AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(N-21)

Introduced by:	American College of Rheumatology, American Academy of Allergy, Asthma & Immunology, American Academy of Dermatology, American Academy of Ophthalmology, American Society of Dermatopathology, Association for Clinical Oncology, Society for Investigative Dermatology
Subject:	Stakeholder Engagement in Medicare Administrative Contractor Policy Processes
Referred to:	Reference Committee B

Whereas, Contractor Advisory Committees (CACs) and other stakeholders have played an important role in review of policy changes put forth by Medicare Administrative Contractors (MACs); and

Whereas, The Local Coverage Determination (LCD) process historically has considered comment and input from a Contractor Advisory Committee, and, in most cases, LCDs require a 45-day comment period; and

Whereas, Our AMA has strong policy in support of robust MAC processes for transparency and stakeholder engagement, including engagement of CACs, in reviewing Local Coverage Determinations (LCDs), and in support of local Medicare CACs in their role as policy advisers; and

Whereas, The 21st Century Cures Act included provisions intended to modernize and strengthen the LCD review process and ensure transparency and stakeholder engagement in MACs' decision making processes, and the Medicare Program Integrity Manual Chapter 13 finalized requirements of the LCD modernization process; and

Whereas, The 21st Century Cures Act and related regulations demonstrate the intent of Congress and CMS to ensure processes for meaningful stakeholder review and input for substantive policy changes; and

Whereas, Some MACs have used Local Coverage Articles (LCAs) to unilaterally issue policy changes that might have the effect of restricting coverage or access, without an attached, supportive LCD, arguing they are only providing billing instructions, when in reality changes could reasonably be expected to have the effect of restricting coverage. In most cases LCAs are coupled with LCDs or a National Coverage Determination (NCD), and the LCA only provides such additional coding/billing or other information as may be needed to implement the coverage policy determined in the LCD or NCD; and

Whereas, MACs issuing changes in coverage policy through LCAs without issuing a proposed LCD are circumventing the notice-and-comment period required of LCDs and other substantive rulemaking, bypassing the stakeholder engagement and transparency in decision making that was intended by Congress; and

Whereas, By issuing LCAs without associated LCDs these MACs are denying stakeholders a meaningful opportunity to review data and decision making criteria, and to provide feedback on proposed changes in coverage policy, and are bypassing consultation with healthcare professional experts and professional societies; and

Whereas, The evidentiary requirements of LCDs are not required in an LCA, and LCAs unilaterally issued without LCDs lack transparency and also do not allow stakeholders to review data or decision criteria, or to submit formal requests for reconsideration of the coverage policy; and

Whereas, These actions by MACs are counter to and not in the spirit of the transparency and increased stakeholder engagement and review intended by Congress in revising the LCD process by way of the 21st Century Cures Act, nor of CMS' improvements to the LCD process following stakeholder feedback to its Request for Information (RFI) in the CY 2018 Physician Fee Schedule; and

Whereas, The significant changes to LCD procedures stemming from the 21st Century Cures Act also allow MACs to change their engagement with traditional CACs, and CACs are no longer being engaged by MACs to function in their roles in reviewing and commenting on proposed policy changes and therefore no longer have a meaningful function; therefore be it

RESOLVED, That our American Medical Association oppose Medicare Administrative Contractors (MACs) issuing Local Coverage Articles (LCAs) that could have the effect of restricting coverage or access without providing data and evidentiary review or without issuing associated Local Coverage Determinations (LCDs) and following required stakeholder processes (New HOD Policy); and be it further

RESOLVED, That our AMA advocate and work with the Centers for Medicare and Medicaid Services (CMS) to ensure no LCAs that could have the effect of restricting coverage or access are issued by MACs without the MAC providing public data, decision criteria, and evidentiary review and allowing comment, or without an associated LCD and the required LCD stakeholder review and input processes, through the modernization requirement of the 21st Century Cures Act (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate to CMS that the agency immediately invalidate any LCAs that it identifies as potentially restricting coverage or access and that were issued without the MACs providing public data, decision criteria, and evidentiary review, or that were issued without an associated LCD and the required stakeholder processes, and that CMS require MACs to restart those processes taking any such proposed changes through LCDs and associated requirements for stakeholder engagement, public data, and evidentiary review (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that Congress consider clarifying legislative language that reinstates a role for local Contractor Advisory Committees in review processes going forward, addressing unintended outcomes of changes in 21st Century Cures Act that allowed local CACs to be left without a voice or purpose. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/13/21

AUTHORS STATEMENT OF PRIORITY

Recent reforms to Local Coverage Determination (LCD) processes used by Medicare Administrative Contractors (MACs) have increased transparency, clarity, and responsiveness to local clinical and coverage policy concerns. However, MACs are still able to utilize Local Coverage Articles (LCAs) to unilaterally issue policy changes that may have the effect of restricting coverage or access, arguing they are only providing billing instructions when instead the changes could reasonably be expected to have the effect of restricting coverage or access.
Unlike with LCDs, by relying on LCAs the MACs can make significant changes without any requirement that they provide data, scientific justification, or evidentiary review related to the decisions, any notice-and-comment period for stakeholder input, nor any opportunity for reconsideration.
One example is MACs' decisions to reimburse administration of certain highly complex biologics at Medicare's simple therapeutic administration rate, without having to provide stakeholders any scientific explanation of why only the simple therapeutic code is being allowed for those drugs and which decision criteria and data are being used by MACs, and providing no opportunity for reconsideration, despite evidence-based considerations showing how these drugs' high complexity and safety risks meet the definitions for reimbursement under the complex chemotherapy codes. These changes have significant repercussions for practices' ability to provide treatment access to patients.
Decisions like this are happening now without data or evidentiary review being provided and without reconsideration available to physicians. Urgent action is required to further reform these processes in order to protect physician practices and patient access to care.

RELEVANT AMA POLICY

Improving the Local Coverage Determination Process D-330.908
1. Our AMA will advocate through legislative and/or regulatory efforts as follows: A. When Medicare Administrative Contractors (MACs) propose new or revised Local Coverage Determinations (LCDs) said Contractors must: (1) Ensure that Carrier Advisory Committee meeting minutes are recorded and posted to the Contractor's website; and (2) Disclose the rationale for the LCD, including the evidence upon which it is based when releasing an approved LCD; B. That the Centers for Medicare and Medicaid Services adopt a new LCD reconsideration process that allows for an independent review of a MAC's payment policies by a third-party, with appropriate medical and specialty expertise, empowered to make recommendations to the Secretary of Health and Human Services that said policies should be withdrawn or revised; and C. That MACs shall be prohibited from adopting another MAC's LCD without first undertaking a full and independent review of the underlying science and necessity of such LCD in their jurisdiction.
2. Our AMA will work with interested state medical and national specialty societies to develop model legislation or regulations requiring commercial insurance companies, state Medicaid agencies, or third party payers to: A. Publish all edits that are to be used in their claims processing in a manner that is freely accessible and downloadable to physicians; and B. Participate in a transparent process that allows for review, challenge, and deletion of unfair edits.
Res. 807, I-15

Support for Maintaining the Medicare Carrier Advisory Committee and Carrier Medical Director D-330.974

Our AMA will: (1) continue its efforts in urging the Centers for Medicare and Medicaid Services (CMS) management to retain and support local Medicare Carrier Advisory Committees and Medical Directors in their role as policy advisers; and (2) urge the CMS to seek input from the AMA and all interested medical societies before proposing any further changes to the Medicare Carrier Advisory Committee (CAC) framework or to the roles and responsibilities of carrier medical directors.
Res. 121, I-01Reaffirmed: CMS Rep. 5, A-10Reaffirmed: CMS Rep. 01, A-20

Changes to the Medical Profession Resulting from Medicare Administrative Contracting Reforms H-390.851
1. Our AMA will review and monitor the impacts of Medicare Administrative Contracting reforms with periodic reports to the House of Delegates, to include at a minimum: (a) growth, nature and outcomes of actions against physicians by Payment Safeguard Contractors, Zone Program Integrity Contractors, and Recovery Audit Contractors; (b) changes in structure and/or function of Contractor Advisory Committees; and (c) changes in access to Medicare Administrative Contractor Medical Directors and other Medicare Administrative Contractor personnel.
2. All information gathered by our AMA regarding the impact of Medicare administrative contracting reforms will be shared in a timely manner with all state and national medical specialty societies.
Res. 710, I-07Modified: CMS Rep. 01, A-17

Uniformity of Operations of Medicare Administrative Contractors H-390.921
It is the policy of the AMA (1) to use its influence and resources to bring about uniformity of business policies and procedures among the Medicare Administrative Contractors, and (2) to investigate and monitor the differing policies and procedures among the Medicare Administrative Contractors with respect to physician reimbursement.
Res. 154, A-90Reaffirmed: Sunset Report, I-00Modified: CMS Rep. 6, A-10Reaffirmed: CMS Rep. 4, I-15

Medicare Part B Contractor Changes D-335.984
1. Our AMA will: (a) register a formal public complaint to the Centers for Medicare & Medicaid Services (CMS) about the need to accept physician input as part of future contract decisions; (b) ask CMS to require that the local Medicare Administrative Contractor and clearinghouse quickly rectify problems, including having more prompt and effective communication with providers; and (c) advocate for legislation or agency policy changes that provide additional resources to be allocated to the Centers for Medicare and Medicaid Services for the specific purpose of enhancing Part B contractor customer service and accountability in billing and enrollment matters.
2. If CMS and the local Medicare Administrative Contractor and clearinghouse fail to effectively address the problems physicians are facing, our AMA will notify elected officials and the public of these failures and the need for redress.
Res. 218, I-08Reaffirmed: CMS Rep. 01, A-18

Physician Input in MAC Contracting Process D-330.943
1. Our AMA will work with other interested members of the Federation to develop mechanisms with the Centers for Medicare and Medicaid Services that meaningful input from physicians and physician associations may be received and appropriately considered in the Medicare Administrative Contractor contracting processes, both those now underway and those in the future, including input on specific potential contract bidders.
2. Our AMA: (a) encourages the Federation to continue to report problems with Medicare Administrative Contractors (MACs), or other Medicare contractors, to the AMA; (b) will advocate that the Centers for Medicare and Medicaid Services (CMS) ensure that MACs are adequately

staffed to handle enrollment, claims review, appeals and other functions in a timely and accurate manner; (c) will advocate that CMS increase training of MAC personnel to ensure they can respond efficiently and effectively to provider inquiries; (d) will advocate that CMS provide sufficient time between announcement and implementation of policy changes to allow contractors to thoroughly understand and adequately prepare to communicate with physicians and other providers about the changes; (e) will urge CMS to publish on its Web site the list of performance standards against which MACs are measured, and a report of each MAC's rating on those performance standards; (f) encourages state medical societies to educate their members regarding MAC performance standards, and to actively petition CMS regarding underperforming MACs; and (g) will advocate that the Centers for Medicare and Medicaid Services impose monetary penalties on MACs that fail to process and pay claims in a timely manner.
Res. 714, I-05Appended: CMS Rep. 5, A-10Reaffirmed: CMS Rep. 01, A-20

Review of Self-Administered Drug List Alterations Under Medicare Part B D-335.983
Our AMA will seek regulatory or legislative changes to require that any alterations to Self-Administered Drug lists made by Medicare Administrative Contractors shall be subject to Carrier Advisory Committee review and advisement.
Res. 811, I-13

Parity of Payment for Administering Biologic Medications H-330.883
Our AMA supports and encourages interested national medical specialty societies and other stakeholders to submit a request to Medicare for a national coverage determination directing Medicare Administrative Contractors to consider all biologics as complex injections or infusions.
CMS Rep. 4, I-15