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AdvaMed
Advanced Medical Technology Association

AdvaMedDx
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May 11, 2016

Via Electronic Mail Only
Steve Phurrough, MD, MPA
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop C4-01-26
Baltimore, Maryland 21244

Re: Coding for Diagnostic Laboratory Tests under PAMA §216

Dear Dr. Phurrough:

On behalf of the members of the Advanced Medical Technology Association and AdvaMed Dx (hereafter AdvaMed), we are writing to provide feedback on proposed coding solutions to implement section 216 of the Protecting Access to Medicare Act (PAMA).

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

AdvaMedDx operates as a division within AdvaMed and represents the world's leading diagnostics manufacturers by advocating for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx 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.

Section 216 of PAMA, in part, requires that new coding solutions be developed to identify advanced diagnostic laboratory tests, such as certain molecular diagnostic tests that meet specific requirements. The legislation requires that coding mechanisms be created to address the development of test-specific codes for certain sole-source laboratory **or** FDA cleared or approved clinical diagnostic laboratory tests and that a mechanism be developed to create unique identifiers for new and existing tests.

To date CMS has not committed to a process for developing the codes required by Section 216 of PAMA nor has the agency disclosed the format of these codes. CMS proposed the use of temporary G codes to address the various coding requirements in the law, but the rule has yet to be finalized.

AdvaMed understands that CMS has been presented with varying proposals regarding the best coding solution to achieve the goals of PAMA. While our membership is not wedded to a particular proposal, we would like to provide feedback on some issues that should be considered by CMS as the agency works to finalize a coding solution.

The issues of greatest concern to AdvaMed members are transparency and consistency. Whatever coding system is adopted should be easy to use and to understand. The new system should be constructed in a way that avoids disruption in coding and minimizes the risk of coverage interruptions once the mandatory data collection period has expired. In order to achieve the desired level of consistency, AdvaMed recommends that any codes that are adopted in order to fulfill the legislative requirements of PAMA be structured and implemented in a way that allows their continued/ongoing use for the life of a test. Ideally this could be accomplished through the development of codes that are permanently assigned to a specific test. This would allow the code assigned to the test during the data collection period to transition into a permanent code without the need to request another code for the same test in the future.

AdvaMed members are also interested in ensuring that the codes that are developed are granular and are issued in a timely manner so that potential test users can avail themselves of these tests as soon as possible. We strongly support establishing a granular code process that will allow code descriptors to be associated with a specific test. Moreover, we are supportive of a process that will allow for frequent updating of the code set, on a quarterly basis at minimum, to allow for ready access and use of newly developed test codes. Lastly, AdvaMed supports a code development system that will allow requestors to sunset or retire a code if needed.

AdvaMed believes that our recommendations align with the intent of PAMA and will improve the process for obtaining codes for these tests, in a consistent and transparent manner, while avoiding unnecessary delays and redundancy.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on this issue and urges CMS to consider and incorporate our recommendations. We also urge CMS to work with us and other stakeholders as the agency moves forward with the implementation and development of codes pursuant to the PAMA directives and to consider comments from AdvaMed members and others who will be providing detailed recommendations on this proposed model.

We would be pleased to answer any questions regarding these comments. Please contact me, Chandra Branham, Esq. Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219, or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

/s/

Donald May
Executive Vice President,
Payment and Health Care Delivery

cc: Edith Hambrick