June 29, 2012

Mr. Jonathan D. Blum  
Deputy Administrator and Director, Center for Medicare  
and Medicaid Services  
Mail Stop 314G  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Mr. Blum:

I am writing on behalf of AdvaMedDx regarding the Centers for Medicare & Medicaid Services’ (CMS) process for updating Medicare’s Clinical Laboratory Fee Schedule (CLFS).

AdvaMedDx member companies produce advanced in vitro diagnostics tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall healthcare costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx is the only multi-faceted policy organization that deals exclusively with issues facing in vitro diagnostic manufacturers both in the United States and abroad.

Each year, CMS establishes payment rates for new or substantially revised laboratory services through a process that differs from the formal review and comment process used with Medicare’s other payment systems. The process used to revise the CLFS each year begins with an announcement in the Federal Register of a public meeting that gives an opportunity for stakeholders to provide comments and recommendations regarding payment amounts for specific tests/procedures being considered for payment. The codes for these tests/procedures are typically posted to CMS’ website about 30 days prior to the public meeting. Sometime after the public meeting, CMS posts its preliminary determinations on its website, and provides a minimal opportunity for additional written comments to be submitted from clinicians, providers, scientific experts, patients and the public.

**Truncated Comment Period in 2011** – Last year, CMS published the Federal Register notice regarding the Clinical Laboratory Public Meeting and CLFS payment determinations for the CY 2012 payment year very early. The public meeting was scheduled for July 18th and the meeting notice stated that a summary of the preliminary payment recommendations would be posted on the CMS website by “early September.” The notice further stated that written comments would be accepted until September 23rd. The public meeting was held on July 18th; however, the preliminary payment determinations were posted later than expected, giving public commenters only a few days, rather than weeks, to respond to the information.

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1 See 76 Fed Reg 10600 (February 25, 2011).
This year’s *Federal Register* notice\(^2\) states that CMS intends to post its proposed payment determinations by September 28\(^{th}\) and the final payment determinations in November, at the same time as the CY 2013 Physician Fee Schedule final rule is published, which again restricts the time period for providing meaningful comment.

**Recommendation:** CMS should provide a reasonable public comment period of at least 30 days to give commenters the opportunity to provide meaningful feedback on the preliminary decisions. The timing of the posting of the preliminary payment determinations and last year’s comment deadline did not allow stakeholders adequate time to respond. Similarly, the anticipated timing of the posting of the preliminary and final payment determinations for the CY 2013 payment year limits stakeholders’ ability to provide meaningful feedback, and also limits CMS’ time and ability to adequately consider any comments it receives.

**Unknown Basis for and Limited Transparency Regarding Decisions** – Each year, manufacturers and other stakeholders develop and present to CMS recommendations regarding the basis for establishing the payment amounts for new clinical laboratory tests that will be paid under the CLFS. However, CMS has frequently failed to adopt the recommendations it receives, despite apparent agreement on particular recommendations by several expert stakeholders. Often, the rationales for the decisions are cursory, lack transparency, and provide insufficient detail to permit stakeholders to fully understand the basis for the decision. We believe this process and level of transparency could be improved.

For example, in the preliminary payment determinations for CY 2012, CMS stated that “cost data did not justify” a particular payment proposal and that “other commenters have provided input that the payment of about $20 for this test is reasonable.” CMS did not expand upon its analysis of the cost data.

**Recommendation:** CMS should be fully transparent in its responses to commenters and provide complete and specific information in its payment determination rationale so that interested parties can readily understand the Agency’s reasoning for its decisions. Further, CMS should be consistent in its analysis, particularly where CMS does not agree with the data, such as cost data, received from stakeholders, and should provide uniform information in its rationale statements.

**Large Volume of New Molecular Tests** – This year, an improved process would be particularly valuable due to the large number of new molecular diagnostic tests for which CMS must make decisions regarding both fee schedule placement (Clinical Laboratory Fee Schedule or Physician Fee Schedule) and payment. The volume and complexity of molecular diagnostic tests presents unique challenges in determining appropriate payment. In light of this, the importance of a transparent process regarding the methods used to reach final determinations regarding molecular diagnostic test payment cannot be overstated.

We understand that CMS will consider payment recommendations and supporting evidence regarding the new molecular diagnostic codes during the July 16-17, 2012, Clinical Laboratory Public Meeting, as well as through comments received in response to

\(^2\) See 77 Fed Reg 31620 (May 29, 2012).
the forthcoming Physician Fee Schedule notice of proposed rulemaking for CY 2013. We support this approach and believe that it will provide an opportunity for input from a broad range of interested parties. However, we remain concerned about CMS’ previous practice of failing to adopt many of the recommendations that come in through these public comment processes without providing adequate explanation or rationale for its decisions.

Again, we urge CMS to provide an adequate public comment period, and to publish more specific information regarding its proposed and final payment determinations for tests considered for payment under the CLFS, similar to the information that is typically provided when responding to comments via the formal notice-and-comment rulemaking process. We look forward to the Agency’s proposals regarding fee schedule placement and payment for these tests, and to participating in the public process.

Thank you for your attention to this matter. If you or your staff has any questions, please do not hesitate to contact Chandra Branham on my staff at cbranham@AdvaMed.org or (202) 434-7219.

Sincerely,

Ann-Marie Lynch
Executive Vice President, Payment and Health Care Delivery Policy
AdvaMed

cc: Elizabeth Richter
Amy Bassano
Marc Hartstein