June 1, 2017

The Honorable Patrick Tiberi

Chairman, Subcommittee on Health

Committee on Ways and Means

U.S. House of Representatives

1135 Longworth House Office Building

Washington, DC 20515

***DELIVERED VIA E-MAIL***

Dear Chairman Tiberi:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to submit comments on the Medicare program. ACLA is an association representing the nation’s leading providers of clinical laboratory services, including large national independent laboratories, reference laboratories, esoteric laboratories, hospital laboratories and nursing home laboratories. The services our members offer include commonly ordered lab tests (*e.g.*, glucose monitoring and blood counts), as well as innovative molecular diagnostic lab tests such as genomic sequencing panels and algorithm-based tests.

Whether tests on the cutting edge of medicine or more routine tests, clinical laboratory services provide cost-effective tools which aid in guiding diagnosis, prevention, and treatment, thereby, avoiding more costly patient interventions and outcomes.

Our members serve a significant Medicare population and have a direct stake in ensuring that services remain accessible to all Medicare beneficiaries. We respectfully share the following proposals for the Medicare program to improve service, increase access, and reduce unnecessary regulations.

1. **ACLA supports accurately capturing private market payor rates by fixing the applicable laboratory definition in the Protecting Access to Medicare Act of 2014 (PAMA).**

Since the enactment of PAMA, ACLA has worked closely and collaboratively with Congress and the Centers for Medicare and Medicaid Services (CMS) on the implementation of Section 216 of PAMA, which established a new method for pricing clinical laboratory services to replace the static Clinical Laboratory Fee Schedule (CLFS) with reimbursement based on private market rates.

ACLA supported Section 216, as Congress clearly intended rates to be based on the broad scope of the laboratory market.[[1]](#footnote-2),[[2]](#footnote-3) As defined by the PAMA statute, “applicable laboratories” are currently required to submit all private market prices for clinical laboratory services.

Unfortunately, the definition for applicable laboratories, as defined by the final rule, is so narrow and restrictive that a September 2016 Health & Human Services (HHS) Office of Inspector General (OIG) report estimated that only five percent of clinical laboratories will be required to submit private market data under PAMA. The same report also estimated that “0 of 6,994” hospital laboratories and only 11,149 out of 235,928 physician-office labs will be required to report.[[3]](#footnote-4)

The exclusion of 95 percent of laboratories, including all hospitals operating large outreach laboratories, will negatively affect the integrity of rate calculations under PAMA. The implications are immense and may lead to laboratories closing across the country, especially in rural and underserved areas, ultimately limiting Medicare beneficiary access to laboratory test services that support patient clinical care management.

We support fixing the applicable laboratory definition to reflect congressional intent by capturing data from all sectors of the laboratory market, including independent clinical laboratories, physician office laboratories, and hospital outreach laboratories.

1. **ACLA supports accurately pricing new clinical laboratory tests through a multi-stakeholder supported and transparent rate-setting methodology.**

New clinical laboratory tests are initially priced by CMS using one of two methodologies. The first is cross-walking, where the reimbursement rate assigned to the new test is priced relative to a similar, existing CLFS test. The second methodology is gap-filling, where a Medicare Administrative Contractor (MAC) is asked to recommend a rate for a new test because there is not a similar, existing CLFS test. Whether new tests are cross-walked or gap-filled, in too many instances, especially for innovative, cutting-edge tests, CMS develops these prices in an opaque process that cannot be replicated by outside experts.

Because there is a lack of transparency, we cannot confirm why the prices are incorrect, but one likely factor is that CMS fails to account for the resources required to develop, maintain, and perform these types of innovative tests. Clinical laboratories depend on fair reimbursement rates for new tests, and if Medicare cannot accurately value these tests, beneficiaries’ access to these tests may suffer.

CMS should revisit how the cross-walk and gap-fill rates are being established for new clinical laboratory tests and adopt the recommendations from multiple stakeholders to use a rate-setting methodology that is transparent and accounts for the variations in resource use.

1. **ACLA urges CMS to clarify the medical documentation required to demonstrate physician intent of laboratory orders.**

Due to unclear documentation requirements for laboratory orders, MACs and Comprehensive Error Rate Testing (CERT) contractors are withholding payments to clinical laboratories. ACLA believes medical records currently capture sufficient supporting documentation to support physician intent, including: the patient encounter, a physician bill, a progress note in the patient’s medical record, and signs, symptoms, and reasons for ordering tests. Even with this documentation, many CERT contractors insist on a physician signature, even though Medicare regulations do not require a physician to sign the laboratory requisition.[[4]](#footnote-5) In other instances, CERT contractors impose unrealistic standards when determining whether the physician “intended to order the test.” The lack of clear rules leads to contractors imposing varying and arbitrary physician intent standards for laboratory orders.

ACLA urges CMS to issue directions to all parties, including CERT contractors, to clarify what the requirements are in an audit of laboratory claims. We believe such standards should reflect the way that physicians document their interactions with and treatment of patients, acknowledging that clinical laboratories do not have influence over physician record keeping.

1. **ACLA supports ending date of service requirements for clinical laboratory tests for Medicare beneficiaries who have been recently discharged from the hospital.**

Current Medicare rules provide that if a laboratory test is performed by a clinical laboratory on a patient’s specimen that was collected while in the hospital, as an inpatient or outpatient, the laboratory performing the test must bill the hospital for the service, rather than bill Medicare directly, even though the test is performed after the patient leaves the hospital. The one exception to the rule is if the test is ordered at least 14 days after the patient’s discharge.

Since this type of testing is typically performed to determine the course of treatment following hospitalization, the hospital does not believe it should be responsible for paying the laboratory for a test the hospital neither ordered nor performed and which was performed after the hospital stay.

While Medicare assumes that the hospital will pay the laboratory for the service then bill Medicare, clinical laboratories performing this testing have found that hospitals have little incentive to take on the responsibility for billing and paying for the laboratory service.

If the patient was an outpatient, laboratories are finding that hospitals are no more willing to assume the responsibility of paying the laboratory and billing Medicare for a test the hospital did not order and was performed after the hospital visit. Hospitals often do not know how to bill for the test, and their Medicare intermediaries may not know whether to cover the test and how much to reimburse for the test.

Often, the only solution is for the patient to wait 14 days before ordering the test so the clinical laboratory can be assured it will be paid. Otherwise, the clinical laboratory is left to the mercy of a hospital who no longer has a relationship with the patient and will likely not reimburse the laboratory. CMS should allow clinical laboratories to bill Medicare directly for these laboratory tests.

**Conclusion**

ACLA appreciates the opportunity to comment on the Medicare program. If there are any questions regarding the above policy proposals, please do not hesitate to contact us by phone at (202) 637-9466 or email at [dcooling@acla.com](mailto:dcooling@acla.com).

Sincerely,



Julie Khani

President

1. ACLA press release, April 1, 2014, “American Clinical Laboratory Association Supports Senate Passage of Provisions for Clinical Laboratory Fee Schedule in SGR Extension Legislation.” [↑](#footnote-ref-2)
2. Senators Orrin Hatch and Richard Burr’s Colloquy, Congressional Record from May 8, 2014: https:/www.congress.gov/congressional-record/2014/05/08/senate-section/article/S2860-1 [↑](#footnote-ref-3)
3. HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016. <https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf>, page 7, Figure 4; page 8, Figure 5. [↑](#footnote-ref-4)
4. The physician signature issue was the subject of significant discussion when CMS proposed to require a signature and then the next year withdrew that requirement. As result, today it is clear that “the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes.” 76 Fed. Reg. at 73304 (Nov. 28, 2011). [↑](#footnote-ref-5)