American
Clinical Laboratory
Association

April 10, 2018

Virginia Muir
National Government Services, Inc.
LCD Comments
P.O. Box 7108
Indianapolis, IN 46207-7108

DELIVERED ELECTRONICALLY to PartBLCDComments@anthem.com

RE: Draft Local Coverage Determination: Administrative Multianalyte Assays with Algorithmic Analyses (MAAA) and Proprietary Laboratory Analyses (PLA) Services (DL37600)

Dear Ms. Muir,

Please accept the comments of the American Clinical Laboratory Association ("ACLA") on the Draft Local Coverage Determination: Administrative Multianalyte Assays with Algorithmic Analyses ("MAAA") and Proprietary Laboratory Analyses ("PLA") Services (DL37600) ("dLCD"). ACLA is a trade association representing the nation's leading providers of clinical laboratory services, including regional and national laboratories. Its diverse membership includes a broad array of clinical laboratories: large national independent labs, reference labs, esoteric labs, hospital labs and nursing home labs.

ACLA members do not support the dLCD's presumptive non-coverage of services represented by administrative MAAA codes and PLA codes, and have a fundamental disagreement with National Government Services, Inc. ("NGS") over the appropriate process for a Medicare Administrative Contractor ("MAC") to determine coverage for a laboratory test. ACLA disagrees vehemently that any service represented by an administrative MAAA code or a PLA code is, by default, not medically necessary and should be presumed not reasonable and necessary until peer-reviewed scientific evidence proves otherwise. Further, the impetus for NGS to propose this dLCD is not clear to ACLA. **We ask that NGS rescind the dLCD and utilize the same process to determine coverage for these tests as it does for all other laboratory tests**. ACLA also recommends that NGS establish an advisory group comprised of laboratory professionals with applicable expertise to serve as a resource to NGS on laboratory services, and to perform reviews of certain laboratory tests, where needed. Such a group could prove useful not only for purposes of assisting NGS with evaluating and reviewing tests addressed by the dLCD but other laboratory services, as well. ACLA welcomes the opportunity to work with NGS on this recommendation and to serve as a resource to NGS on laboratory-related issues.

Administrative MAAA and PLA Code Background - The American Medical Association (AMA) has defined MAAAs as procedures that utilize multiple results derived from panels of analyses of various types including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid-based assays (*e.g.*, proteins, polypeptides, lipids, and carbohydrates). Algorithmic analysis, using the results of these assays as well as other patient information (if used), is then performed and reported typically as a numeric score(s) or as a probability. The results of individual component procedure(s) that are inputs to the MAAAs may be provided on the associated laboratory report; however, these assays are not reported separately using additional codes. The MAAA procedure codes encompass all analytical services required for the algorithmic analysis (*e.g.,* cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection) in addition to the algorithmic analysis itself. By their nature, MAAA procedures are typically unique to a single clinical laboratory or manufacturer and the AMA CPT® Editorial Panel typically creates codes for these tests in two CPT coding categories: Category I and administrative. A MAAA test to which the AMA has not yet assigned a Category I code may be assigned an administrative code.

PLA codes were created in response to the Protecting Access to Medicare Act ("PAMA") and approved by the AMA CPT® Editorial Panel. They are a new addition to the CPT code set and establish unique codes for those laboratories or manufacturers that want to more specifically identify their tests. Tests fulfilling the requirements for obtaining a PLA code must 1) be performed on human specimens and 2) requested by the clinical laboratory or the manufacturer that offers the test.

There are many reasons why a laboratory might apply for a PLA code, including to comply with the "unique code" requirement to qualify as an advanced diagnostic laboratory test (ADLT).[1] However, securing a PLA for operational reasons does not mean that the service lacks value or medical necessity. Further, several tests represented by PLA codes historically have been covered and billed to Medicare under different CPT codes that were not unique to the tests. Under the dLCD, services for which reasonableness and medical necessity were already established and accepted would now be automatically denied.

Non-Coverage – The categorical non-coverage of services represented by certain types of codes confuses the purposes of coding and coverage. AMA Coding processes are not intended, and should not be used, for purposes of determining coverage of services. The categorial non-coverage of a service based on the type of code assigned to it is not appropriate and should not be used in lieu of stakeholder engagement with the MAC regarding coverage. The determination about what services are reasonably and medically necessary should be made prospectively, rather than as part of a reconsideration process. This is the process that NGS uses for all other laboratory tests, and it should be used for tests represented by administrative MAAA codes and PLA codes, as well.

[1] 42 C.F.R. § 414.502.

Medicare contractors and many commercial payors determine coverage for laboratory tests by working with stakeholders to establish the diagnoses and circumstances for which the tests are considered reasonable and medically necessary. NGS's approach should be the same: it should assess the merits of each test individually, rather than apply presumptive non-coverage.

Moreover, it is a MAC's obligation under its statement of work to proactively make coverage determinations rather than delegate that function, practically speaking, to the organization tasked with establishing CPT codes. In the case of administrative MAAAs, the dLCD would essentially make the AMA CPT® Editorial Panel a *de facto* coverage entity, rather than a body charged to create codes to describe medical procedures. CMS and providers rely on MACs to effectively perform their coverage determination function to enable timely access to medically necessary services for Medicare beneficiaries.

Impact – ACLA was supportive of the AMA's creation of PLA codes in response to PAMA requirements. The dLCD's categorical non-coverage and requirement of peer-reviewed evidence for reconsideration will discourage applicants from securing PLA codes and diminish the utility and value of the PLA code assignment process. The process was not developed or meant to assess the medical necessity of PLA services, yet NGS proposes to use it for this purpose.

Tests identified by administrative MAAA codes and PLA codes do not necessarily lack evidence of their analytical and clinical validity, clinical utility, or reasonableness for the Medicare population. ACLA member laboratories apply a rigorous and consistent process to validate their tests, including those represented by administrative MAAA codes and PLA codes. Additionally, any laboratory performing a laboratory test on a specimen obtained from a patient in New York State (NYS) must secure approval through the NYS Clinical Laboratory Evaluation Program, under which a laboratory can perform only those assays for which the analytic and clinical performance characteristics have been established (validated), or if already established, verified at the site where the assay will be performed. As several tests represented by PLA codes also historically have been covered and billed to Medicare under different CPT codes that were not unique to the tests, their reasonableness and medical necessity already were established and accepted. Under the dLCD, these services are presumed not reasonable or medically necessary and automatically denied.

In summary, the impact of the dLCD is negative on many fronts: deterring future administrative MAAA and PLA code applications, denying coverage for services previously covered, and potentially discouraging the development and introduction of new services to serve beneficiary needs.

Reconsideration – Putting the onus on the provider to request coverage through the LCD Reconsideration Process lacks transparency and is inefficient and burdensome for both NGS and providers. The dLCD does not clearly state the conditions under which a test would be considered reasonable and necessary. To provide for coverage only through the reconsideration process would result in each reconsideration being a *de novo* review without

the benefit of any guidance or lessons learned from previous providers' submissions of similar tests. This process is inefficient and burdensome for both NGS and providers, and will increase the number of reconsideration requests awaiting determination – whether the requests have merit or not. ACLA is concerned that these inefficiencies could further exacerbate the potential for backlog and delay.

In addition, there are many types of evidence to support coverage for a test, beyond the peer-reviewed evidence NGS would require in the reconsideration process. The Medicare Program Integrity Manual identifies many other types of sources as evidence, including medical opinion derived from consultations with medical associations or other health care experts, randomized clinical trials, and consensus of expert medical opinion. While general acceptance by the medical community may be evidenced in peer-reviewed medical journals, the Medicare program does not require peer-reviewed evidence for coverage. Instead, the "broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached."[2]

In closing, ACLA does not support NGS's proposed categorical presumptive non-coverage of tests represented by administrative MAAA codes and PLA codes. It is unclear what problem NGS is hoping to solve through issuance of the dLCD. We ask that NGS rescind the dLCD and utilize the same process to determine coverage for these tests as it does for all other laboratory tests. ACLA welcomes the opportunity to work with NGS to address its concerns about the value of the services in question and to serve as a resource on laboratory-related issues, including on establishment of a laboratory advisory panel to assist NGS with reviews of these and other tests. Should you have questions or wish to discuss, please do not hesitate to contact me at swest@acla.com or 202-637-9466.

Sincerely,

Sharon L. West
Vice President, Legal & Regulatory Affairs

cc: Carolyn Cunningham, MD
Laurence Clark, MD

[2] CMS Medicare Program Integrity Manual, CMS Pub. 100-08, Chapter 13, Section 7.1 (Rev. 608, 08-14-15).