October 4, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Sent via email to MAC Procurement @cms.hhs.gov

Re: MAC Consolidation and Contract Award Period of Performance RFI

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Medicare Request for Information on Medicare Administrative Contractor (MAC) Consolidation and Contract Award Period of Performance. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians.

MAC Consolidation

As is noted in the RFI, CMS paused consolidation of its MAC geographic jurisdictions in 2014 in order to promote program stability and in 2016, CMS announced that the pause was permanent. However, CMS is now revisiting the topic of integrating Part A/B Jurisdictions 5 and 6 to form Jurisdiction "G" and Jurisdictions 8 and 15 to form Jurisdiction "Q". The current proposed consolidation would task two MACs instead of the current four, with processing claims and making coverage policy for millions of Medicare beneficiaries in 11 states and administer Home Health and Hospice (HH&H) services for 34 states and U.S. territories. Generally, the CAP is unsure why CMS is exploring this change now, which the agency had previously determined was "not in the best interest of the MAC program." Additionally, the CAP has concerns about the effect that the proposed consolidations could have on coverage decisions and their impact on the local Medicare populations. We also believe that workload distribution and cybersecurity risks are examples of consolidation aspects that require further analysis.

Consolidation aspects that may require further analysis

As is explained in the RFI, CMS established a prime contract award limitation of 26 percent to balance workload allocation and limit the risk to the Medicare program. However, CMS has not indicated how the new workloads would be distributed among the two MACs if the proposed consolidation occurs. If CMS implements the proposed consolidations, the CAP recommends that CMS ensure an equitable workload

distribution among all MACs. This would help maintain a fair distribution of the percentage of A/B workload, manage risk, and maintain competition for MAC contracts.

Disadvantages of MAC consolidation

The CAP is concerned about the effect the proposed consolidation could have on coverage decisions and their impact on the local Medicare populations. While we understand there are benefits to uniform coverage policies, and we have advocated for increased MAC consistency and transparency, we have also seen how consolidation and coordination between MACs can lead to the spread of a poorly developed LCD, inappropriately limiting coverage for Medicare beneficiaries. Further consolidations could mean further adoption of coverage policies that were not developed locally with appropriate stakeholder input, which may exclude or limit coverage for Medicare populations, and which may not reflect the specific geographic region they are intended to serve. We strongly believe that LCDs should not become de facto National Coverage Determinations (NCD) without being subjected to the more rigorous NCD requirements.

This is especially true given our continuing concerns around the 2018 changes to Medicare's Program Integrity Manual, which we believe have diminished the advisory role of CAC members as to the nature of clinical practice and the needs of local patient populations. MACs no longer adhere to the same mechanisms for making coverage policy, and there is more confusion than clarity around how stakeholders are expected to participate in the LCD process. The CAP has also faced immense challenges in requesting revisions to an LCD, including unreasonably protracted timeframes that can follow even after an acknowledged reconsideration request. As we have communicated to CMS¹, the CAP filed a formal reconsideration request to several MACs for revisions to the Special Histochemical Stains and Immunohistochemical Stains LCD, and it has taken years to see the issuance of revised final LCDs (while some MACs are still failing to take at various stages action).

In consideration of these issues, the CAP strongly encourages CMS to address existing flaws in the current LCD process before considering any further MAC consolidations so as not to exacerbate existing problems with the local coverage process. Addressing these flaws will require greater oversight by CMS to ensure consistency among MACs in LCD development processes, including an opportunity for meaningful exchange during MAC meetings for all physicians and stakeholders to identify and address issues related to the scientific evidence, clinical practice, and the needs of patients within the context of a local coverage policy. It further requires a timeframe for MACs to complete LCD reconsideration requests to keep pace with advances in science and to provide Medicare beneficiaries with the timely tests and services they need. Finally, it requires CMS to monitor and ensure that MACs do not exceed their scope of authority by impinging upon the practice of medicine through physician scope of practice restrictions.²

¹ https://documents.cap.org/documents/CAP-Letter-to-CMS-Ongoing-Concerns-About-LCD-Process_02232024.pdf

https://documents.cap.org/documents/CAP-Letter-to-CMS_MAC-Scope-of-Authority-Issue-002.docx

Also, the CAP has concerns with how consolidation may impact vulnerabilities related to cybersecurity. As you know, the health care sector is particularly vulnerable to cybersecurity risks and the stakes for patient care and safety are particularly high. Our members and their patients are still feeling the fallout from the February Change Healthcare cyberattack, and we have recently learned about the security incident involving Wisconsin Physicians Service Insurance Corporation (WPS). We urge CMS to further consider the risks association with consolidation when it comes to cybersecurity.

Issues to be addressed if CMS expands MAC consolidation efforts beyond those specified in the RFI

As above, the CAP is not in favor of further MAC jurisdiction consolidations. As mentioned above, with fewer MACs, local coverage policies approach national coverage status without being subjected to the more stringent NCD requirements. Specifically, consolidation could mean further spread of the flawed Molecular Diagnostic Services (MolDX) program to a jurisdiction that does not currently participate in the program. Other MACs who participate in the program, with or without choice, must adopt identical molecular coverage policies for their jurisdictions, which currently cover over 28 states. By further imposing the MolDX program on other MAC jurisdictions, CMS is essentially elevating the program to national status, allowing MolDX to make national coverage policies without the rigorous national coverage determination requirements.

MAC Contract 10-year Period Performance

The CAP appreciates the time and effort required to perform MAC contract negotiations. We further understand that improved efficiencies can result from longer contract periods. Under Section 509 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, CMS already has the authority to extend MAC contracts from 5 years up to a maximum of 10 years before contracts must be rebid. Current MAC contracts are typically one base year and six option years, which CMS may unilaterally extend to 10 years based on MAC performance. CMS is now proposing to issue a full 10-year contract to MACs at the time a contract is awarded.

The CAP recommends that all 10-year contracts include mandatory periodic reviews to ensure MAC performance compliance, and that CMS adheres to federal regulations that require the agency to make available to the public the performance of each MAC with respect to such performance requirements and measurement standards.

Thank you for considering our recommendations on CMS' proposed Medicare MAC Consolidation and Contract Award Period of Performance. If you would like to discuss this issue further, please contact Nonda Wilson, MS, Manager for Economic and Regulatory Affairs at the CAP, at nwilson@cap.org or 202-354-7116.