Trinity Health

October 18, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Preliminary 2018 Clinical Laboratory Fee Schedule

Submitted electronically to: CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the Preliminary 2018 Clinical Laboratory Fee Schedule. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Trinity Health includes 93 hospitals, as well as 115 continuing care locations that include PACE, senior living facilities, and home care and hospice locations. Our continuing care programs provide nearly 1.9 million visits annually. Committed to those who are poor and underserved, Trinity Health returns almost $1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with Graduate Medical Education (GME) programs providing training for 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

Medicare currently pays for clinical diagnostic laboratory tests (CDLTs) under the Clinical Laboratory Fee Schedule (CLFS). CLFS rates have historically been updated to make statutory, across-the-board updates or when payment for a new test is added. A final 2016 Medicare CDLTs payment systems rule from CMS, however, revises the Medicare payment system for clinical diagnostic laboratory tests, and effective January 1, 2018, these tests will be subject to a private payer rate-based fee schedule. Private payer rates for laboratory tests from applicable laboratories will be the basis for the revised Medicare payment rates for most laboratory tests on the CLFS beginning in January 2018. On September 28, 2017, CMS released the preliminary revised fee schedule, which shows the current and estimated rates for 2018-2020. While the data collection portion of the revised clinical laboratory payment system was only applicable to specific labs; the revised fee schedule will be applicable to all laboratories. Trinity Health is concerned by the significantly deficient data collection process used to establish these new clinical laboratory payment rates, which resulted in unreliable and unsustainable rates, as described further below. This process falls short of Congress' laudable goal – through the Protecting Access to Medicare Act (PAMA) – of establishing a market-based system. **Therefore, Trinity Health urges CMS to swiftly suspend implementation of the draft payment rates until these data deficiencies can be addressed, and instead for CMS to engage stakeholders on ways to improve the PAMA data process and calculation thereby establishing a clear path forward for the clinical laboratory community and the Medicare beneficiaries who rely on its services.**

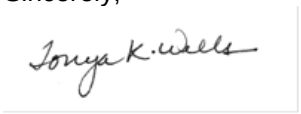
The payment data collected by CMS for the CLFS does not result in an accurate weighted median of private payer rates for most tests on the CLFS. Trinity Health concurs with the broader stakeholder community, including national, regional, and community independent laboratories; hospital laboratories; physician office laboratories; and diagnostic manufacturers, that the data used to set the proposed rates would not stand up to statistical validity review. The data sources used to determine the preliminary rates do not appear to reflect the various market segments, which CMS has the authority to consider in order to validate the data submitted. For example, in Albany, New York the majority of laboratories – including the hospital outreach laboratory at Saint Peter's Health Partners – were excluded from the data collection process resulting in data skewed towards the two major commercial reference laboratories in that region. It is also clear from stakeholder review that the overly burdensome regulatory requirements resulted in the submission of inaccurate and incomplete laboratory payment data from those laboratories that were asked to submit. This inaccurate and incomplete data is not reliable for use in its current form.

Specifically, Trinity Health urges CMS to:

- Modify the PAMA regulation to address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers;
- Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and
- Provide a transparent process to allow for the validation of the data collected by CMS.

We appreciate CMS' ongoing efforts to improve payment systems across the delivery system. If you have any questions on our above comments, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,



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