



COLLEGE of AMERICAN PATHOLOGISTS

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Janet Brock
Director, Division of Policy Coordination
and Implementation

Dear Ms. Jensen and Ms. Brock,

On behalf of the College of American Pathologists (CAP), thank you for the recent opportunity to provide feedback to CMS on Medicare's Program Integrity Manual and revisions to the local coverage determination (LCD) process (Rev. 863, 02-12-19).

The CAP is pleased that CMS adopted some of our recommendations regarding Contractor Advisory Committee (CAC) meetings, including making them open and providing a summary of the evidence that was considered by the contractor during the development of a LCD, as well as adding an explanation of the rationale that supports a determination. While we believe these changes may help by increasing transparency in the LCD process, we are concerned that they have come at the expense of meaningful opportunity for CAC members to provide input on the realities of practice in their local jurisdictions. The reshuffled portfolio of meeting formats that are now available, including "touch base" and open public meetings, has left CAC members without a pertinent opportunity to relate proposed coverage policies to their practical role as CAC members, which is intrinsically and necessarily their expertise as local practitioners, rather than as technical subject matter experts.

Specifically, as we discussed on our call, "touch base" meetings do not include coverage policy discussions and open meetings, while necessary for public comment and testimony, are ill-suited for CAC members to address and interactively discuss with the contractor medical directors, the realities of practice and the needs of patient populations within specific jurisdictions, which are critical for shaping local coverage determinations. We appreciate CMS's focus on flexibility and interest in spreading best practices to different jurisdictions. Nonetheless, we have become progressively concerned that this reorganization of the LCD process has "thrown the baby out with the bathwater" in seeking to parallel the very differently resourced NCD process, and we respectfully urge CMS to consider our recommendations, which are summarized below and followed by more detail.

Primary recommendations:

1. Reestablish CAC meetings as a venue for CAC members to share their relevant expertise, which is primarily in representing the local practice community, and secondarily in discussing relevant evidence as technical subject matter experts.
2. Require MACs to hold CAC meetings for the purpose of soliciting CAC consultation prior to the development of all new local coverage policies. It is a positive step to solicit CAC member input before development of a coverage policy, but CAC members are left out of the process altogether if a MAC decides not to hold a CAC meeting.

Secondary recommendations:

3. MACs should select CAC meeting times that offer the greatest opportunity for participation by CAC members (MACs should work with CAC representatives to determine scheduling times).
4. Give CAC members more time and more meaningful context in which to review materials prior to CAC meetings.



5. Meeting materials provided to CAC members should include at a minimum the specific hypothesis/rationale/proposal for coverage/non-coverage under consideration, rather than simply providing a bibliography of evidence and a voting questionnaire with minimal to no context.
 6. Improve audio technology for teleconference meetings.
1. **CAC Meeting Format:** An essential element of local coverage policy is the patient and practitioner populations, and their needs and capabilities within specific jurisdictions. CAC members are a critical source of this information for MACs. Under the new LCD guidelines, CAC meetings are no longer a venue for CAC members representing the local practice community to interact with MACs on coverage issues. The sole purpose of CAC meetings now is to obtain advice from subject matter experts (SMEs) regarding the strength of published evidence, and have CAC members vote on the evidence. The selection of CAC members differs radically (and appropriately) from that of MEDCAC, and their roles need to align with the needs of the corresponding process. MEDCAC members are selected from a broad pre-existing panel for their national subject matter expertise to participate in assessing/formulating NCDs. In contrast, a well-functioning LCD will be reflective of the circumstances of practice in the jurisdiction for which it is developed, and the uniquely necessary resource for this is a body reflective of the local practice community. This is how CAC representatives are selected, but this is no longer how they are utilized.

As above, the implicit redefinition of CAC representatives as SMEs represents both a mischaracterization of their role and a loss of what they uniquely and necessarily bring to the local coverage process. The CAC members reflect the local practice community and provide unique insight into the actual nature of local practice and needs of local patient populations. Under the current structure these insights and information has no effective venue.

Recommendation: Restore a CAC meeting environment that encourages CAC member participation as local advisors from the practitioner community by working with the MACs, to reestablish the CAC member advisory role in CAC meetings (*as historically intended*) rather than SMEs.

2. **CAC Meeting Frequency:** Under the new LCD guidelines, the holding of CAC meetings is at the sole discretion of the MACs, which means CAC members may be left out of the LCD process altogether if a MAC does not choose to hold a CAC meeting. As previously stated, this lack of a uniform process denies MACs valuable information about the practice environment in their local jurisdiction and we therefore recommend restoring uniformity to the holding of CAC meetings.

Recommendation: Change the text in Chapter 13, §13.5.2.2 to read, “The frequency of the CAC meetings is at the discretion of the MAC and will be based on the appropriateness and on the volume of LCDs that require CAC consultation as part of the LCD process. **However, contractors shall hold CAC meetings for the purpose of soliciting CAC consultation prior to development of all coverage policies.**”

3. **CAC and Open Meeting Logistics:** CAC meetings, when held, are now envisioned as aligning with the MEDCAC process. However, there are distinct and substantial differences between these two processes, in resources and purposes. For example, only published evidence relevant to a coverage consideration is allowed to be discussed at CAC meetings, whereas MEDCAC hears from ALL stakeholders, including practitioners, patients, and advocacy groups. Further, MEDCAC meetings take place over an entire day while CAC meetings are often brief, lasting anywhere from minutes to hours. CAC members are also typically given only 2 weeks to prepare for meetings and receive only an unstructured bibliography of the evidence being considered by



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the MAC, while MEDCAC panel members receive a dossier of materials well in advance in order to prepare for a meeting.

Additionally, CAC meeting times have moved from evenings to daytime, in part to accommodate multijurisdictional meetings across time zones. However, daytime meetings impede participation by CAC members who are practicing physicians.

Virtual meetings are becoming the standard for CAC meetings and, when held, sometimes present audio challenges, depending on the type of technology that a MAC uses, making it difficult to hear speakers clearly and for the audience to ask questions.

Finally, MAC medical directors vary in their skills as meeting hosts, sometimes failing to clearly enunciate a speaker's name, place of practice, or other relevant information, and often failing to repeat audience questions, so that those participating by phone can hear.

Recommendations:

1. Consider scheduling times that are most conducive to CAC member participation (MACs should work with their CAC representatives to determine scheduling times)
2. Give CAC members more time (e.g. one month) to review meeting materials/evidence prior to CAC meetings
3. Meeting materials provided to CAC members should include at a minimum the specific hypothesis/rationale/proposal for coverage/non-coverage under consideration, rather than simply providing a bibliography of evidence and a voting questionnaire with minimal to no context
4. Improve audio technology for conference call meetings.

Thank you again for allowing us to express our concerns and recommendations on the recent revisions to PIM Chapter 13 and the LCD process. Should you have any questions regarding our comments, please do not hesitate to contact Nonda Wilson, MS, at nwilson@cap.org, 202-354-7116.

Sincerely,

College of American Pathologists