Medical Group Management Association®

October 23, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The Medical Group Management Association (MGMA) appreciates the opportunity to submit comments on the preliminary Clinical Laboratory Fee Schedule (CLFS) rates for the calendar year 2018 posted by the Centers for Medicare & Medicaid Services (CMS) on Sept. 22, 2017. We are deeply concerned that, if finalized, draft CLFS rates will result in significantly reduced access to critical point-of-care laboratory testing for Medicare beneficiaries due to the problematic approach CMS took when implementing the Protecting Access to Medicare Act (PAMA) of 2014. We strongly urge CMS to modify the existing PAMA regulations through issuance of an interim final rule effective Dec. 1, 2017 that holds calendar year 2017 rates in place until CMS has conducted targeted market segment surveys (reference laboratories, physician office-based laboratories, independent laboratories, and hospital outreach laboratories) to ensure the integrity and accuracy of data. CMS has the authority to validate and adjust preliminary rates to ensure congressional intent is fulfilled and rates accurately reflect private market payments across all market segments.

With a membership of more than 40,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

Section 216(a) of PAMA requires CMS to revise the Medicare reimbursement methodology for services furnished under the CLFS using a market-based approach, based on commercial payer pricing data reported by applicable laboratories. During PAMA CLFS rulemaking, MGMA and other stakeholder groups strongly urged CMS to establish a data collection period at a minimum of six months *after* the final rule was issued in 2016. This request was based on extensive experience implementing major changes to Medicare programs by stakeholder organizations and physician group practices. CMS instead mandated a complicated, detailed, confusing, and voluminous data collection requirement for a mostly retrospective data collection period that began approximately six months before the final rule was issued. CMS further exacerbated difficulties by seeking six months of data when three months would have reduced the reporting burden and could have redirected resources and attention toward ensuring data accuracy. The data collection undertaking constituted an impossibility for a number, if not all, of our members to do accurately and completely. Many clinical laboratories, including the largest reference laboratories that have sophisticated payments systems and that hired additional staff, struggled to collect accurate data within the specified data collection timeframe and to timely submit. All of the foregoing

underscores that clinical laboratories were required to comply with a regulation that constituted an impossibility.

Not surprisingly, as a result, preliminary rates reflect massive cuts well in excess of what Congress had intended and what was forecasted. CMS' summary of preliminary data estimates that new CLFS rates will save Medicare approximately $670 million in calendar year 2018 alone, a substantial increase from the $390 million in savings CMS initially projected (81 FR 41097). The new 2018 rate for 75 percent of test codes on the CLFS would be lower than the 2017 fee schedule rate. In fact, for 58 percent of tests, the cuts are so steep that reductions would have to be phased-in over multiple years, as the preliminary rates exceed 10 percent of current rates and PAMA established a maximum per-year reduction.

The impact of projected payment cuts for clinical laboratories is not inconsequential. MGMA is extremely concerned that, if finalized, proposed CLFS rates will result in significantly reduced access to laboratory testing for Medicare beneficiaries, particularly those in rural geographic areas, and impede the critical role point-of-care testing plays in patient care. Rapid, accurate clinical testing in a physician office setting is invaluable in the treatment of acute illness and ongoing management of chronic conditions, and can help avoid emergency hospitalizations. Real accounts across the country convey the serious threat of preliminary rates to patient outcomes. An MGMA member in a medically underserved area in Oregon reported: "In our specialty, we use lab tests to monitor all of our patients progress and health status. There is no better indicator for Endocrine conditions. This requires a lot of extra work outside of any actual visit. If we are forced to close our own in-house lab, our providers will still have to order to monitor their conditions. Our state has a large rural area with limited access anyway. If clinic labs close in these areas, their limited access may completely dry up." A family care clinic in rural North Carolina reported that clinicians were able to intervene and divert a patient to the emergency department after A1c results produced in an in-office lab showed critical levels, potentially mitigating a dire consequence. Point-of-care testing is far more than just a convenience to patients; it has the potential to save lives.

The foregoing underscores the importance of taking immediate action to assess and validate the accuracy of payment data, and to do so in a transparent manner using reliable, verifiable, data sources. Building a new payment structure from flawed materials will only result in inaccurate payment rates for clinical laboratories, which undermines the very intent of PAMA and impairs the infrastructure of point-of-care testing. There is no practical or meaningful way for stakeholders to evaluate the accuracy of submitted data or CMS' aggregation based on the data made publicly available. We urge CMS to conduct a market-based segmented survey to validate the final amounts and adjustment before allowing the new pricing methodology to proceed as planned. CMS has numerous claims databases and sources and additional methods that would enable the agency to conduct targeted surveys. Gathering more, massive, voluminous data from a larger pool of newly defined applicable laboratories or conducting audits of individual laboratories is not necessary and would further divert attention from making meaningful improvements to clinical care.

We appreciate your consideration of these comments. If you have any questions, please contact Mollie Gelburd at mgelburd@mgma.org or 202.293.3450.

Sincerely,

/s/

Anders Gilberg, MGMA
Senior Vice President, Government Affairs