



AdvaMedDx

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Statement of AdvaMedDx

Centers for Medicare & Medicaid Services Clinical Laboratory Public Meeting for New Clinical Laboratory Test Payment Determinations for Calendar Year 2015

July 14, 2014

Good afternoon. My name is Chandra Branham, and I represent AdvaMedDx. AdvaMedDx functions as an association within AdvaMed – the Advanced Medical Technology Association. 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 our thoughts regarding CMS' implementation of Section 216 of the Protecting Access to Medicare Act of 2014.

AdvaMedDx supported reforms to the Clinical Lab Fee Schedule (CLFS) that we believe will strengthen the payment process for diagnostic tests by improving transparency and creating a formal mechanism for expert input. During 2013 and 2014, we worked with other stakeholders, including the American Clinical Laboratory Association (ACLA), the Coalition for 21st Century Medicine (C21), and others in an effort to build consensus around policy changes that would bring much needed change to the outdated CLFS system.

Our comments today will focus on three elements of the new law:

- 1) the new Expert Advisory Panel,
- 2) new statutory requirements regarding transparency, and
- 3) coding issues.

1) **Expert Advisory Panel**

AdvaMedDx has long supported the development of an advisory body with members who have experience and expertise in clinical laboratory operations, commercial test development and diagnostic reimbursement. We also support inclusion of patient and clinician perspectives in the advisory panel.

The statute requires the advisory panel to be established by July 1, 2015. The size and composition of the panel were not specified in the law. The law states that the panel should consist of individuals with experience in laboratory science, health economics, molecular pathology, clinical laboratory tests, and similar fields.

Because CMS is directed to assemble the advisory panel before laboratories begin reporting private payer data, we believe Congress intended that the panel lend its expertise and advice to CMS regarding the assignment of payment rates to new tests through the crosswalk or gapfill process and on other aspects of the new law, including the process for reporting private payer data to CMS. We hope that CMS will seriously consider the panel's advice.

We recommend that CMS include on the panel individuals with recent direct experience in the clinical laboratory industry. Individuals with real-world experience understand how clinical laboratories operate and can shed light on how policies can be operationalized. We urge CMS to include individuals with technical expertise in developing, validating, and performing clinical laboratory tests; diagnostic test manufacturers; laboratorians; individuals with expertise in pharmacoeconomics and/or health technology assessments; patient representatives; and clinicians who use laboratory test results in clinical practice.

The composition of the panel also should reflect the laboratory industry's diversity, and should include the viewpoints of independent clinical laboratories, hospital laboratories, and physician office laboratories. We sincerely hope that CMS will take full advantage of the resources available through this expert advisory panel and will seek its advice on how new tests should be paid.

Finally, to maximize the value of the panel, we encourage CMS to carefully consider the many issues related to the development of the panel, its role and the processes it will follow– including when and how often the panel should convene and the development of meeting agendas. We hope to have opportunities in the coming months to interact with CMS to explore these issues.

- ***Recommendation: CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and that patient and clinician perspectives are represented. We also recommend that stakeholders have an opportunity to provide input on the advisory panel's charter, role, processes, and meeting agendas.***

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 CMS' failure to adopt the recommendations it receives, even when the agency appears to agree with a particular recommendation. The rationales provided by CMS to support its payment decisions are often cursory and provide insufficient detail to permit stakeholders to fully understand the basis for the decision. Furthermore, it is unclear whether and to what extent the agency takes stakeholder comments into consideration in making its determinations.

In addition to decisions about crosswalking or gapfilling, CMS will now be responsible for establishing payment amounts for tests on the CLFS based on very large amounts of private payer data that will be reported to CMS by applicable laboratories. We fully expect that, given this large amount of data and the very short timeframe for implementing a new system, errors will occur. We strongly urge CMS to establish a process by which a lab or manufacturer can request "re-review" of a proposed rate. Such processes exist in other contexts within the Medicare program (e.g., PFS and OPFS).

Recommendations:

- ***AdvaMedDx recommends that CMS be more transparent in its responses to commenters by providing complete and specific information in its payment determination rationale so that interested parties can readily understand the Agency's decision.***

- *We also urge CMS to ensure that there is sufficient transparency in the rate-calculation and rate-setting processes. Stakeholders should be able to review preliminary payment rates, prior to their effective date, and request that CMS review potentially inaccurate rates. To facilitate this, CMS should publish preliminary payment rates at least three months prior to their effective date.*

3) Coding Issues

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 new law includes three specific coding provisions:

- First, it requires CMS to assign temporary HCPCS codes to identify new ADLTs and tests that are cleared or approved by the FDA;
- Second, the law requires CMS to assign unique HCPCS codes for existing advanced diagnostic lab tests (or, ADLTs) and tests that are cleared or approved by the FDA that do not currently have a unique code; and
- Third, the law authorizes CMS to adopt a process by which a laboratory or manufacturer offering an ADLT or an FDA-cleared or -approved test may request a unique identifier for the test.

Recommendations:

- *New tests – CMS should consider allowing laboratories and manufacturers to submit requests for temporary codes to identify new ADLTs and new tests that are cleared or approved by the FDA. Assignment of temporary HCPCS codes should take place on a quarterly basis.*
- *Existing tests – CMS should develop a process, through subregulatory guidance, to issue unique HCPCS codes for existing ADLTs and existing clinical laboratory tests that are FDA-cleared or –approved, and that are currently billed with a miscellaneous code or are not assigned to an existing CPT or HCPCS code. We recommend that this assignment of unique HCPCS codes apply only to existing tests that were paid by Medicare as of the date of enactment of PAMA and that CMS develop an expedited process for submitting unique HCPCS requests to facilitate the collection of 2015 rate-setting data..*
- *Unique identifiers – Finally, the law authorizes CMS to allow a laboratory or manufacturer offering an ADLT or an FDA-cleared or -approved test to request a unique identifier for the test. The law states that the unique identifier could be a HCPCS code, a modifier, or something else. Given the recommendation above to assign unique HCPCS codes to new and existing ADLTs and FDA-cleared or -approved tests, CMS should consider assigning HCPCS codes as the unique identifier.*

We understand, however, that a test could ultimately be assigned to a CPT code that is less granular than its original HCPCS code, and that does not uniquely identify the test. In such a case, we urge CMS to clarify that a lab or manufacturer will be able to request a unique

identifier for the test (i.e. reinstatement of the original HCPCS code or assignment of another method to uniquely identify the test).

Conclusion

In conclusion, AdvaMedDx supported many of the payment reforms that were included in Section 216 of PAMA, and has worked closely with many of the other stakeholders here today regarding implementation of the law. We have focused on issues that are significant for AdvaMedDx members understanding that the range of issues involved in building a new payment process based on private market data is complex and that CMS faces numerous challenges to fully implement these reforms. As always, AdvaMedDx is happy to serve as a resource now and in the future as CMS proceeds with rulemaking.

AdvaMedDx appreciates the opportunity to make these comments today. We look forward to the agency’s proposals regarding payment for these tests, and to participating in the public process.

Thank you.