October 23, 2017

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on Preliminary CY 2018 Clinical Laboratory Fee Schedule (CLFS) Prices under PAMA Section 216(a)

American Medical Technologists (AMT) submits the following comments on the Centers for Medicare and Medicaid Services’ (CMS) preliminary pricing for the Medicare Clinical Laboratory Fee Schedule (CLFS) under section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA). The proposed pricing was released by CMS on September 22, 2017.

AMT is a national, nonprofit certification organization and professional society for clinical laboratory professionals and related allied health personnel. Among AMT’s current active membership of over 77,000 professionals are nearly 10,000 certified Medical Technologists, Medical Laboratory Technicians, Laboratory Assistants, Phlebotomists, and Laboratory Consultants. In addition, many of the approximately 58,000 Registered Medical Assistants currently certified by AMT perform waived and moderate complexity testing in physician office laboratories (POLs) and other clinical settings. All of AMT’s member-certificants in the laboratory-related disciplines stand to be directly or indirectly impacted by CMS’s proposed CLFS overhaul.

The CMS preliminary CY 2018 CLFS fails to achieve Congressionally mandated market pricing. By excluding a substantial segment of the laboratory industry, CMS’s definition of “applicable laboratory” has resulted in a markedly inadequate, unrepresentative, and biased data reporting sample. The agency’s own analysis reveals that only 21 of the more than 9,000 hospital laboratories nationwide submitted price and volume data. Hospital labs and POLs account for 44% of Medicare testing services, yet fewer than 1% of those entities reported data. More than 99% of laboratories that were paid for laboratory services under Medicare Part B reported no data to CMS. Of the entities that did submit data, only 1.1% were hospitals and just 1.85% of data was collected from laboratories serving rural areas.
The vast majority of data was collected from a few large independent laboratories whose business models depend on offering steep discounts to private payers in return for assured volume. Community hospital outreach labs and most POLs do not enjoy the same economies of scale but offer a level of localized services to dispersed Medicare populations that cannot be matched by the large reference labs; yet these community-based labs were prohibited from participating in the PAMA reporting exercise.

The flawed data collection model will result in massive cuts to fees paid under the CLFS, particularly for the most commonly ordered tests. Over the first three years (2020-2022), prices will be reduced by over 24% from the existing National Limitation Amounts (NLA) for the 25 top tests (by Medicare fee schedule payments), and by approximately 28% for the top 20 tests. Nine of the top ten tests will see decreases of more than 30%, tempered only by PAMA’s statutory limitation on the percentage of price decrease that can be implemented in each of the first three years.

The artificially depressed prices will disproportionally impact access for the most vulnerable Medicare patients. If the draft prices are finalized, many clinical laboratories will be unable to survive the double-digit annual percentage reductions in payments for Medicare lab services. Lab closures and consolidations will especially impact Medicare beneficiaries in rural and post-acute care settings, which are heavily reliant on local and regional independent labs and community hospital outreach testing to service their Medicare populations. COLA, a nonprofit accrediting organization that accredits nearly 8,000 clinical laboratories in clinics, physician offices, and other patient care settings, warns that implementation of the proposed PAMA pricing will dramatically reduce the availability of “near patient testing,” and consequently, will reduce access for the frailest Medicare beneficiaries and will harm patient care.

Serious questions persist over the accuracy and completeness of the initial data submitted. Laboratory stakeholders have raised numerous concerns that collecting and reporting private payor data to CMS was very challenging, particularly since the first data reporting period was retroactive. While laboratories undoubtedly did their best to submit accurate data, it is clear from the data made available by CMS that many laboratories did not understand what was to be included or excluded from reporting, or were unable to access information from their systems accurately. Examples of data anomalies include:

- CPT 80048 had rates from $0.01 to $27,356.01
- CPT 80053 had rates from $0.01 to $65,081.33
- A price of $0.00 was reported for 2.4 million tests, which represents one percent of the test volume submitted by applicable laboratories

PAMA implementation must be delayed while CMS addresses these shortcomings. For both legal and policy reasons, CMS should not proceed to finalize the draft prices released on September 22nd. Rather, the agency should postpone the new pricing in
recognition that the data reporting results are neither accurate nor representative of the broad clinical laboratory market. The proposed cuts go far beyond what Congress envisioned and what the Office of Management and Budget projected. In addition, some proposed cuts violate the statutory limit on how much a test can be reduced each year. Accordingly, CMS should suspend implementation of the draft payment rates until issues with market exclusion, data accuracy, and unsustainable rates are addressed.

We appreciate the opportunity to submit these comments on behalf of American Medical Technologists, a national leader in allied health professional credentialing.

Sincerely,

Michael N. McCarty
AMT Legal Counsel

cc: Jeffrey Lavender, President, AMT
    Christopher A. Damon, JD, Executive Director, AMT
    AMT Government Affairs Committee