March 15, 2018

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

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Peter Roskam
Chairman
Committee on Ways and Means
Subcommittee on Health
2246 Rayburn House Office Building
Washington, DC 20515

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
Subcommittee on Health
1236 Longworth House Office Building
Washington, DC 20515

Dear Chairman Brady, Ranking Member Neal, Chairman Roskam, and Ranking Member Levin:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), we are pleased to submit the following comments in response to your request for information on ways to prevent and treat opioid abuse and dependence in the Medicare program. Clinical laboratories are integral players in the healthcare infrastructure in the United States. They are responsible for examining human specimens to provide information for diagnosis, prevention and treatment of diseases. They also play an important role in addressing the growing opioid crisis in the United States.

AAB is a trade association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists, medical laboratory technicians, and physician office laboratory technicians and is committed to the pursuit of excellence in clinical laboratory testing by enhancing the professional skills of each of its members; promoting more efficient and productive operations; and representing the interests of its members. NILA represents regional and community independent clinical laboratories and advocates for policies that help advance access to quality clinical laboratory services around the country. A significant number of NILA member laboratories provide toxicology (drug testing) services as part of their portfolio, and some NILA member laboratories are solely toxicology laboratories.

Toxicology laboratories are independent clinical laboratories that detect drugs, including illicit drugs and drugs of abuse, in human urine and blood specimens. Toxicology laboratory results are important for pain management medication monitoring, addiction management monitoring, workplace testing and law enforcement. Toxicology laboratories have long played an integral role in the healthcare continuum by providing data to healthcare providers to monitor effective pain management and evaluate patients

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struggling with drug addiction and abuse. With the nation in the grips of an opioid crisis, the toxicology laboratory's role in detecting opioid misuse and monitoring and evaluating patients has become more critical than ever. The Centers for Disease Control and Prevention (CDC) recommends that screening for substance use and abuse before and during the course of an opioid prescription is a critical component in curbing the opioid epidemic.[1] In addition to providing laboratory data for direct patient management, toxicology laboratories are poised to provide drugs of abuse data to health officials, health departments, epidemiologists and policy makers to help inform public health interventions.

In response to the questions raised in the RFI, AAB and NILA offer the following specific comments regarding the role of clinical laboratories in the opioid epidemic and within the Medicare program:

Overprescribing/Data Tracking

1. **Perverse Incentives in Medicare:**

   Due to the volume of tests performed in various populations, laboratories have access to centralized data on opioid abuse, illicit drug use, and other trends that could be useful in addressing the opioid crisis nationally. Such a repository of laboratory data, if collected and maintained, could be available to relevant agencies and stakeholders. This data could be instrumental in detecting and identifying geographical areas with increasing abuse and misuse (e.g., regional increases in heroin usage can be detected using centralized laboratory data and can help to direct resources to particular areas of the country). The data can be de-identified so as not to violate HIPAA laws or patient confidentiality.

2. **Electronic Prior Authorization:**

   Providers should only order testing for drugs that they suspect might be present (given symptoms or physical evidence) or based on previous patient experience. It is the role of the provider, not the laboratory, to authorize tests that are ordered. Laboratories do not order tests for patients. As more insurance companies require prior authorization for some of the laboratory screening/confirmation testing to detect and monitor prescription and illicit drug use, there is concern that laboratories might not be reimbursed for tests ordered by physicians. This practice is already creating reimbursement challenges for clinical laboratories in the private payor space and should not be required for Medicare reimbursement on the Clinical Laboratory Fee Schedule (CLFS).

3. **Prescription Drug Monitoring Program (PDMPs):**

   It would be useful for the Centers for Medicare & Medicaid Services (CMS) and clinical laboratories to have access to data produced by PDMPs to supplement prescription monitoring adherence test reports to ensure that information in the PDMP is relayed to the prescribing clinician. Currently, there is no access granted to a laboratory provider to a PDMP.

[1] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

Communication and Education

1. **Prescriber Notification and Education:**

   Laboratories can provide continuing education to prescribing providers about the interpretation of test results. The provider's (or prescriber's) ability to appropriately and accurately interpret results from a toxicology test is critical to determine the drugs of abuse circulating in communities, in addition to understanding the evolving landscape of emerging drugs. Most NILA member laboratories already provide continuing education to providers who order toxicology tests and other types of testing within the Medicare population.

Treatment

1. **Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT**):

   The laboratory's role in this process cannot be understated and is often overlooked. Laboratories provide empirical data for providers (including pharmacists and substance abuse programs) in order to manage clinical care more precisely. This is done by monitoring optimal levels of drug treatment or determining compliance to an OTP or MAT program to reduce beneficiary waste of funds due to non-adherence to a program. For more information, see the American Association of Clinical Chemists (AACC), guidance document for using Laboratory Drug Tests to combat opioid addiction and overdoses. AAB and NILA support the position of this guidance document for evidence-based recommendations for urine drug testing.

2. **Reimbursement:**

   Health care providers must rely on diagnostic testing to help inform most of the decisions they make. This becomes even more important when monitoring a patient on pain medication, both to help follow progress in pain management and to help ensure dependence is not developed. For this reason, the infrastructure of independent clinical laboratories in this country must be strengthened. Unfortunately, many independent clinical laboratories are curtailing services and reducing coverage due to recently passed legislation, the Protecting Access to Medicare Act of 2014 or PAMA.

   The goal of the PAMA statue was to make Medicare reimbursement for clinical laboratory services closer to private market rates. However, when CMS implemented PAMA, only 0.7 percent of the laboratory market was represented in CMS's data collection and analysis.[2] The final rates for the Part B CLFS did not represent a full market-based payment system for laboratory services as Congress intended in PAMA. This resulted in broad cuts to the CLFS, because a large percentage of higher-priced private payor data was excluded from the analysis.

   When considering the broad impact from PAMA, the majority of reimbursement for toxicology laboratories is tied to the Part B CLFS. While it varies by state, state Medicaid fee schedules often reimburse up to a certain percentage of the Medicare CLFS. Private payor contracts

[2] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

operate in a similar manner. If the Medicare CLFS serves as the basis for reimbursement, the cuts imposed by PAMA create a devastating ripple effect through Medicaid and private payors, putting laboratory services broadly at risk.

An integral part of the battle against the opioid epidemic requires accurate and timely clinical laboratory tests. Some NILA members have used their margins to invest in advanced technology and to fund opioid research and development projects. The cuts imposed by PAMA threaten the ability of toxicology laboratories to adapt and be nimble to the evolving opioid crisis. NILA members are poised to play a key role in the nation's opioid response. **AAB and NILA recommend that the Ways & Means Committee immediately re-evaluate the cuts imposed to the CLFS by PAMA and help pass legislation that will ensure that quality clinical laboratory services are protected and that patient access is not hindered.**

Thank you for reaching out to the stakeholder community for feedback regarding the opioid crisis as it relates to the Medicare population. Please feel free to contact us directly should you have any questions or if AAB and NILA can be of any further assistance.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Administrator