

March 17, 2019

Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Street, S.W.  
Washington, D.C. 20201

**RE: National Correct Coding Initiative Policy Manual for Medicare Services 2019  
Updates for Pathology/Laboratory Services**

Dear Administrator Verma:

The undersigned organizations, representing a broad range of stakeholders involved with offering clinical laboratory and pathology services critical to improving the health of Medicare and Medicaid beneficiaries are writing to express our serious concerns with certain, recent updates to the Pathology/Laboratory Services section of the National Correct Coding Initiative (“NCCI”) Policy Manual for Medicare Services, as well as corresponding updates to the Policy Manual for Medicaid Services (“Coding Policy Manual”), which took effect January 1, 2019. These changes, which reflect a fundamental disconnect with current laboratory testing procedures, were issued without notice or stakeholder input and if allowed to proceed, will be highly disruptive to coding and payment for clinical laboratory and pathology testing services.

We urge you to withdraw these changes and to work with stakeholders to address any concerns the Centers for Medicare & Medicaid Services (“CMS”) may have regarding billing for clinical laboratory and pathology services. Any evaluation of these policies should reflect the current standard of care in test ordering and performance and include an opportunity for stakeholders to review and provide comment on draft policies prior to their finalization and implementation.

**Specific Pathology Issues**

In Chapter X of the Coding Policy Manual, Correct Coding Solutions, the outgoing CCI contractor, made several, major changes to its coding guidance, including a new instruction stating *“if a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service.”*

This instruction is overbroad and unclear. It is unclear what constitutes “a laboratory procedure” per the new manual revisions. Many laboratory tests are performed in batches or using multiplex processes that produce multiple, different, clinically significant reportable test results. Per the changes in the manual, if each batch or multiplex process is treated as a single procedure, tests ordered for different patients but processed in a batch could constitute a single procedure. Additionally, if each test performed using a multiplex process is considered a single procedure, many procedures that currently are reported with test-specific codes would need to be reported using miscellaneous or unlisted procedure codes. This would violate AMA guidance to use the

most specific CPT codes, create difficulty for Medicare claims processors in determining the exact test(s) performed, create a heavy claims processing burden for Medicare Administrative Contractors (MACs) and State Medicaid Programs, create substantial delays in payment for laboratory providers, and result in much more limited data being “applicable information” for rate setting purposes under the new Clinical Laboratory Fee Schedule under Section 216 of the Protecting Access to Medicare Act.<sup>1</sup>

The Coding Policy Manual makes other changes that contradict longstanding coding guidance and will substantially increase administrative burden, including,

1. Section F.7 would prohibit reporting of a Tier 1 or 2 molecular pathology CPT code with another code (such as a Genomic Sequencing Procedure (GSP), Multianalyte Assay with Algorithmic Analysis (MAAA), or Proprietary Laboratory Analysis (PLA)) whose descriptor includes testing for the same analyte. We do not believe this statement is required. The current NCCI Procedure to Procedure (PTP) edits do not allow for this type of reporting.
2. Section F.8 would prohibit the use of multiple component codes when billing for a Next Generation Sequencing (NGS) procedure and would require the reporting of an unlisted molecular pathology procedure code if there is not a single code for the specific combination of markers comprising the procedure. This policy contradicts coding guidance that states Tier 1 and Tier 2 codes may be used to describe genes using next generation sequencing. This policy also decreases transparency of testing on patients and increases administrative burdens on laboratories, MACs, and State Medicaid agencies. Some laboratories perform NGS for operational efficiencies, but report only those specific, medically necessary tests actually ordered for a patient. Laboratories should be permitted to bill for testing as ordered consistent with coverage policies.
3. Section F.9 states that PTP edits bundling Tier 1 molecular pathology codes describe procedures that “should not routinely be performed or reported together,” and lists various full sequence analysis/duplication-deletion code pairs as examples.<sup>2</sup> This instruction runs counter to the express consideration of the American Medical Association Current Procedural Terminology (CPT®) Editorial Panel’s recognition of the differences between full sequence analysis and duplication-deletion testing, the role of each in patient diagnosis, and the fact that these tests are commonly performed and reported together (because sequencing alone is commonly not sufficient to make a diagnosis).

These new policies not only run counter to the way physicians order and laboratories perform testing, but also require laboratories to submit claims to Medicare and Medicaid contractors that follow coding policies which contradict long-standing AMA guidance.

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<sup>1</sup> The concerns raised in this letter are unrelated to the issue of reporting multi-channel chemistry tests under panel codes when there are panel codes under the CPT® codebook. The changes to Chapter X of the coding Policy Manual for 2019 to make such reporting mandatory are not being challenged here.

<sup>2</sup> Corresponding updates were made to the NCCI Policy Manual for Medicaid Services, also effective January 1, 2019.

Honorable Seema Verma, Administrator

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### **Process Concerns**

We are very concerned about the process by which these updates were promulgated. Despite the significant impact that the Coding Policy Manual updates are likely to have, stakeholders were notified of these changes, without any chance for input, only a few weeks before their effective date. Clinical laboratory and pathology testing services are very diverse—considering analyte, specimen types, and platforms. As such, it is important that CMS consider stakeholder input when developing any revisions to the Coding Policy Manual. Any such changes should also reflect current laboratory test ordering practices and work flow.

### **Conclusion**

Unless withdrawn, the sweeping approach taken in these updates will seriously disrupt laboratory billing and claims processing by MACs and State Medicaid Programs and could require significant revisions to the CPT code set. This does not advance the policies of reducing provider burden and is not in the best interests of Medicare and/or Medicaid beneficiaries.

Again, we respectfully request that CCS/CMS withdraw these updates and work with stakeholders to address concerns the Agency may have about clinical laboratory and pathology billing processes while avoiding problematic unintended consequences.

In addition to the points summarized in this letter, we attach more detailed correspondence submitted by several of the undersigned stakeholders describing significant concerns with the Coding Policy Manual updates.

Sincerely,

AdvaMedDx  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Society for Microbiology  
Association for Molecular Pathology  
Coalition for 21<sup>st</sup> Century Medicine  
College of American Pathologists  
Physician Fee Schedule Pathology Payment Coalition  
Point of Care Testing Association

#### Attachments

Correspondence from the American Clinical Laboratory Association dated December 14, 2018  
Correspondence from the Association for Molecular Pathology dated February 28, 2019  
Correspondence from the Coalition for 21<sup>st</sup> Century Medicine dated December 21, 2018  
Correspondence from the Point of Care Testing Association dated March 14, 2019