

## ASSOCIATION FOR MOLECULAR PATHOLOGY

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

Re: Request for Information concerning consolidation of A/B Medicare Administrative Contractors (MACs) for Jurisdiction 5 (J5) and A/B HH+H MAC Jurisdiction 6 (J6) into "Jurisdiction G"; for consolidation of A/B MAC Jurisdiction 8 (J8) and A/B HH+H MAC Jurisdiction 15 (J15) into "Jurisdiction Q"; and 10-Year MAC Contract Award Period of Performance

Delivered electronically to MAC\_Procurement@cms.hhs.gov

Dear Ms. Brooks-LaSure:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide comments about the Center for Medicare and Medicaid Services' (CMS) plans to consolidate Medicare Administrative Contractor (MAC) regions as described in the recent request for information. AMP is an international medical and professional association representing approximately 3,000 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, infectious disease, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

MACs have a significant role in shaping the reimbursement of clinical laboratory tests as they make local coverage determinations (LCD) establishing coverage or non-coverage for services within their jurisdiction. Further, CMS is greatly dependent upon MACs during the gap-filling process for selected new CPT codes. MACs report payment rates to CMS, which then calculates a median to establish the Medicare payment rate on the Clinical Laboratory Fee Schedule (CLFS). Consolidation of MACs will create less granularity in the gap-filling process, and the gap-fill rate may not accurately reflect the diverse needs within a broadly consolidated MAC Jurisdiction. Given the importance of MACs in making coverage and payment decisions, AMP continues to believe that patients, providers, and the greater medical community are best served by the presence of multiple MACs, and we are generally concerned by CMS' proposal to consolidate A/B J5 and A/B HH+H J6 into "Jurisdiction G" and the A/B J8 and A/B HH+H J15 MACs into "Jurisdiction Q".

In response to CMS seeking information on the disadvantages of MAC consolidations, AMP believes it's important for the agency to consider how MACs use varying standards for information gathering and review and are inconsistently transparent in their relationships with stakeholders. A multiple-MAC system allows patients and providers to advocate directly to their MAC and

increases the potential for invaluable scientific discourse and dialogue between stakeholders and payers. For instance, the importance of a multiple-MAC system has been made abundantly clear to AMP during the course of our work responding to draft local coverage determinations. Though some MACs release similar draft LCDs for an assay, they often respond individually to AMP's presentation of scientific data in a manner that reflects their local constituencies' needs.

We also find that some MACs are less than successful at serving as operational contacts and at bridging the gap between the payer and provider community. MAC consolidation would limit patient and provider opportunities to engage, reduce competition, and diminish varied input into key decisions, which is essential to ensure a full complement of evidence and experience is considered in coverage determinations. AMP is also supportive of additional opportunities for stakeholders to weigh in before MACs implement changes. Losing this variety would be particularly harmful in the field of molecular diagnostics, where technology and scientific knowledge are evolving at a rapid pace. Practitioners and stakeholders at AMP and other specialty groups keep abreast of changes in the field as they occur. It is necessary for MACs to utilize AMP and other resources as tools to ensure that coverage determinations are made using the best and most current science. We are generally concerned that MAC consolidation would grant additional work to MACs that have been less successful with working with organizations like AMP. We understand that the consolidation of A/B J5 and A/B HH+H J6 into "Jurisdiction G" and the A/B J8 and A/B HH+H J15 MACs into "Jurisdiction Q" would create the need for CMS to revisit the longstanding A/B MAC prime contract award limitation of 26%. AMP supports the current limitation since it was established to support a vigorous level of competition for A/B MAC contracts.

Importantly, CMS has not described what the agency views as the rationale for further MAC consolidation. The agency only provides a brief history in the RFI, noting that in 2023, CMS decided to reverse its decision to permanently pause all consolidation efforts. There are now twelve MAC jurisdictions, but only seven companies have contracts that provide claims-related and benefit administration services related to Part A and Part B benefits. Further, several MACs are owned by the same parent company. Additionally, AMP would like to note that the Molecular Diagnostic Services (MolDX) program is administered in several states by different MACs. Thus, there is already reduced diversification in the LCD and gap-filling processes strengthening the power of LCDs to be almost as encompassing as NCDs. While AMP greatly values the expertise of the MolDX program, we also believe it is CMS' responsibility to continue to support a robust multiple-MAC system. CMS now has fewer jurisdictions than it had originally intended and, further, even fewer companies and programs are involved in executing the work. Before CMS moves forward with any plans, it is imperative that CMS publicly state the reasons for proposing to consolidate any jurisdictions so that AMP and other interested stakeholders can more meaningfully engage in this effort.

Thank you again for the opportunity to comment on these important issues. If you have any questions, please contact Annie Scrimenti, Associate Director, Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,

Maria E. Arcila, MD President, Association for Molecular Pathology