July 8, 2019

VIA EMAIL: Sarah.Shirey-Losso@cms.hhs.gov
CLFS_Annual_Public_Meeting@cms.hhs.gov

Ms. Sarah Shirey-Losso
Director, Division of Ambulatory Services, CMS
7500 Security Blvd.
Mail Stop: C4-10-07
Baltimore, MD 21244

Re: Comments on Automated Chemistry Test Panels

Dear Ms. Shirey-Losso:

AdvaMedDx appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding payment for certain codes for automated chemistry tests and for other panel tests.

AdvaMedDx operates as a division within the Advanced Medical Technology Association (AdvaMed) and represents the world’s leading diagnostics manufacturers by advocating for the value and 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.

Panel Tests
When CMS implemented the PAMA statute, panel tests presented some difficult issues. These issues were not addressed by CMS in its proposed rule nor was there any mention in CMS’ CLFS final rule of how payment would be made for tests typically paid as part of automated test panels or how private payer data would be reported.

Prior to 2018, CMS applied an “Automated Testing Panel” grouper or pricing logic for ATP multichannel tests, which was discontinued on January 1, 2018. Instead, claims for individual automated multichannel tests are to be billed using existing CPT codes, unless the test being performed is described by a specific CPT code representing a panel. Payment rates for the individual test codes, as well as the panel codes, are set at the median of private payer data reported by applicable laboratories – per the PAMA statute.
The statute requires CMS to establish payment for individual tests at the weighted median of private payer rates as reported by applicable laboratories. There is no provision under the statute for applicable laboratories to collect and report private payer rates, or for CMS to determine pricing, for test bundles. Establishing a different pricing or payment method for automated multi-channel chemistry tests would not align with the intent of the statute. Additionally, given the data collection period for the next PAMA cycle has just concluded (Jan-Jun, 2019), establishing a new methodology or new codes in 2020 would render the data collection useless for setting market-based rates for 2021-23.

Despite a November 2018 GAO report suggesting otherwise, there is no evidence that laboratories are engaging in inappropriate billing practices, such as unbundling panel codes. We therefore recommend that CMS take no action based on that GAO report or other information without clear evidence that such practices are occurring. Should CMS find that certain laboratories are engaging in such practices and inappropriately unbundling panel codes, CMS should address those individual situations in a targeted manner.

Otherwise, CMS should follow the current procedures established under the PAMA statute, and evaluate respective tests based on laboratory-reported private payer rates, taking into consideration the input of the Advisory Panel and stakeholder recommendations.

We appreciate the opportunity to provide these comments to CMS and are happy to respond to any questions you may have. Please feel free to contact me at cbranham@advamed.org or (202) 434-7219.

Sincerely,

Chandra N. Branham, JD
Vice President, Payment & Health Care Delivery Policy
AdvaMed/AdvaMedDx