



**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Education. Innovation & Improved Patient Care. Advocacy.*

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February 19, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

RE: CMS-1653-NC; Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts

Dear Mr. Slavitt:

Thank you for the opportunity to comment on CMS-1653-NC. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

We are pleased to support the Centers for Medicare and Medicaid Services (CMS) in their efforts to examine and improve coverage for Medicare and Medicaid patients through an evaluation of Medicare Administrative Contractors (MACs) and their coverage determination processes. AMP commends CMS' efforts to ensure that coverage determinations are made efficiently and ethically, and that providers are used as a resource to inform coverage determinations.

As your request for information notes, CMS relies on MACs as "primary operational contacts" between the Medicare fee-for-service program and providers across the country. Consequently, MACs should be obligated to serve as equitable intermediaries, thoroughly and conscientiously considering the input of physicians and stakeholders who are current on changes to rapidly evolving fields of research, science, and medicine.

Increasing and improving dialogue between CMS, MACs, and stakeholders ensures that Medicare patients receive the benefit of and access to the most up-to-date clinical science, which ensures that patients experience safe and effective care. Transparency and stakeholder engagement are critical to ensuring that the MACs are successful in their endeavors to appropriately and fairly make coverage assessments. Below we make the following recommendations to CMS regarding the awarding and administration of MACs.

**1. CMS should exercise its authority to oversee the work of the MACs in a timely and transparent manner.**

AMP urges timely and transparent MAC performance reviews by CMS. In its April 2015 report to Congressional requestors, the Government Accounting Office found that, while CMS's performance assessments of MACs were extensive they were not always timely. To achieve true performance assessment and incentives based thereupon, CMS must provide timely contractor performance assessment reports as part of MAC quality metric evaluations and incentive awards. For instance, annual or biennial review analogous to the CLIA standards for laboratories would be suitable. Extension of contracts up to the 10 year maximum should be based on acceptable performance in these regular reviews. Furthermore, only minimal information is released to the public about MAC performance data. Although CMS collects more than 80 quality metrics, MAC performance evaluations such as QASP Medical Review are reported in aggregate. Reporting only overall performance scores for each contractor does not enable the necessary transparency for key stakeholders, especially providers and Medicare beneficiaries, to know how their local contractor is performing in each of the key metrics and how it compares to other A/B MACs. AMP recommends that evaluation ratings criteria for each key performance element be made available to the public, to the extent possible.

**2. MACs should be assessed on their transparency and public engagement as a measurement of their level and quality of service.**

The quality of a MAC's service is directly related to the MAC's willingness to engage with stakeholders in order to make an accurate assessment of a service's value and, consequently, an appropriate coverage determination. In order to evaluate a MAC's level and quality of service, transparency in regards to its relationships with stakeholders and local coverage determinations (LCD) should be a key measure evaluated by CMS.

MACs will play an important role in shaping the future of precision medicine highlighted by presidential initiatives such as the "precision medicine initiative" and the "cancer moonshot". When constructing draft coverage determinations, we recommend that MACs consult with subject matter experts to ensure the policies accurately reflect current medical practice. Laboratory LCDs should focus on specific areas of disease to allow careful consideration of the merits for coverage both by the MAC and by the stakeholders. LCDs covering entire fields of laboratory medicine (e.g. molecular pathology) should be avoided.

MACs need to take efforts to increase transparency where currently none exist. Though providers often submit thorough and robust responses to draft coverage determinations, it is our members' experiences that individual MACs can be frustratingly opaque regarding their protocols for reviewing and closely assessing comments. MACs should be assessed on the thoroughness of their responses to providers, which should include at minimum an explanation of why the evidence failed to influence current MAC policies. CMS should additionally consider the MACs timeline for finalizing a coverage determination as reflective of the MACs engagement with input from stakeholders. If, for example, a final coverage determination is released the day after comments are due from stakeholders, it is unlikely that the MAC had time or capacity to closely and appropriately examine all comments. CMS may want to consider monitoring the time it takes to respond to comments on draft policies and finalize policies as a metrics.

Furthermore, we recommend that CMS establish a publicly available action plan to address MAC's whose performance does not meet the outlined performance standards. Besides making it clear what penalty applies to poor performers, CMS should develop a clear plan in conjunction with the MAC to improve their performance.

We recommend the following metrics be considered.

- Does the carrier perform in a way that promotes the availability of novel services related to genomics and precision medicine?  
Metric: Evidence of this performance might be based on the number of LCDs providing coverage for novel services offered in the previous 3 years.
- Does the carrier have a written, transparent policy for implementation of CMS requirements for establishing local coverage decisions (LCD)?  
Metric: The policy is available to the public.
- Does the carrier have documentation that the LCD policy has been implemented and is effective?  
Metric: Customer survey shows MAC has adhered to LCD policy.
- Does the carrier have a written policy for consultation and inclusion of medical sub-specialties in its jurisdiction in the development of local coverage decision?  
Metric: Records showing local physicians who specialize in the field were consulted.
- Does the carrier have evidence of the implementation and effectiveness of physician consultation policy?  
Metric: Customer survey shows MAC has adhered to physician consultation policy.
- Does the carrier utilize evidence based guidelines in the development of its coverage policies?  
Metric: LCD documents show citations from evidence based guidelines (e.g. NCCN, professional society guidelines).
- Does the carrier have a procedure in place to assess more recent medical developments that are not recognized in available guidelines?  
Metric: The procedure is available to the public.
- How many LCDs has the carrier issued in the past year for newly identified laboratory and pathology services?  
Metric: The number of LCDs. Outliers should be flagged for further investigation.
- How many CPT codes were covered in a single LCD?  
Metric: The number of CPT codes covered by the LCD. Outliers should be flagged for further investigation.
- How many LCDs has the carrier developed in the past 3 years?  
Metric: The number of LCDs. Outliers should be flagged for further investigation.
- Does the MAC meaningfully solicit and assess comments related to their draft LCDs?  
Metric: Number of times the MAC adopts other jurisdiction's policies without considering and integrating comments received during the public comment period (There are many instances that AMP has observed this type of "carbon copy" adoption.)

Also, we recommend that CMS evaluate the services offered to patients in different jurisdictions to ensure that the appropriate level of care is afforded to all Medicare beneficiaries. Precision medicine is a rapidly changing field with new advancements and modifications to national guidelines made on a yearly basis. Therefore, a routine review of LCDs should be conducted.

Further, the recent introduction of ICD-10 codes has added a new level of complexity to determining coverage of services by the MACs. Failure to accurately cross-walk ICD-10 codes from ICD-9 codes may result in denial of payment for previously covered services. The cost of these services may be passed on to the patient. Transparency is needed to determine if patients in different jurisdictions are being offered different levels of service.

We recommend the following metrics be considered.

- Annual review of LCDs to allow timely recognition of medical advances  
Metric: The time between LCD reviews
- Publication of CPT denials by ICD10 code to allow evaluation of what services have been denied to patients  
Metric: Public availability of this information

**3. Each year, a number of clinical laboratory services are priced through a statutorily defined gapfill process. CMS should assess MAC's adherence to this process as a measurement of quality of service.**

When CMS determines a service should be gapfilled, the regulations outlining the process specifically require MAC participation in the first year by setting carrier-specific amounts. CMS should evaluate whether MACs follow all of the processes prescribed to them under 42 CFR 414.508(b). These regulations state that:

Gapfilling is used when no comparable existing test is available.

- (1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:
  - (i) Charges for the test and routine discounts to charges;
  - (ii) Resources required to perform the test;
  - (iii) Payment amounts determined by other payers; and
  - (iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
- (2) In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts.
- (3) For a new test for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the carrier-specific amounts will pay for the test appropriately.

CMS should develop metrics based on the above criteria to ensure that MACs are complying with their legal obligations in regards to the development of gapfilled codes. Many MACs shirk their responsibilities when determining valuations for gapfilled codes and fail to meet with interested constituents when engaged in this process and aggregating the data required above. MACs should be evaluated on their work with labs to determine "charges for... tests and routine discounts to charges; resources required to perform the test; and payment amounts determined by other payers." This will ensure that coverage decisions are fair and informed.

We suggest the following metrics be considered.

- Did the carrier disclose, in a timely manner, the methodology used by the carrier in gathering information and determining pricing for new CPT codes that are reimbursed under the CLFS?  
Metric: Rationale for determining MAC gapfill values for new CPT codes are available to the public.
- Does the carrier have an established methodology for collecting appropriate data from providers within its jurisdiction for the gapfill process as detailed in 42 CFR 414.508(b)?  
Metric: The policy is available to the public.

#### **4. MACs should be evaluated based on the relationships with health care providers within their jurisdiction.**

MACs should be assessed on their ability to develop strong customer service to local laboratories, which will be affected by coverage determinations. In order to develop metrics on customer service, CMS may establish an online MAC evaluation form to assess stakeholder engagement.

Alternatively, MACs could be required to hold quarterly calls with stakeholders, modeled on CMS' National Provider Calls, which provide an opportunity to MAC leadership to engage providers on thematic issues and to broadly improve relationships between MACs and the provider community.

MACs could be assessed on the transparency of their relationships with community members. Currently many health care providers lack understanding regarding how MACs make coverage determinations, and MACs should be assessed on their ability to provide, clear, easily assessable educational materials on the coverage determination process.

We recommend the following metrics be considered.

- Does the carrier have a written quality management plan in place that addresses performance with regard to patient and practitioner satisfaction in an ongoing manner?  
Metric: Evidence of the implementation and effectiveness of the quality management plan including records of quarterly calls with stakeholders and stakeholder satisfaction surveys.
- Does the carrier solicit and facilitate the participation of laboratories within its jurisdiction when its CAC deliberates on pathology and laboratory issues?  
Metric: Records showing pathologists/laboratories participation. Customer survey shows MAC has adhered to stakeholder participation policy. Open comment periods on the CAC meeting agenda. Opportunities for remote participation via teleconference or webcast.

#### **5. Stakeholder assessments of MACs should be publicly available.**

Patients and payers are benefited by transparency of community grievances with MAC processes and decisions. Stakeholder assessments of MACs, both positive and negative, should be publicly shared. Any efforts taken to improve stakeholder engagement (including public comment boxes and/or stakeholder assessment forms) should be made public.

#### **6. Under the Protecting Access to Medicare Act (PAMA), CMS was authorized to consolidate the MAC jurisdictions. CMS should continue to utilize a coverage determination process that relies on multiple MACs for clinical laboratory services.**

AMP continues to believe that patients, providers, and the greater medical community are best served by a coverage determination system for clinical laboratory services that relies on the presence of multiple MACs. 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.

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 coverage determinations for a test, they often individually respond to AMP's presentation of scientific data in different manners. For example, AMP has had very different experiences working with Palmetto GBA and with National Government Services (NGS) in finalizing coverage determinations for Non-Small Cell Lung Cancer testing in their various jurisdictions. NGS worked closely and transparently with AMP members, and their final policy was informed by input and support from labs in their jurisdiction. During these interactions, NGS served as the "primary operational contact" between CMS and providers in the NGS jurisdiction, fulfilling their obligations as a MAC.

AMP has firsthand experience working with MACs which are less than successful at serving as operational contacts and at bridging the gap between the payer and provider community. Relying on one MAC would limit patient and provider opportunities to engage.

Further, decreasing the amount of MACs to one or just a few would result in losing the varied approach to coverage determinations the current scheme is intended to foster. Competition and varied input is critical to the coverage process employed by the MACs, ensuring a full complement of evidence and experience is considered in coverage determinations. Losing this variety would be particularly harmful in the field of molecular diagnostics where the technology is constantly evolving. Practitioners and stakeholders at AMP and other specialty groups keep abreast of changes 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. To this end, some MACs have been far more successful than others. It is CMS' responsibility to continue to support a multiple-MAC system until all MACs can be relied upon to do the necessary and integral work of engaging with stakeholders.

AMP thanks you again for the opportunity to comment on these important issues. If you have any questions, please contact Tara Burke, Policy Analyst, at [tburke@amp.org](mailto:tburke@amp.org).

Sincerely,

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AMP President