November 23, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1621-P
P.O. Box 8016,
Baltimore, MD 21244–8016.

Re: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule (CMS 1621-P)

Dear Acting Administrator Slavett:

The American College of Physicians (ACP) appreciates this opportunity to provide comments and recommendations regarding the *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule*, which addresses the requirements contained within the Protecting Access to Medicare Act of 2014 (PAMA) to revise payment and coverage methodologies for clinical laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS).

The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College recognizes the challenge faced by the Centers of Medicare and Medicaid Services (CMS) in crafting regulations and policy consistent with PAMA. Our comments, which have been developed in consultation with the American Medical Association, highlight the need to accomplish this mandated regulatory implementation without eroding the current availability of site-of-service, physician office laboratory (POL) diagnostic testing offered by many of our members to their Medicare-covered patients. CMS has a long history of recognizing the value of

these POL services, which provide patient convenience, as well as ensure increased patient adherence, physician quality oversight, and provide a framework for improved care coordination. These benefits are particularly important to an aging Medicare population, whose ability to access many services are hampered by transportation and financial limitations. The College makes the following recommendations for CMS to consider with the goal of assisting the Agency in fulfilling its legislatively mandated implementation, while supporting the sustainability of these important POL services.

Recommendation 1: Extend timeline for implementation and allow six months before initiating reporting.

The College strongly urges the Agency to revise the implementation timeline. We expect that it would be difficult to provide meaningful consideration of the comments and recommendations provided by stakeholders and, where warranted, modify the final rule, and issue subregulatory guidance in time for the January 1, 2016 data reporting deadline.

Equally important, the proposed implementation time table does not provide applicable clinical laboratories adequate time to prepare for and then comply with the reporting obligations—which are detailed, resource intensive, ambiguous in some areas, and confusing. This will be difficult for all clinical laboratories subject to reporting, but to the extent physician-office–based laboratories (POLs) must report the complexity of the statute, the proposed rule, and the interplay of the various provisions will be overwhelming. This new law and resulting proposed rule is the most significant change to occur on the Medicare Clinical Laboratory Fee Schedule (CLFS) since 1984 when Medicare began paying for clinical testing services.

We recommend that CMS provide applicable laboratories at least six months prior to the start date of data collection so that applicable laboratories understand the PAMA requirements, are able to develop the digital and administrative infrastructure, and beta test it**.** In light of the Agency's statutory authority to impose $10,000 per day civil monetary penalties for the failure to report or misrepresentation or omission with respect to a clinical diagnostic test, fairness dictates that applicable laboratories have time to scale their reporting capabilities—particularly POLs and their organizations which did not have a role in the passage of PAMA and most remain largely unaware of the data collection and reporting requirements. This additional time will also provide CMS with the opportunity to beta test the Agency's registration process for applicable laboratories and data transmission processes and protocols.

Recommendation 2: Retain the proposed POL low expenditure threshold exclusion.

The College supports CMS's proposal to establish a POL low expenditure threshold exclusion regarding reporting requirements. The Agency has proposed that any entity that would otherwise be an applicable laboratory, but that receives less than $50,000 in Medicare

revenues under section 1834A and section 1833(h) of the Act for laboratory tests furnished during a data collection period, would not be an applicable laboratory for the subsequent data reporting period. The Agency has further indicated that excluding certain entities with CLFS revenues below a $50,000 threshold would not have a significant impact on the weighted median private payor rates. With this threshold, using Medicare utilization data, CMS estimates that there are only 17 tests whose utilization is completely attributed to laboratories that would not be reporting because they fell below a $50,000 threshold.

CMS has stated that, with a $50,000 revenue threshold, the exclusion of data from POLs and independent laboratories with total CLFS revenues below that threshold, did not materially affect the quality and sufficiency of the data needed to set rates. The Agency indicates that it is able to substantially reduce the number of entities that would be required to report (94 percent of physician office laboratories and 52 percent of independent laboratories) while retaining a high percentage of Medicare utilization (96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report.

The low threshold exclusion is appropriate given the negative impact the data collection and data reporting requirement (and associated risk of civil monetary penalties) would have on POLs. The data collection obligations require access to expensive back office software and powerful data analytics. Mastering new software and reporting requirements will re-allocate staff time and practice resources away from other CMS priority areas such as quality reporting, meaningful use, and alternative delivery and payment practice transformation. We are concerned that the complexity and risk of the data collection and reporting requirement will cause many POLs to reduce or forgo offering clinical testing services given the rapidly compounding demands of other federal regulatory, quality, and delivery reform programs. The College strongly supports the decision to exclude the overwhelming majority of POLs from the reporting requirement.

Recommendation 3: When the Agency evaluates whether to impose a civil monetary penalty, the size of the clinical laboratory and resources are considered as mitigating factors.

We also urge CMS to explicitly include in the final rule mitigation factors that include size and resources when the Agency evaluates whether to impose civil monetary penalties and the amount. The size of civil monetary penalties should be commensurate with the size of the applicable laboratory. The impact of the civil monetary penalty will vary depending on the size and resources of a clinical laboratory and will have a disproportionately negative impact on POLs if an adjustment is not made to ensure that POLs are not crippled by such sanctions.

Recommendation 4: Permit any clinical laboratory to voluntarily engage in data collection and report private payor rates including otherwise excluded hospital-based clinical laboratories or POLs.

Improved care coordination and promoting patient centered care often means ensuring services are delivered efficiently, at the point-of-care, and coordinated and communicated quickly to the patient, caregivers, and the medical team. POL testing supports these goals. Patients who must seek test services at another location incur added expense and may delay or forgo testing altogether. In addition, there is added administrative expense when clinical testing is performed outside of a POL as results must be tracked down and additional steps taken to ensure patients receive results and information is distributed to the health care team. Low compliance, higher acuity, and increased administrative burdens take a toll on patient health outcomes, undermine migration to new delivery models, and cost the health care system.

In light of the above, we have concerns that the weighted median price generated from the independent laboratories' data alone will depress the pricing to the point that POLs are no longer able to provide rapid and accurate testing when a patient is at their physician's office. The College would welcome the opportunity to work closely with the Agency and others within the medical community to undertake both data modeling and forecasting to evaluate these issues in greater detail**.** In addition, we strongly urge CMS to permit all clinical laboratories that are not otherwise required to engage in data collection and reporting to voluntarily do so to help provide a sample from these settings to inform the above analyses.

Recommendation 5: When a POL is subject to the data collection and reporting requirements, CMS should notify the POL at least six months prior to the start of the data collection period.

Even with limitations on the number of POLs that will be responsible for reporting, the POLs that must report may not have the resources, including the data analytics, to assess whether they will be subject to the reporting requirement the first year of reporting and every third year thereafter. CMS has claims datasets and the analytics to assess whether a POL meets the reporting requirements based on prior year claims. We strongly urge CMS to provide POLs with advance notice that the POL will be subject to the data collection and reporting requirements. This will enhance the accuracy and reliability of the data that CMS will rely upon to calculate the weighted median of private payer prices and mitigate the risk of civil monetary penalties.

Recommendation 6: Reduce data collection period from 12 months to 3 months.

We strongly urge the Agency to reduce the data collection period from a full calendar year, every three years for clinical diagnostic tests to three months of data collection every three

years (“3-3”). The data collection burden of reporting every private payer price for all tests for a full year will divert already scarce health care resources to administrative tasks instead of to providing clinical care and services. This reporting requirement will fall heavily on POLs—physician practices that are already facing quality reporting, meaningful use requirements, and implementation of alternative delivery and payment models. The 3-3 data collection requirement will ensure that the Agency has current and accurate data. It will also reduce the likelihood that well-intentioned clinical laboratories—particularly POLs—are not faced with serious civil monetary penalties due to data errors precipitated by the overwhelming volume of data that they must track, verify, and report.

Conclusion

The College believes the above recommendations will allow for the required revision to payment and coverage methodologies for clinical laboratory tests paid under the Clinical Laboratory Fee Schedule, while providing increased recognition of the unique circumstances related to providing diagnostic laboratories services on-site within the physician office**. We further encourage the Agency to use its fullest authority to ensure that this new pricing methodology continues to support the sustainability of POLs and allows Medicare patients to benefit from the many advantages of this service.** Please contact Christine Myers at 202 261-4513 or cmyers@acponline.org if you have any questions regarding these comments or would like to discuss them in more detail.

Respectfully,

Wayne J. Riley, MD, MPH, MBA, MACP
President
American College of Physicians