Lee Fleisher, MD
Chief Medical Officer and Director
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Fleisher:

The undersigned organizations write to share concerns with revised processes implemented by the Centers for Medicare and Medicaid Services (CMS) in October 2018 regarding development and implementation of local coverage policies. Sound coverage development and implementation processes support Medicare beneficiaries' access to medically necessary and appropriate health care services. However, our experience leads us to have concerns regarding lack of transparency and deteriorating and haphazard stakeholder engagement, as further detailed below.

Many of the undersigned organizations – as well as affiliated representatives of Carrier Advisory Committees (CACs) – have raised these concerns with Medicare Administrative Contractors (MACs) and the Coverage and Analysis Group (CAG) at CMS over the past three years. While we appreciate the willingness of these teams to work with us on issues on a case-by-case basis, we believe wholesale changes are needed to effectuate necessary improvements, and we appreciate the opportunity to share our concerns and recommendations below.

Lack of Opportunity for Public Notice and Comment

Our organizations are concerned that MACs are establishing policy without providing adequate opportunity for notice and comment. This can occur, for example, when contractors issue local coverage articles (LCAs) that include diagnosis and billing codes that establish coverage pursuant to a national coverage determination (NCD) or local coverage determination (LCD). While we recognize that CMS intentionally moved such codes to LCAs to reduce barriers to making small coding changes to coverage policies – particularly routine changes in coding that might occur on an annual basis – we note that coverage often comes down to whether a specific HCPCS or ICD-10 code is specified in an LCA. Now that the codes have been transitioned into LCAs, there are few opportunities for comment, which increases the risk that coverage is inappropriately foreclosed based on the failure to include an individual code in an article. While there are some cases when LCAs are issued at the same time as draft LCDs, when MACs may seek notice and comment on both the draft LCD and LCA concurrently, there have been too many cases where there are no comment opportunities available for new or revised LCAs.[1] And while increased MAC responsiveness under the new process may enable speedy resolution, such timely resolution is not guaranteed, and public notice and comment could prevent potentially harmful oversights from being effectuated in the first place.

[1] A few examples include:

- Billing and Coding: Complex Drug Administration (A58544)
- Billing and Coding: Wound Care & Debridement – Provided by a Therapist, Physician, NPP or as Incident-to (A53296)
- Removal of Benign Skin Lesions (A54602)
- Tetanus Immunization (A58872)
- Use of Amniotic Membrane Derived Skin Substitutes (A56155)

Furthermore, we also note that there is no requirement that MACs implement a notice period that applies before a standalone LCA takes effect. As such, when MACs issue new standalone LCAs, providers can be subject to essentially new coverage requirements and restrictions without any time to familiarize themselves with the new requirements, educate billing and coding staff, and/or update any IT systems to accommodate the changes. Such an outcome places significant burden on providers and increases the risk of improper billing, not to mention the harm to patients if LCAs inappropriately restrict coverage of medically necessary services.

Challenges with Contractor Advisory Committee Engagement

Contractor Advisory Committee (CAC) members serve as a vital link between MACs and health professionals in each jurisdiction. They offer their on-the-ground experience with current medical practice, coding, and billing to evaluate and advise on coverage policies, including their experience with complicated medical procedures and policy implementation, and they have historically engaged with contractor medical directors (CMDs) and other MAC officials through open lines of communication and vibrant and productive relationships. As part of their work, CAC representatives regularly coordinate with their specialty societies, like our own organizations, as they provide formal and informal input to the Medicare contractors. Our organizations are regularly in contact with our respective networks of CAC representatives and engage with them to ensure that they are supported and that our specialties' voices are represented in the development of important coverage policy.

Since the new processes were implemented in October 2018, our organizations have received increased reports of challenges with MACs' engagement with CAC members, including a weakening and devaluation of the relationship between CMDs and CAC members. Prior to the October 2018 changes to the LCD process, the full CAC would meet regularly, 3 to 4 times a year depending on jurisdiction. Meetings typically occurred on a Saturday or after business hours, in-person, and at a central location. This allowed for active participation by CAC representatives. Under the revised process, meetings are now occurring less frequently, typically as conference calls that take place on weekday afternoons or early evening, or in more difficult-to-reach locations. These meetings are scheduled without consultation of CAC members regarding their availability or ability to participate, despite guidance from CMS that MACs must work with CAC members to select a meeting location that will optimize participation. The revised approach to scheduling creates barriers to participation and active engagement, particularly for clinicians who see patients. Furthermore, Medicare contractors appear to be holding more targeted meetings focused on narrow topics, rather than convening the full CAC. This approach creates that risk that CAC members may be inappropriately excluded if a contractor is not aware of or fails to prioritize a nexus between the topic and a given specialty.

Even more concerning, however, is how MACs have undermined the advisory role that CAC members were intended to serve. According to Chapter 13 of the Medicare Program Integrity Manual:

> The purpose of the CAC is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MAC and the healthcare community. CAC members should serve in an advisory capacity as

representatives of their constituency to review the quality of the evidence used in the development of an LCD.[2]

To our dismay, MACs are failing to rely on CAC representatives to perform this function, resulting in CAC members being effectively cut out from the evidence review process. In one example, rather than requesting that CAC representatives review the quality of the evidence collected to support the development of a draft LCD addressing wound care, a CMD convened a separate panel of "subject matter experts" to review and assess evidence. This panel deliberated during a scheduled CAC meeting, yet CAC representatives were not given the opportunity to comment on the evidence or contribute to deliberations. Notably, even among the panelists, there was no meaningful evidentiary discussion.

In another example, in the development of a multi-jurisdictional LCD, two MACs issued a draft LCD without sharing evidence or soliciting feedback from CAC members on the quality of the evidence. CAC members were only provided an opportunity to offer feedback in the public meeting required after issuance of a draft LCD, rather than through a separate CAC meeting, as envisioned in Chapter 13 of the Medicare Program Integrity Manual. Furthermore, our CAC representatives report that even when their feedback is offered or questions are raised in such meetings, their feedback does not appear to be meaningfully considered. Such actions illustrate how contractors have de-prioritized CAC engagement and devalued their advisory responsibilities.

Meaningful engagement by CAC representatives enables contractors to benefit from the education, experience, and expertise of individuals who engage in patient care on a daily basis and can put evidence into context based on their practice area. Failure to uphold the advisory role of CAC members can result in reduced access to care, harm to Medicare beneficiaries, and unnecessary burden on health care practitioners.

Finally, we are concerned that MACs are attempting to represent multijurisdictional meetings with subject matter experts as CAC meetings – even going so far as to call them "multijurisdictional CAC meetings." However, we disagree that such subject matter experts serve as CAC representatives or that these meetings stand as CAC meetings. According to Chapter 13 of the Medicare Program Integrity Manual, section 13.2.4.3, MACs are required to establish one CAC per state or jurisdiction, or may have a multi-jurisdictional CAC, with representation from each state. Furthermore, based on longstanding precedent and widespread common understanding, CAC members are recommended by their specialty societies. Indeed, Chapter 13 states that CAC members "should serve . . . as representatives of their constituencies" and that MACs "shall endeavor to ensure each specialty that serves on the CAC shall have at least one member and a designated alternative approved by the MAC." CAC representatives are also understood to typically serve extended terms of at least a year (and most commonly several years), over which time they regularly develop strong working relationships with contractor medical directors. The ad-hoc nature of the multijurisdictional meetings, where subject matter experts serve on a one-time basis, is not consistent with the established and ongoing nature of CAC appointments. We are concerned that contractors are representing these multijurisdictional meetings as CAC meetings in a manner that could ultimately serve to obviate the role of traditional CAC meetings and – in the process – the advisory role of CAC representatives.

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[2] Centers for Medicare & Medicaid Services. Chapter 13 – Local Coverage Determinations. *Medicare Program Integrity Manual.* Rev. 863, 02-12-19. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf. Accessed October 12, 2021.

Process Challenges and Lack of Transparency Regarding Coverage Policies

As our organizations have navigated the updated LCD development and reconsideration processes, we have been disappointed to find that, while MACs are held to certain timelines as outlined in Chapter 13 of the Program Integrity Manual, there are several stages for which no timelines are specified, leaving little transparency for stakeholders as they follow contractors through the review and determination process. For example, a MAC has 60 days to determine if a new LCD request is complete or incomplete, but once the determination is made that the request is complete, there is no required timeframe for the MAC to develop and issue a draft LCD. The same is true for requests for reconsideration – a 60-day timeline applies for the MAC to determine if the reconsideration request is valid, but there is no requirement regarding the timeline for reissuing a draft LCD. The lack of strict timelines leaves stakeholders in limbo as they may wait months or even years for MACs to take action in response to complete and valid requests.

Our organizations have also observed an increasing reliance by MACs working collectively across jurisdictions to convene subject matter experts on policies of interest. However, there is little clarity on when and how such panels are convened, or how individuals are selected to serve in these roles. In several instances, we have only learned of the panels by happenstance, and it is often unclear how panelists are identified and vetted to verify their level of expertise.

Recommendations

To address the concerns detailed above, we offer the following recommendations:

- ***CMS should ensure that any new LCAs, or any updates reflecting non-routine changes in coding, are subject to notice and comment.*** Such a change would ensure that stakeholders have adequate opportunity to inform the diagnosis and billing codes that truly define a coverage policy. However, to preserve some of the efficiencies sought by CMS, routine revisions to LCAs that simply reflect annual updates to specific HCPCS or ICD-10 codes would not require notice and comment.
- ***CMS should require contractors to provide a public notice period before new or revised LCAs take effect.*** Such a notice period would allow providers time to prepare for changes in coverage policies that the LCAs may require.
- ***CMS should ensure meaningful engagement of CAC representatives through policies that establish minimum meeting frequency requirements for the full CAC to meet, and minimum CAC member participation thresholds, and requirements for MACs to provide CAC representatives opportunity to review and advise on evidence prior to the issuance of a draft LCD. CMS should also require contractors to allow all CAC representatives to comment, ask questions, and actively participate during multi-jurisdictional CAC meetings.*** Implementation of such policies would facilitate MAC engagement with CAC representations and reaffirm and effectuate the advisory role of CAC members.
- ***CMS should update Chapter 13 of the Medicare Program Integrity Manual to provide greater clarity and transparency regarding timelines for developing and issuing draft LCDs following a request for a new LCD or a reconsideration request. MACs should be required to issue draft LCDs within 180 days of a determination that a request is complete or valid.*** Stakeholders would benefit from greater transparency and certainty that MACs will act in an expedited manner to address harmful gaps in coverage policy that may exist in the absence of a new or revised LCD.

- ***CMS should require contractors to notify all CAC members of the convening of expert panels, and to offer CAC representatives the opportunity to work with their societies to nominate panelists. MACs should also apply objective criteria in the vetting and selection of experts.*** Formalizing a nomination and selection process for the establishing of expert panels would increase transparency, support stakeholder engagement, and ensure that selected panelists are appropriately qualified to advise on the applicable coverage policies.
- ***CMS should implement and publicly report performance metrics that hold MACs accountable for adhering to applicable LCD timelines, standards for CAC engagement, and other process improvements detailed above.*** Establishing performance metrics and implementing public reporting would increase MACs' incentives for maintaining high performance levels, while also increasing transparency for the stakeholder community.

Thank you for your consideration of our concerns and recommendations. We look forward to working with you and your team to achieve resolution on the issues we raised above. If you have any questions, please feel free to reach out to Chad Appel, JD, Director of the Center for Professional Advocacy at the American Podiatric Medical Association, at cappel@apma.org or (301) 581-9234.

Sincerely,

American Podiatric Medical Association
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Ophthalmology
American Association of Orthopaedic Surgeons
American College of Foot and Ankle Surgeons
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Occupational Therapy Association
American Orthopaedic Foot & Ankle Society
American Physical Therapy Association
American Society of Hand Therapists
American Society of Podiatric Surgeons
College of American Pathologists
Alliance of Wound Care Stakeholders
Coalition of State Rheumatology Organizations