diagnostic laboratory tests (ADLTs). Lessons learned from these experiences guide our comments in support of a clinically appropriate and streamlined coverage processes to provide uniform coverage for Medicare beneficiaries for advanced diagnostics. As part of this effort, we support the use of LCDs that reflect the knowledge gained from public comment.

I. Proposed LCD Framework

Section 216 of PAMA amended the Social Security Act by adding section 1834A(g) which reforms the issuance of local coverage policies by the MACs for clinical diagnostic laboratory tests. We agree with CMS that in PAMA Congress intended to create "*an expedited LCD process for clinical diagnostic laboratory testing.*"[5]

To implement PAMA, CMS has proposed a revised LCD process for all new clinical diagnostic laboratory test LCDs published on or after January 1, 2015. This LCD framework is consistent with the current requirements in MACs contained in Chapter 13, section 13.7.3 of the Medicare Program Integrity Manual (PIM). The proposed new process would allow any person or entity to request an LCD or the MAC to initiate an LCD regarding clinical diagnostic laboratory testing.

Under the proposed framework MACs would publicly post draft LCDs at any time, and allow for a 30 day open comment period at a minimum. Each draft LCD must present the criteria the MAC would use in establishing whether a specific clinical diagnostic laboratory test or a group of tests are covered or non-covered. The MAC would review, analyze, and take under consideration all public comments on the draft LCD. The MAC would be required to respond to

[3] 79 Fed. Reg. 40318, 40378 (July 11, 2014).
[4] http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCatHome/MolDx
[5] 79 Fed. Reg. 40318, 40379 (July 11, 2014).

all public comments in writing and post their responses on a public website. This process will apply to all clinical diagnostic laboratory testing LCDs except those that are being revised to liberalize an existing LCD or other limited reasons.[6]

II. Specific Recommendations

In enacting PAMA, Congress sought to increase transparency, involve stakeholder input, and expedite beneficiary access to covered tests. As part of this effort, we support the use of LCDs which include public comment for coverage decisions. We propose the following recommendations to strengthen and improve the proposed LCD process consistent with PAMA.

A. Coverage Advisory Committee Meetings

Under the current contractor process after the draft LCD is made public, MACs are required to hold an open meeting to discuss the draft LCD with stakeholders. In addition to the open meeting, the MACs must present the draft policy to the Carrier Advisory Committee (CAC) that represents the clinical expertise of its geographic area. CACs allow a unique opportunity for CAC members to provide practical information regarding a draft policy since they are providers delivering services in the community. They also help preserve the integrity of the comment process by encouraging face-to-face dialog between the MAC medical director and community stakeholders represented by CAC members.

In a change of policy, CAC presentations will no longer be required. CMS proposes that for draft LCDs where the MAC determines that a CAC meeting would contribute to the quality of the final policy, the MAC has discretion to take draft LCDs to the CAC. CMS explains that "*We believe CACs may be a better resource and used more efficiently in the development of LCDs if the MAC is able to select which draft LCDs are presented to a CAC for discussion, as opposed to taking all LCDs to the CAC.*"[7] However, the proposed rule lacks any criteria for when a diagnostic test would be appropriate for a CAC. Accordingly, a MAC might find that no LCDs required presentation to a CAC. In contrast, CMS has issued detailed guidance on "Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee"[8] and MedCAC meetings are widely and closely tracked by the healthcare community.

We are concerned that MACs may limit the use of CACs and deprive an opportunity for clinical expert input and a transparent process for stakeholders. Recently, MACs have used contracted outside part time medical directors or anonymous subject matter experts rather than their Contractor Advisory Committee members. The use of these special advisors and experts has not been transparent and their decisions and rationales are not subject to public comment.

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[6] Other exceptions to the proposed LCD rule include: being issued for a compelling reason; making a non-substantive correction; providing a clarification; making a non-discretionary coverage or diagnosis coding update; making a discretionary diagnosis coding update that does not restrict; or revising to effectuate an Administrative Law Judge's decision on a Benefits Improvement and Protection Act (BIPA) 522 challenge.

[7] 79 Fed. Reg. 40318, 40379 (July 11, 2014).

[8] http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10

We recommend that before a MAC can issue a non-coverage policy for a clinical laboratory diagnostic test, the MAC must refer the issue to a CAC. In the event the MAC involves the CAC in the development of an LCD, CMS would require that the public comment period be extended to allow for the CAC to be held before the final policy is issued.

In addition, we believe there is value in encouraging the MACs to have discussions with stakeholders via webinars if it is not possible to hold regular public meetings.

B. Blanket Non-Coverage LCDs

C21 is concerned that MACs may try to meet the LCD requirement through the use of "blanket" policies that non-cover a wide variety of tests. In the proposed rule, CMS states that the draft LCDs would need to outline the criteria the MAC would use when determining whether a "specific clinical diagnostic laboratory test" or a "group of tests are covered or non-covered." In our experience, these types of non-coverage policies are not based on clinical and scientific evidence. Our concern is that a blanket non-coverage policy could non-cover a new test, or group of new tests, without review of evidence. This is not the thorough scientific review on which LCDs are to be based according to Program Manual guidance to MACs. Nor does a blanket non-coverage policy allow new tests to be adjudicated on a claim by claim basis prior to the establishment of a formal LCD.

For example, the MolDX program operates under a master LCD which provides non-coverage for all laboratory tests which assess DNA, RNA, proteins, or metabolites, unless coverage is provided by MolDX.[9] The non-coverage of all un-reviewed tests for "DNA, RNA, proteins and metabolites" encompass nearly all laboratory tests – except perhaps for elements such as sodium and potassium. The actual range of tests and the lack of clinical justification for exclusion from coverage by the LCD is not stated; the opposite of what the public should expect from LCDs.

In the final rule, CMS should make clear that before a MAC non-covers a specific test, the MAC should thoroughly review the specific clinical and scientific basis for non-coverage for the individual test and issue a draft LCD with the MACs justification for such non-coverage.

C. "Compelling Reason"

The proposed rule allows contractors to by-pass the LCD process for "other compelling reasons" but the agency does not define what would constitute a compelling reason. The Program Integrity defines "Compelling Reasons" to include a highly unsafe procedure/device.[10] CMS should narrowly define "compelling reasons" and should provide additional examples of a

[9]Molecular Diagnostic Tests (MDT) (L33599). http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33599&ContrId=234&ver=5&ContrVer=1&Date=10%2f21%2f2013&DocID=L33599&bc=AAAAAAgAAAAAAA%3d%3d&

[10] Ch 13 LCDs 13.7.3 (4-9-04).

"compelling reason." For example, a "compelling reason" may exist when a MAC must issue an LCD establishing or limiting coverage in a certain way based upon a non-discretionary mandate from a supervising regulatory authority (e.g., CMS national policy) and when public comment cannot meaningfully affect the mandate."

D. Role of Coverage Articles

The proposed rule does not address the role of coverage articles. As part of MolDX, Palmetto issues articles addressing various other aspects of the LCD implementation process, including coding guidelines, billing and medical review procedures. MolDx has effectively set up other processes, such as coverage determinations by "article."

Recently, MACs have published articles of non-coverage for stated reasons such as a test "does not have sufficient data" or is "experimental" or "does not sufficiently impact physician decisions." In particular, MolDX has taken the position that non-coverage for "statutory reasons" can be made by articles and finds affirmation for this position in the Program Integrity manual.[11]

We believe that reasons such as a test "does not have sufficient data" or is "experimental" or "does not sufficiently impact physician decisions" are in fact medical necessity decisions, and as such should follow the LCD process. CMS should make clear to its MACs that statutory exclusions include limited categories such as (a) screening tests in the *absence* of symptoms and (b) other titular statutory exclusions such as eyeglasses, and that CMS should direct MACs that "lack of enough evidence" is a statutory exclusion of the reasonable-and-necessary category, the exact category for which the LCD process is required.

E. 45-Day Comment Period

Currently once a draft LCD is published, at least 45 calendar days are provided for public comment. CMS proposes to require only a 30-day public comment period after a proposed LCD is published.

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[11] Palmetto GBA has coverage articles on their MolDX website that list excluded tests. http://www.palmettogba.com/palmetto/MolDX.nsf/docsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Excluded%20Tests?open&Start=1&Count=100&Pg=1&navmenu=Browse^By^Topic. While these tests are excluded as not meeting a statutory benefit category, the basis for the exclusion is often based on a lack of clinical utility or insufficient literature. For example, the coverage article for 9p21 Genotype Test notes:

> "Palmetto GBA has completed a review on the 9p21 Genotype Test. To date, there is insufficient evidence to support the required clinical utility for the established Medicare benefit category. Therefore, the 9p21 test is a statutorily excluded test." Coding and Billing Guidelines (M00082). http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Excluded%20Tests~8X6KQT1088?open&navmenu=Browse^By^Topic.

Based on our experience at the local contractor level, 45 days is often required to respond to clinical and scientific policy questions addressed in the draft LCD. While a laboratory may have this information readily available if they initiated the request for coverage, under the current and proposed process any person or entity is allowed to request an LCD (for example, a competitor) and a MAC may release a complex draft LCD with no prior warning to the public. Therefore, it is not reasonable that stakeholders and members of the public would be prepared to review, research and respond to an unexpected LCD in 30 days. Often, national associations may want to comment on the LCD, but require a longer timetable than several weeks. In point of fact, CMS acknowledges in the proposed rule that in some event members of the public may not be able to submit comments within the 30 calendar day window so that a MAC would have discretion to extend the comment period.

CMS models the 30 day comment based on the statutory requirements for the National Coverage Determination (NCD) process which CMS believes is generally adequate to allow for robust public comment. The NCD is a useful model but differs in several key respects from the LCD process. NCDs follow a publicly posted "tracking sheet" that lists the topic and the expected date of a proposed and final decision which often is posted a half year in advance of any release of a proposed decision. Additionally, the NCD process normally involves two separate 30 day comment periods (initial period upon opening of the NCA and a second upon posting a proposed coverage decision memorandum). The process for communicating NCD is significantly more sophisticated and robust, using tools such as listserv messages to inform stakeholders of newly opened NCD. Such tools are not uniformly used by contractors. Finally, CMS only opens 10 to 12 NCDs a year so there are far fewer decisions at the national level. Under the PAMA provisions each MAC jurisdiction will now be required to do LCDs for clinical diagnostic laboratory test so the LCD volume will be drastically higher than the NCD volume.

We recommend that the MACs continue with the present 45-day process. This would be consistent with the time period that CMS provides the MAC to take all comments under consideration, prepare responses to those comments, and develop a final policy. We also note that Congress did not mandate a change to comment period timeline or make reference in PAMA to the statutory timeframe for the 30 day NCD comment period.

F. <u>MAC LCD Website</u>

Under the proposed LCD framework labs could potentially be attempting to track and comment on multiple draft LCDs in numerous jurisdictions. C21 recommends that CMS and the MACs should work together to develop electronic tools for the MACs to communicate new LCD policies. Because the burden on stakeholders is much higher (some needing to monitor multiple contractor websites for numerous new LCD) and the short time frames upon which to submit comments, the risk of insufficient notice of a draft LCD policy is quite high. We recommend that the MACs be required to use RSS or Listserv messages to communicate automatically that new policies are posted for review. Alternatively, a site similar to www.regulations.gov that can be used to collect and aggregate all new policies from all contractors into a single location could be jointly used by all MACs.

G. Opportunity to Interact with Contract Medical Directors

It is critical for laboratories developing innovative advanced diagnostic tests to have the opportunity to interact with Contract Medical Directors (CMD) to present clinical data and discuss coverage policies. We commend MolDX and other MACs for their openness in meeting with laboratories as they are developing and validating new tests, and prior to the diagnostic test clinical evidence being reviewed and evaluated by the CMD.

Advanced diagnostic laboratory testing is a field that is rapidly evolving in both the underlying technology and application of testing for the management of patients. Like private payer medical directors, CMDs are not expected to know the details of underlying technology and specific clinical uses of every ADLT. However, these CMD interactions enable an opportunity for peer-to-peer education between Lab Directors and CMDs, and for ADLTs to be put into the context of the clinical scenario in which they are utilized.

Some laboratories in certain MAC jurisdictions do not have the same opportunities to meet with CMDs outside of public LCD Contractor meetings which are held infrequently. Part of any coverage process reform should involve a commitment to meet with laboratories in person or via phone similar to the process at the Food and Drug Administration (FDA).

H. LCD Effective Date

CMS proposes to make the final LCD effective immediately upon publication. This effective date would be different than under the current LCD process which includes a notice period of at least 45 calendar days before a final LCD is effective). Again CMS models this change on the NCD process with a goal to make tests available to beneficiaries more quickly.

We support the goal of providing access to the beneficiary immediately upon coverage. However, we would recommend retaining the 45-day effective period for LCDs that non-cover or reduce coverage. This allows the providers and patients time to review the final decision and transition care as appropriate. It also allows stakeholders time to correct mistakes that may have occurred in the MAC publication process, which has less dedicated staff than the NCD and federal rulemaking processes.

III. CMS Should Enhance the Uniformity of Coverage Decisions

As noted, C21 has extensive experience with MAC claims processing for ADLTs, and with the MolDX program in particular since 2011. We have supported the concept of a specialized coverage program for advanced diagnostic test coverage determinations. We appreciate Palmetto's efforts to envision, launch, and continually enhance the MolDX program.

In the proposed rulemaking, CMS has not addressed its authority in section 216(g)(2) of PAMA to designate one or up to four MACs to establish coverage policies and process claims for clinical laboratory tests. However, the agency does encourage "*MACs to collaborate on such*

policies across jurisdictions[12]." As CMS considers whether to implement this authority we recommend that the agency solicit public input through a notice and comment proposed rulemaking.

C21 urges CMS to consider public input on the appropriate process and criteria to consolidate the MAC jurisdictions that process laboratory claims. Laboratory medicine is rapidly evolving and its advancements require specialized knowledge to evaluate these new technologies and engage with the laboratory industry. More importantly, the increasing number of ADLTs that are billed to only one contractor nationally provides even greater rationale for limiting the number of contractors that process these claims to a specialized few that have or can develop structured processes for coverage determination and claims processing. MAC consolidation with clear established standards could increase beneficiary access to new tests and provide administrative simplification for contractors and laboratories.

Conclusion

C21 strongly supports PAMA's goals of increased transparency, involvement of stakeholder input, and expedited beneficiary access to covered tests. We believe the recommendations noted above will strengthen the proposed LCD framework and are consistent with the PAMA goals of increased transparency, greater stakeholder input, and expedited beneficiary access to covered tests.

The C21 would be pleased to offer further explanation or clarification of any of its comments should CMS find such information useful in reaching its decisions for PAMA implementation.

Sincerely,

John W. Hanna
Chair, C21 Reimbursement & Policy Workgroup

[12] 79 Fed. Reg. 40318, 40379 (July 11, 2014).