AMERICAN OSTEOPATHIC ASSOCIATION

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Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Verma:

The American Osteopathic Association (AOA), on behalf of the nearly 130,000 osteopathic physicians and osteopathic medical students it represents, is pleased to share insight on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2018 Preliminary Payment Rates and Crosswalking/Gapfilling Determination.

We appreciate that CMS is charged with implementing the Protecting Access to Medicare Act of 2014 (PAMA) requirements to collect data from laboratories regarding private payer rates in order to reprice Medicare reimbursement for laboratory services. However, we are concerned that the process that has been implemented to collect and use that data is flawed and will lead to lowered payment that will challenge many laboratories' ability to continue to provide clinical testing services. In fact the preliminary payment rates show precipitous declines in payment rates. The statutory 10 percent per year cap on payment rate decreases does little to mitigate this trend, as the year-over-year application of the 10 percent decrease will ensure rates continue to drop at up to 10 percent per year in 2019, 2020, and thereafter at potentially more precipitous rates.

Data Collection Methodology
Physician office-based laboratories (POLs) are ill-equipped to participate in the extensive data collection required by the policy. We appreciate that CMS recognized this fact and limited the volume of POLs that are required to report. However, the result of the lack of POL reporting is that the private payer rates for POLs are not adequately represented in the data reported to CMS. As a result, the Medicare rates that are based on the reported data do not reflect the costs of providing the clinical testing services in the POL setting. This divergence between costs and reimbursement will force some POLs as well as many other smaller clinical laboratories to discontinue some laboratory services.

Laboratories that did report faced several challenges. Despite, physician organizations' urging of CMS to establish a data collection period at a minimum six months after the final rule was issued in 2016, 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. These data reporting requirements and timelines were impossible 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 submit timely. All of the foregoing underscore that clinical laboratories were required to comply with a methodologically challenged regulation that did not reflect physician organizations' experience in implementing major changes to Medicare programs.

Access to Care
Physicians in all practices rely on accurate and timely test results to appropriately diagnose and treat patients. As the Clinical Lab Fee Schedule (CLFS) methodology would result in lower payments that are not aligned with the costs of providing the service, many laboratories (including but not limited to POLs) may no longer be able to provide such services. This trend would shift the volume of clinical laboratory services to fewer laboratories, and likely larger ones, that can sustain the provision of services to Medicare beneficiaries under lower CLFS rates. As a result, we are concerned that many physicians will have to wait longer to get test results to diagnose or treat patients, and patient care will also be delayed.

In fact, some of the most commonly used assays that physicians rely upon for diagnosis and disease management face tremendous drops in reimbursement according to the preliminary payment rates. Hemoglobin A1C (HCPCS Code 83036) is used in the treatment of diabetes. Physicians rely on this assay to appropriately adjust insulin levels and other treatments for their diabetic patients. The preliminary payment rates show a 36.2 percent cut for this assay. This decrease is mirrored in the preliminary payment rates for other common assays used by primary care physicians: Complete CBC – HCPCS 85025, Comprehensive Metabolic Panel – HCPCS 80053, and Assay Thyroid Stimulating Hormone – HCPCS 84443; which all have decreases greater than 35 percent. As patient outcomes are largely dependent on appropriate diagnosis and the active and successful management of disease, we are concerned that the preliminary CLFS payment rates would negatively impact clinical outcomes.

We are especially concerned about the impact on rural and underserved areas where many of our members provide care. Physicians in these areas routinely rely on in-house laboratory services or those provided by smaller laboratories. We have long advocated for greater access to care in these areas and are concerned that the negative impact of the new CLFS rates will limit this access and diminish the quality of care due to longer wait times or more inconvenient sites of care.

CY 2018 Payment Rates
In the Physician Fee Schedule CY 2018 proposed rule, CMS notes in the that feedback from reporting laboratories indicated an inability to report during the time allotted under the final rule implementing the PAMA lab provisions. To ensure the fairness in reimbursement and avoid undue burdens relating to reporting requirements, we urge CMS to identify alternate methods of identifying Medicare payment rates for clinical laboratory fee services.

Additionally, we urge CMS to modify the existing PAMA regulations through issuance of an interim final rule effective December 1, 2017, that holds the current rates in place until CMS has conducted targeted market segment surveys (reference laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to validate and adjust the final fee schedule payments calculated based on the data collection to ensure congressional intent—payment rates that accurately reflect private market payments across all market segments—is achieved.

Conclusion
We appreciate the opportunity to share these comments with CMS and invite any questions to Nick Schilligo, Vice President for Public Policy, at nschilligo@osteopathic.org, or (312) 202-8185.

Sincerely,

Mark A. Baker, DO
President