

**STATEMENT
of
AdvaMedDx**

**Centers for Medicare and Medicaid Services
Information Session: Discussion on New Genetic Testing Codes**

July 18, 2011

Good morning. My name is Ann-Marie Lynch, and I am here representing AdvaMedDx. AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing *in vitro* diagnostic companies both in the United States and abroad.

We appreciate CMS's effort in conducting this information session to discuss payment for the new codes for genetic testing that have been developed by the CPT Editorial Panel. CMS faces a number of critical decisions relating to these codes, and we appreciate CMS's attention to seeking knowledgeable input from stakeholders in advance of making these decisions.

- The number of new codes the CPT Editorial Panel has proposed this year -- about 100 -- is unprecedented.
- Further, the tests that are described by these codes are complicated and involve some of the most advanced techniques currently available. The new codes classify the tests by analyte, while previously laboratories have described these tests using codes that specify the steps but not what is tested. Thus, even though Medicare has been paying for some of these tests for some time, little information is available from the claims stream or otherwise about the nature of these tests for particular analytes and what is involved in performing them. Accordingly, establishing payment rates that pay fairly for these tests without risking a precipitous decline in payment rates that might threaten their availability is unusually challenging.
- Finally, CMS faces decisions of where to place these codes -- on the physician fee schedule or the clinical laboratory fee schedule. To our knowledge, this issue has not surfaced in such an evident way before, and we appreciate CMS's willingness to discuss the issues associated with these assignments. Choosing one route versus the other for a particular test changes the procedures that may be used to establish payment rates, but neither escapes the fundamental problem of discerning how to establish appropriate rates.

The work group convened by the CPT Editorial Panel took many meetings and well over a year to develop these codes. Determining appropriate payment rates is likely to require well more than the usual information and the usual timeframe. We strongly urge CMS to wait to

implement these new codes until it can assemble complete and reliable information to inform the decisions and ensure that it sets payment rates in an accurate manner.

In particular, we suggest that CMS consider mounting a careful study by expert clinicians of the steps involved in the various tests that will be coded with the new codes. For some tests of specific analytes, laboratories may employ different methods, reflecting alternative clinical approaches and/or the specific genes that are examined. Other factors, such as the level of automation are also important to consider. We believe that the most reliable approach to acquiring information on the range of practices in the field would be to see how tests for a given new code are currently coded. To ensure a comprehensive picture, laboratories could be instructed, while continuing to use the existing method codes for payment, to specify the new codes in a comment field. The resulting claims could then be used to develop the needed information about the different method steps that are being used.

Other information is also important in establishing rates for these tests. Data on the steps involved in performing the test should be supplemented with additional information including the uses and clinical value of the test, payment rates from other payers, and other factors reflecting not only immediate resource use but also the investments necessary and the risk involved in bringing a reliable test to market and the value of the test in clinical practice

Accordingly, we suggest that CMS exercise its administrative discretion to delay exclusive reliance on the new codes for Medicare payment purposes. A year or more may be needed to gather and analyze the needed information and to provide a public comment period. Given the complexity of the issues, CMS should consider delaying using the new codes for payment purposes at least until January 2013 or January 2014.

We look forward to continuing to engage with CMS regarding improvements to the process for developing new test payment determinations, and we hope that the agency will consider our suggestions for ensuring payments for this set of new codes are accurate and appropriate, so that they facilitate rather than interfere with the availability of these critical tests. Further, we commend CMS for holding this meeting and strongly recommend that the agency establish a standing advisory panel comprised of clinical and laboratory payment experts. Such a panel would provide a venue for CMS to receive the benefit of such technical expertise in a sustained fashion.

Thank you again for the opportunity to provide comments.