August 25, 2017

The Honorable Kevin Brady
Chairman, House Committee on
Ways & Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Pat Tiberi
Chairman, Health Subcommittee
House Committee on Ways & Means
1102 Longworth House Office Building
Washington, DC 20515

RE: ACLA Submission to Medicare Red Tape Relief Project

Dear Chairmen Brady and Tiberi:

The American Clinical Laboratory Association (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 including commonly ordered lab tests (e.g. glucose monitoring and complete blood counts), as well as innovative molecular diagnostics lab tests such as genomic sequencing panels and algorithm-based tests.

Our members serve a significant Medicare population and have a direct stake in ensuring that services remain accessible to all Medicare beneficiaries. We respectfully submit the attached proposals for the Medicare program to the House Committee on Ways and Means Medicare Red Tape Relief Project. We believe these proposals support the Committee's efforts to reduce unnecessary regulations and deliver better care for Medicare beneficiaries.

If there are any questions regarding the proposals, please contact David Cooling, Director, Government Relations, by phone at (202) 637-9466 or email at dcooling@acla.com.

Sincerely,

Thomas B. Sparkman, RPh, MPP, JD
Vice President, Government Relations

ATTACHMENT: ACLA Medicare Red Tape Relief Project Submission

ACLA Proposal #1

Short Description: Improve the Clinical Laboratory Fee Schedule (CLFS) to accurately reflect the private market, while reducing regulatory burden on providers.

Summary: The intent of Section 216 of the Protecting Access to Medicare Act (PAMA), which ACLA supported, was to establish market-based pricing for clinical laboratory services under the CLFS based on reporting of private market data from the broad scope of the laboratory market, including independent laboratories, physician office laboratories, and hospital outreach laboratories.[1,2] Unfortunately, the definition of an "applicable laboratory" to submit such data, as defined by the CMS 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 (and permitted) 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]

The mandated exclusion of 95 percent of laboratories from reporting, including all hospitals operating large outreach laboratories, will negatively affect the integrity of rate calculations under PAMA, and cannot possibly result in market-based CLFS rates as Congress intended. All laboratories will be affected, even if they were prohibited from reporting data to establish the new CLFS rates. 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. Just as exclusion of entire categories of labs from the data set for the new CLFS rates can skew the results, calculation of the rates using a volume-weighted median of the reported data is inconsistent with the expressed intent of Congress to develop a market-based pricing mechanism because the result produced will be reflective of large independent laboratories located primarily in urban areas, not small and regional laboratories, hospital laboratories, physician office laboratories, rural laboratories, or nursing home laboratories.

This volume-weighted median approach also creates significant and unnecessary reporting burdens. The PAMA statute requires the reporting of every private price point for every test on the CLFS, and the associated volumes at each of those price points. For many laboratories subject to the reporting requirement for the first data collection and reporting period, the work necessary to report the data involved months of dedicated effort from numerous personnel, the creation and implementation of new information technology systems, and millions of data points

[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."
[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
[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.

to be reported to CMS. This significant and costly regulatory burden is unnecessary to achieve the objective of Congress.

Related Statute/Regulation: PUBLIC LAW 113–93 (Section 216) Protecting Access to Medicare Act of 2014; CMS-1621-F: Final Rule Implementing Section 216 of Protecting Access to Medicare Act (PAMA)

Proposed Solution: ACLA supports reforming Section 216 of PAMA to broaden the base of laboratories reporting private market data to establish new CLFS rates, while simultaneously simplifying the data reporting requirements. This goal can be achieved by amending the definition of "applicable laboratory" to be more inclusive, and replacing the volume-weighted median methodology with an alternative that does not overemphasize the pricing of any particular segment of the laboratory market. While stakeholders work to implement this proposed solution, ACLA requests CMS delay implementation of the CLFS rates to avoid potential disruptions to Medicare beneficiary access. ACLA looks forward to working with Congress to develop legislation that will result in a truly market-based fee schedule, without overburdening laboratories with unnecessary reporting requirements.

ACLA Proposal #2

Short Description: Clarify the medical documentation required to demonstrate physician intent of laboratory orders.

Summary: 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, the CERT contractor insists on a physician signature, even though Medicare regulations do not require a physician to sign the laboratory requisition.[4] In other instances, the CERT contractor imposes 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.

Related Statute/Regulation: 42 CFR 410.32(a) – Ordering Diagnostic Tests; 42 CFR 410.32(d)(2)(i) – Medical Necessity; Medicare Benefit Policy Manual Chapter 15 Section 80.6 – Requirements for Ordering and Following Orders for Diagnostic Tests; Medicare Claims Processing Manual Chapter 16 Laboratory Services

Proposed Solution: CMS should promptly issue public written directions to all parties, including MACs and CERT contractors, to clarify what the requirements are in an audit of laboratory claims. We believe such standards must 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 and should not be penalized for the failure of a physician to produce documentation for laboratory reimbursement when neither CMS nor Congress has given the physician any incentive to do so.

[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).

ACLA Proposal #3

Short Description: Improve the accuracy of pricing new clinical laboratory tests.

Summary: 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 or contractors develop these prices in an opaque process that cannot be replicated by outside experts. When CMS selects a cross-walk, the agency's decision may not align with comments received during the public comment period, and since CMS does not publicly release what other factors it considered in making its decision, it leaves the public with little to no understanding of the agency's thinking.

Because there is a lack of transparency, we cannot confirm why the prices are incorrect, but one likely factor is that the contractor 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 be limited.

Related Statute/Regulation: 42 CFR §§ 414.507(g), 414.508(b)

Proposed Solution: 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.

ACLA Proposal #4

Short Description: Reform the date of service or hospital billing requirements for clinical laboratory tests for Medicare beneficiaries in the outpatient setting.

Summary: A combination of current Medicare regulations dictate whether a lab can bill Medicare for the tests that it runs, or if it must bill the hospital from which the beneficiary was recently discharged, which could then bill Medicare. Certain advanced tests consisting of Molecular Pathology, Multiple-analyte Assays with Algorithmic Analyses (MAAA), and Advanced Diagnostic Laboratory Tests (ADLT), are ordered by the physician to inform treatment decisions in the future; are performed after the beneficiary leaves the hospital; and do not impact patient care during their stay in the hospital when the sample was collected; yet must be billed by the performing laboratory to the hospital if the beneficiary was recently discharged. The exception to the rule is if a test is ordered greater than 14 days after the patient is discharged, the performing laboratory bills Medicare directly. In contrast, for beneficiaries with Medicare Advantage or private insurance, the laboratory bills the insurer directly, and the hospital has no responsibility in the process. This dual system creates significant confusion and complexity for the hospitals, physicians, laboratories, and beneficiaries.

While Medicare assumes that the hospital will pay the laboratory for the advanced testing performed and then that hospital will bill Medicare, clinical laboratories have found that hospitals have little incentive or administrative capacity to take on the responsibility for billing Medicare, paying a laboratory, or contracting with each outside laboratory for testing that does not impact the hospital stay. This is due to the hospital not having a role in the performance of, or decision making from the result of, the advanced test.

Many advanced tests are performed by just a few laboratories or even a single laboratory, which means that only a limited number of MACs have any coverage position or familiarity with the testing. When the advanced tests are billed by the independent laboratory, the coverage and payments have been established with the appropriate MAC. However, if the tests must be billed by the hospital, it may be billed to a MAC unfamiliar with certain tests, leading to a disparity in coverage for beneficiaries based solely on when the test was ordered.

Often, the only solution to eliminate the complexities and confusion in hospitals with the current regulations in place is for the physician to wait 14 days before ordering advanced tests. This can cause a significant delay to the physician who finds medical necessity in the advanced test, as well as the beneficiary who may receive delayed treatment or care as a result. Otherwise, the payment for the test is in doubt, as the hospital no longer has a relationship with the beneficiary and will likely not reimburse the laboratory.

Related Statute/Regulation: 42 CFR 414.510; 42 CFR 410.42; 42 CFR 411.15(m); 78 Fed. Reg. 74939 (Dec. 10, 2013); 80 Fed. Reg. 70348 (Nov. 13, 2015); 81 Fed. Reg. 79594 (Nov. 14, 2016).

Proposed Solution: CMS should reduce regulatory burden and allow clinical laboratories to bill Medicare directly for these advanced laboratory tests, regardless of when the test is ordered, just like the agency does with Medicare Advantage and private payers.

ACLA Proposal #5

Short Description: Reduce regulatory burdens on laboratories forced to comply with unnecessary and burdensome HHS subregulatory requirements in the form of FAQs which expanded the laboratory information included in an individual's designated record set (DRS) subject to access requests under the Health Insurance Portability and Accountability Act (HIPAA).

Summary: Last year (01/07/16) under the auspices of the HIPAA Privacy Rule and through only a blog posting, the HHS Office for Civil Rights (OCR) issued FAQs expanding the laboratory information included in an individual's DRS that is subject to individual access, with a focus on genetic testing. These immediately final FAQs, which have the force of subregulatory guidance, were issued without seeking stakeholder input or comments.

ACLA met with OCR during the final year of the Obama Administration to seek changes, but there was no resolution. Since then, member laboratories have been proceeding thoughtfully and carefully to ensure that they continue to comply with the HIPAA Privacy Rule and respond to individual requests for access to their protected health information (PHI) in a timely and complete manner. The FAQs, however, are both unclear and overly prescriptive in some respects and use terms that are not consistently familiar to or used by the laboratory industry (*e.g*., "full gene variant"). A more effective way to ensure laboratory covered entities' full compliance with guidance like these FAQs would have been to solicit input informally prior to issuing FAQs. While soliciting input on subregulatory guidance can take time and resources, given the highly technical issues such as genetic information generated from next generation sequencing tests and the steep monetary penalties, informal discussions beforehand would have been a sound investment.

Genetic testing is an evolving sector of the laboratory industry, and so is the application of the HIPAA Privacy Rule to PHI that is generated in the course of genetic testing. We recognize that as covered entities, laboratories have a responsibility to provide access to certain information related to genetic testing just as they would for other kinds of testing (*e.g*., chemistry panels); however, due to the nature of genetic testing information and the size of the files generated, the designated record set for genetic testing may differ from that maintained for other types of testing.

One critical issue ACLA would like confirmed in guidance is that a laboratory is required to provide an individual with access only to information that the laboratory already maintains as part of a DRS, and that there is not an affirmative obligation to maintain information solely for the purpose of responding to an individual's request for access to genomic information. As defined in the HIPAA Privacy Rule, a DRS is a group of records maintained by a covered entity, including medical records maintained by or for a covered health care provider, or "records used, in whole or in part, by or for the covered entity to make decisions about individuals." It is important to note that some of the files that may be generated in the course of performing genetic testing are quite large and require significant storage resources, notwithstanding the fact that they are electronic files. Therefore, many laboratories do not maintain these files beyond the time required by applicable regulations and standards. We believe a laboratory has satisfied its responsibility in responding to an individual's request for access to PHI when it provides the

information that was requested and that the laboratory maintains as part of a DRS at the time of the request.[5] There is, however, no affirmative obligation to maintain this information, if it is the laboratory's policy not to keep it.

Related Statute/Regulation: 45 CFR § 164.524 - Individuals' Right under HIPAA to Access their Health Information; related subregulatory guidance in the form of FAQs posted to HHS HIPAA website:

- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#newlyreleasedfaqs

Issued as final in the form of a blog post issued 01/07/16:

- https://wayback.archive-it.org/8315/20170119091538/https://www.hhs.gov/blog/2016/01/07/understanding-individuals-right-under-hipaa-access-their.html

Proposed Solution: ACLA requests that the following modifications (additions and deletions) be made to the FAQs issued by OCR to improve clarity and ensure that labs are not required to create burdensome additional and new information:

> **Does an individual have a right under HIPAA to access from a clinical laboratory the genomic information the laboratory has generated about the individual and maintains as part of the designated record set?**
>
> Yes. An individual has a right under the HIPAA Privacy Rule to access, upon request, PHI about the individual in a designated record set maintained by or for a clinical laboratory that is a covered entity. The designated record set includes ~~not only~~ the laboratory test reports ~~but also~~ and also may include the underlying information generated as part of the test, as well as other information concerning tests a laboratory runs on an individual, if the laboratory maintains that information as part of the designated record set. For example, a clinical laboratory that is a HIPAA covered entity and that conducts next generation sequencing (NGS) of DNA on an individual must provide the individual, upon the individual's request for PHI concerning the NGS, with a copy of the completed test report, ~~the full gene variant information generated by the test~~, as well as any other information in the designated record set concerning the test.
>
> **Does an individual have a right under HIPAA to access more than just test results from a clinical laboratory?**
>
> Yes. Under the HIPAA Privacy Rule, an individual has a general right to access, upon request, PHI about the individual in a designated record set maintained by or for a clinical laboratory that is a covered entity. A test result or test report is only part of the designated record set a clinical laboratory may hold. To the extent an individual requests access to all of her information held by the laboratory, the laboratory is required to provide access to all of the PHI about the individual in its designated record set. This

[5] We understand that if a laboratory covered entity does not maintain the PHI that is the subject of an individual's request for access, and the laboratory knows where the requested information is maintained, it must inform the individual where to direct the request for access. *See* 45 C.F.R. § 164.524(d)(3).

could include, for example, completed test reports and the underlying data used to generate the reports, test orders, ordering provider information, billing information, and insurance information, if that information is used to make decisions about the patient and is maintained by the laboratory as part of the designated record set.

ACLA Proposal #6

Short Description: Reduce the regulatory burden of providing the Advance Beneficiary Notice of Noncoverage (ABN) requirement.

Summary: An ABN is issued by a provider, including an independent clinical laboratory, to a Medicare beneficiary where Medicare payment is expected to be denied. Under current rules, an electronic or an e-mail copy of an ABN is not permissible regardless of patient preference. Only a paper copy of an ABN is permitted. If this paper copy is not provided to the patient, the laboratory may not issue a bill for a non-covered service.

Often, the laboratory is not patient-facing and must rely on another provider to deliver an ABN, particularly if that provider is the one ordering the lab test. It is not uncommon for a provider to not deliver an ABN to his patient. Since the laboratory is not patient-facing, it does not always know whether an ABN was delivered, and when Medicare does not cover a test that was already performed because no ABN was obtained, the laboratory has no recourse to seek payment for the services it performed. Allowing the patient to choose an electronic ABN could facilitate provider delivery and notification to the laboratory.

Related Statute/Regulation: Medicare Benefit Policy Manual Chapter 30 – Financial Liability Protections

Proposed Solution: Allow a patient to choose how he would prefer receiving an ABN, whether that be an electronic or a hard copy. If a laboratory is not patient-facing, has no input on whether a patient receives an ABN, and has no information to believe a service is non-covered, the laboratory should be able to bill for and be reimbursed for the service.

ACLA Proposal #7

Short Description: Close the anatomic pathology in-office ancillary services (IOAS) exception.

Summary: Numerous studies have demonstrated that physician self-referral of anatomic pathology services leads to overutilization of those services, increasing costs to the healthcare system and potentially compromising patient care. For anatomic pathology, the Government Accountability Office (GAO) found that "self-referred anatomic pathology services increased at a faster rate than non-self-referred services from 2004 to 2010. Self-referring providers likely referred over 918,000 more anatomic pathology services" than they would have if they were not self-referring, costing Medicare approximately $69,000,000 more in 2010 than if self-referral was not permitted. GAO concluded that "financial incentives for self-referring providers were likely a major factor driving the increase in referrals."[6] Referrals of anatomic pathology services should be based on the best interest of the patient, not by the potential for a profit merely by making the referral.

Related Statute/Regulation: Section 1877(b) of the Social Security Act (42 U.S.C. 1395nn); H.R. 2066, the Protecting Integrity in Medicare Act (PIMA)

Proposed Solution: ACLA urges the enactment of H.R. 2066, the Protecting Integrity in Medicare Act (PIMA). PIMA would resolve this issue by amending the in-office ancillary services (IOAS) exception to the Ethics in Patient Referrals Act (also known as the Stark Law) to exclude anatomic pathology services from the exception, thus prohibiting the use of the exception to bill Medicare for self-referred anatomic pathology services, for which the exception was never intended.

[6] US Government Accountability Office, *Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer*, GAO-13-445 (Washington, DC, 2013), https://www.gao.gov/assets/660/655442.pdf.