AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G 200
Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing regarding ongoing concerns with the local coverage article (LCA) process. The AMA previously wrote to the Centers for Medicare & Medicaid Services (CMS) in July 2022 on this topic. Unfortunately, the situation has continued to deteriorate.

Physicians and patients have faced issues with local coverage determinations (LCDs) for many years. Efforts to reform the process were attempted in the 21st Century Cures Act and accompanying regulations in 2016-2018. While several policy changes did help to advance transparency and efficiency in the process, others inadvertently created a back door through which Medicare Administrative Contractors (MACs) could subvert the formal coverage determination processes to implement substantial changes with important patient care and safety implications bypassing any input from physicians or other interested parties.

Specifically, CMS indicated that certain diagnosis and procedure codes would be moved from LCDs to LCAs. Unlike LCDs, LCAs are not independently subject to notice and comment, nor are they subject to the same criteria as LCDs, including reasonable and necessary standards and evidentiary support standards. LCAs are intended only to provide guidance; they are not intended to determine coverage. Importantly, LCAs can, but are not required, to be paired with accompanying LCDs.

It is the AMA's understanding from multiple medical specialty societies that in recent years, MACs have increasingly taken advantage of the LCA process to advance coding changes with resulting substantial implications on coverage and access to physician services, seemingly to circumvent the LCD process, which comes with more substantive transparency requirements.

As a result, physicians may be subject to substantial new coverage requirements or restrictions included in LCAs without any opportunity for public input, which we worry could disproportionately restrict access for historically marginalized and underserved communities. Furthermore, because there is also no required notice period for LCAs before they take effect, physician practices often have little to no time to familiarize themselves and their billing staff with the new coding requirements or update their IT systems to accommodate the changes, placing a significant burden on practices and increasing the risk of improper billing. Most importantly, without required input nor sufficient notice prior to implementation, these

decisions can result in serious patient safety ramifications, such as a lack of clinical oversight and supervision for administering complex drugs as just one of many examples.

Importantly, MAC-specific LCAs can also result in inconsistent applications of coverage and payment policies, meaning Medicare beneficiaries in certain parts of the country may not have equal access to services, products, and drugs they are entitled to receive under Medicare, which could exacerbate existing inequities. While the AMA supports the use of LCDs and LCAs to foster innovation and customize and/or expand benefits, the AMA is strongly against using LCDs/LCAs as a vehicle to restrict access to goods and services Medicare beneficiaries would otherwise be entitled to receive. We believe this defies the intended purpose of the Medicare LCD/LCA process and find any reductions in coverage and/or access to Medicare beneficiaries that result from LCA changes, which do not require stakeholder or public input, to be unacceptable.

Prior to the 21st Century Cures Act-related changes in 2018, MACs were required to hold a minimum of three Contractor Advisory Committee (CAC) meetings a year as a venue to discuss draft LCDs and other Medicare coverage-related issues with physician and other expert CAC representatives. Under the revised process, CAC meetings now occur intermittently at the discretion of the MAC at often inconvenient times for practicing physicians. Medicare contractors appear to be moving increasingly towards informal meetings on narrow topics with "subject matter expert (SME) panels," with limited advance notice, transparency, or public engagement, including from CAC representatives. Medical specialties are often not made aware of such meetings, or if they are, the process to nominate an SME remains informal and opaque. When nominations are offered, they are often denied without justification. These changes represent yet another way physician input has been muted in the Medicare coverage determination process.

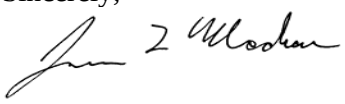
Despite CMS assurances that under the revised rules, interested parties can engage informally with their MACs to resolve such coverage issues on a case-by-case basis, repeated stakeholder attempts to do so have been ignored. MACs have rebuked multiple meeting requests citing a lack of sufficient evidence, which is concerning considering the fact that MACs are not required to provide any evidence to justify their LCA changes in the first place. Medical specialty society representatives have also been told MAC workgroup meetings are designed to remedy such coverage concerns and inconsistencies. However, these meetings include no formal participation from physicians or other clinical experts and are not transparent to the public. **Without a formal process in place to ensure transparency and feedback for LCAs, there is no way to guarantee MACs will take input from physicians or other experts into account.**

Accordingly, the AMA urges CMS to strengthen the transparency of the LCA/LCD development process by:

- Establishing criteria for new LCAs and changes to existing LCAs including reasonable and necessary parameters, patient safety considerations, and evidentiary support standards;
- Establishing a public notice and comment process for new and revised LCAs, particularly those that impact multiple jurisdictions;
- Establishing an LCA determination/redetermination request process and timeline for stakeholder recommendations for new LCAs or changes to existing LCAs; and
- Making all meetings concerning Medicare coverage determinations (including SME panels and MAC workgroup meetings) available to the public with ample notice and opportunities for public input.

We believe these changes can meaningfully improve the integrity and accuracy of Medicare coverage determinations, improving patient access to care and safety in the process. Thank you for your consideration of these comments. To further discuss the content of this letter, please contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,



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