CLINICAL LABORATORY
FEE SCHEDULE REFORM
COALITION

August 28, 2014

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1612-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Lab Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY2015 [CMS-1612-P]

Dear Administrator Tavenner:

The Clinical Laboratory Fee Schedule (CLFS) Reform Coalition is pleased to submit comments in response to the above-captioned Proposed Rule addressing payment policies under Medicare Physician Fee Schedule. Our comments specifically address the proposal to revise the Local Coverage Determination (LCD) Process for clinical diagnostic laboratory tests.

The CLFS Reform Coalition is a collaboration of diagnostic/laboratory stakeholders formed with the goal of facilitating modernization of the Medicare CLFS to reflect market-based transactions and the value of the information furnished by clinical diagnostic laboratory tests.

The reform provisions included in Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014 make significant and fundamental changes to the CLFS and to the coverage provisions for clinical diagnostic laboratory tests. PAMA Section 216 requires that any "coverage policy with respect to a clinical diagnostic laboratory test" be developed and promulgated in accordance with the well-established LCD process. We are pleased that CMS is taking the opportunity of the Medicare Physician Fee Schedule Proposed Rule for CY2015 to propose a modernized and streamlined LCD development process for clinical diagnostic laboratory tests.

We agree that basing the revised process on successful components of the National Coverage Decision (NCD) process is wise and presents a solid basis for continuing to improve the LCD process overall. At the same time, there are a few areas in the proposal that present CMS with an opportunity to further improve the LCD process.

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1. Length of the Comment Period: 45 versus 30 Days

The proposed process provides a 30 day public comment period rather than the minimum 45 day comment period currently required under the LCD process. CMS notes this is consistent with the length of time allowed for comments under the NCD process. We are concerned that 30 days may be insufficient time for stakeholders to respond meaningfully. First, although 30 days may be sufficient for submission of comments under the NCD process, there are typically two such 30 day comment periods for each NCD—i.e., a first 30 day period on the opening of the NCD process to solicit comments to help inform CMS's initial consideration and a second 30 day period upon publication of the Preliminary Decision Memorandum to solicit comments on the proposed coverage policy. Therefore, stakeholders typically have a combined 60 days to develop and submit comments during the consideration of an NCD.

In addition, because laboratories may operate across the country, they must monitor a number of contractor websites to identify when a draft LCD has been posted for comment. Often, the drafts are not identified until 1 or 2 weeks after the draft LCD initially was posted. With a 30 day comment period, this leaves little time for stakeholders to review the draft policy, develop an appropriate response—including gathering published clinical evidence to support the comments—obtain internal organizational approval, and finalize and submit the comments.

Therefore, to allow for sufficient time to develop productive comments on draft LCDs for clinical diagnostic laboratory tests, we recommend that CMS maintain the current 45 day period for notice and comment.

In addition, we urge CMS to develop a user-friendly, nationally-established notification process that will allow stakeholders to be notified whenever draft LCDs become available for review. A consolidated electronic portal, similar to websites such as http://www.regulations.gov, can serve as an efficient and effective tool for collecting and making available in one place all proposed LCDs together with comments responding to the drafts. In addition, we recommend that CMS establish a LISTSERV to provide notice of new draft LCDs that have been posted (similar to LISTSERV notices that advise subscribers about changes in NCDs). This will reduce potential lag between the time an LCD is posted and the time stakeholders become aware of the posting.

2. Concerns about Bypassing the LCD Process for "Compelling Reasons"

We are concerned about CMS's proposal to allow MACs to issue LCDs through a different process than the one proposed in the Proposed Rule when "compelling reasons" are presented. Although we understand the goal of foreseeing unusual circumstances where the proposed LCD process might not be feasible, we believe it important for CMS to provide guidance to the MACs as to what kinds of circumstances would constitute "compelling reasons."

CMS should provide guidance that a "compelling reason" for a MAC to issue an LCD without following the proposed LCD process is when the MAC is required to establish or limit 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.

Without clear guidance on what is intended by "compelling reasons," MACs could use this exception to the LCD process to publish LCDs or similar documents which make reasonable and necessary decisions without going through the appropriate notice and comment process comprehended under the Proposed Rule.

3. Requirement to Follow the LCD Process Whenever a Policy Statement "Restricts Coverage"

We would also encourage CMS to define the term "restricts coverage." For example, a coding edit that precludes payment for certain combinations of procedure and diagnosis codes clearly restricts coverage. **CMS should be clear that any policy "restricts coverage" if it would result in a denial of coverage of a service based on the reasonable and necessary criteria under Soc. Sec. Act § 1862(a)(1)(A)**. All such policies are LCDs and must be developed and issued through the proposed process and communicated in an LCD document. Other means of communicating such changes, including but not limited to "coding" articles, web postings or any means other than through publication of an LCD, are unacceptable.

4. Obtaining Clarifications on Draft Policies: Open Public Meeting versus Webinar

We support CMS' intent to use modern electronic means of communication to streamline the LCD process. However, these tools must be appropriately managed to meet this intended goal.

We agree that MACs can solicit feedback and share their analyses electronically without requiring open, public meetings to obtain such feedback. However, we note that the open public meeting process does more than simply serve as a forum for stakeholders to make presentations in support of or in opposition to draft LCDs. The open, public meeting process allows stakeholders to interact with other stakeholders and to ask clarifying questions of the contractor. These meetings provide information that enriches the comments to the contractors. **To allow for continued interaction and an opportunity to ask clarifying questions, we urge CMS to require contractors to hold a webinar early in the comment cycle of a draft LCD in which interested stakeholders can participate.** A webinar is much easier and less costly to set up than an open meeting so would seem to be an ideal approach to maintain some of the benefits of the open public meeting process while cutting out the more costly and cumbersome steps.

5. Laboratory MAC Consolidation

CMS did not propose any changes to its current MAC structure in the Proposed Rule. PAMA Section 216 provides the Secretary the authority to consolidate lab coverage decisions or both coverage decisions and claims processing decisions into 1 to 4 MACs. This is a structure similar to that used to develop LCDs and process claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). While the DME-MAC model is generally recognized as a successful one, we would encourage CMS to proceed cautiously while deliberating whether to exercise the authority to consolidate lab coverage development or claims processing functions and, if so, how many laboratory MACs should be the target number to take advantage of concentrated expertise and efficiencies while maintaining some flexibility consistent with the local coverage process.

Therefore, we recommend that changes to the MAC structure for clinical diagnostic laboratory coverage (or coverage and claims processing) first be vetted through notice and comment rulemaking.

6. Standards of Evidence

We appreciate that CMS did not propose any changes to the acceptable levels of evidence required as a part of the LCD process. 42 CFR § 410.32 requires that the treating physician use test findings in the management of the patient. We support this requirement that clinical diagnostic laboratory tests be useful to inform treating physicians' patient management decisions and urge CMS to instruct the MACs that this is an appropriate standard for assessing coverage for clinical diagnostic laboratory tests.

However, some MACs have recently expanded coverage requirements for clinical diagnostic laboratory tests by requiring proof of "clinical utility" as demonstrated by both changes in clinical decision making and improvements in health outcomes. Requiring proof that a clinical diagnostic laboratory test improves health outcomes presents an unreasonably high bar for coverage for most clinical diagnostic laboratory tests. Most clinical diagnostic laboratory tests inform diagnoses, predict clinical outcomes associated with a disease state, predict or assess responses to treatment, or identify risks associated with treatments. It is the treatments which can result in improved outcomes, not the diagnostic tests *per se*.

Although one should have a well-grounded basis for concluding that a change in patient management should lead to an improvement in health outcomes, for many diagnostic tests, proving an impact on health outcomes is not feasible. The time and cost involved may be too great, and the technology may have advanced to a different platform by the time the study is completed.

Unfortunately, those MACs requiring that a diagnostic test itself demonstrate improved health outcomes are not recognizing the appropriateness of change in patient management as an

outcome for clinical diagnostic laboratory testing and are sending chilling messages to those investing in new clinical diagnostic laboratory tests that Medicare coverage will be denied for a clinical diagnostic laboratory test that does not demonstrate an improvement in health outcomes.

We recommend that CMS make clear that, as a part of the LCD process, "clinical utility" is demonstrated whenever a diagnostic test is used to inform patient management decision making.

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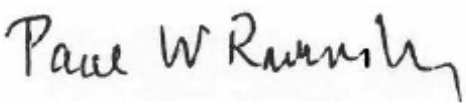
If you have any questions about our comments, please contact me at 202-756-8794 or by e-mail at pradensky@mwe.com. Thank you.

Sincerely,



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