



## Statement of AdvaMedDx

### Centers for Medicare & Medicaid Services Clinical Laboratory Public Meeting for New Clinical Laboratory Test Payment Determinations for Calendar Year 2016

July 16, 2015

Good morning. My name is Chandra Branham, and I am here today representing AdvaMedDx. AdvaMedDx is an association within the Advanced Medical Technology Association – or AdvaMed – and our member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

We appreciate this opportunity to present this statement concerning several of the proposals being considered for the CY 2016 Clinical Laboratory Fee Schedule.

Our comments today will focus on:

- 1) The proposed modification for drugs of abuse testing and the two proposed G codes; and
- 2) Transparency of information that is made available prior to the CLFS public meeting.

#### 1) **Drugs of Abuse Test Codes**

CMS has proposed to delete 30 G codes, most of which were established by CMS last year to replace AMA-CPT codes that were eliminated from the CPT code set for 2015. CMS has further proposed to continue to not recognize the new CPT codes (80300 through 80377) that were established by the AMA for drugs of abuse tests for CY 2015; and, to propose two new G codes to be used to bill for drug screening and drug testing for any number of drugs or drug classes, any procedure or methodology, and any source, per day.

AdvaMedDx has engaged in discussions with our member companies, with other associations, including ACLA and others, and with some of our members' laboratory customers, and we are concerned that CMS is proposing a coding solution to address what CMS and its contractors have noted as a utilization issue. We agree with concerns expressed by others that the two proposed G codes, if finalized, will not address CMS' stated concerns about the potential for overpayments when providers bill for individual drug tests. CMS is instead proposing that providers bill a single code that would pay a set amount regardless of the number of drugs that are being tested.

We are concerned that CMS' refusal to adopt the CPT codes for drugs of abuse testing has repeatedly caused confusion among providers regarding appropriate coding. The current proposal does not help this situation. Stakeholders, including CMS, participated in the CPT process, which was meant to encapsulate concerns from all stakeholders. For CMS to later depart from the consensus on previous work is concerning, and results in CMS proposals such as this one that are inconsistent with multi-stakeholder input.

It is arguable that assigning only two G codes, one for any number of screening tests and another for any number of definitive drug tests, could also present opportunities for overpayments to occur. It is difficult to determine what would be the “typical” number of tests provided and billed with the single G code, but a single code and thus a single payment rate spanning one test to 15 or more is too broad and does not reliably reflect the costs of providing these tests. Further, it is not clear that this approach is the most appropriate and effective means of addressing overutilization, which would be more likely to be remedied through coverage policy and provider education together with CMS’ adoption of the CPT codes for these tests, which would permit a detailed understanding of what tests were being ordered and provided.

Limiting billing for these tests to only two codes also reduces the level of granularity, limiting payers’ ability to know with certainty which tests were actually provided. This is particularly problematic when the trend has, for a number of years, moved in the opposite direction, with payers seeking greater coding granularity in order to better understand what tests are being provided and paid for.

AdvaMedDx has long supported more granular coding for diagnostic tests. Granular codes can improve transparency and allow CMS as well as other payers to identify the tests for which they are paying.

The PAMA legislation that was passed last year included coding provisions requiring CMS to assign unique HCPCS codes for tests that currently do not have a unique code, and to adopt a process by which a provider or manufacturer may even request a unique identifier if the HCPCS code for its test is not sufficiently granular.

In addition to the retreat from granularity in the CMS proposal, the establishment of new G codes that may or may not be used by other payers creates confusion and may frustrate the intent of PAMA to base payment amounts for laboratory tests on what private payers are paying.

**Recommendation:** AdvaMedDx recommends that CMS adopt the CPT codes specific to these assays. In the alternative, AdvaMedDx recommends that CMS retain the existing 2015 G codes through 2016, while it gathers additional information from stakeholders and observes the pattern of use under these codes. In addition, CMS might consider requiring providers to report the CPT codes for the actual tests performed, along with the G codes (existing or proposed), so that the Agency can continue to gather information to better understand what may be considered “typical” billing for these tests.

## 2) **Transparency**

Each year, manufacturers and other stakeholders develop and present recommendations to CMS during this public meeting regarding the basis for establishing the payment amounts for new clinical laboratory tests under the CLFS. AdvaMedDx has commented many times about the level of transparency associated with the rationales provided by CMS to support its payment decisions. The rationales are often cursory and provide insufficient detail to permit stakeholders to fully understand the basis for the decision.

**Recommendation:** AdvaMedDx reiterates our recommendation that CMS improve transparency by providing complete and specific information in its payment determination

rationales so that interested parties can readily understand the Agency’s decisions, particularly in the event that a stakeholder decides to request reconsideration of a final determination.

**Conclusion**

In conclusion, AdvaMedDx has significant concerns regarding the proposal to use only two G codes to bill for multiple drugs of abuse tests furnished on a given day. The proposed policy does not address CMS’ stated concerns about overutilization and overpayments and could lead to more, not fewer, incidents of inappropriate billing. Finally, we urge CMS to provide for greater transparency and access to information in the decision-making process.

AdvaMedDx appreciates the opportunity to make these comments today.

Thank you.