AMERICAN CLINICAL LABORATORY ASSOCIATION

September 9, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

**RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P, RIN 0938-AV33)**

Dear Administrator Brooks-LaSure,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the abovementioned proposed rule ("Proposed Rule").[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of health care delivery through policies that expand access to life-saving testing services.

ACLA's comments on the Proposed Rule focus on the following areas:

- Clinical Laboratory Fee Schedule (CLFS) phased-in payment reductions and other policies
- Expansion of colorectal cancer screening and reducing barriers to access for diagnostics
- Policies related to reporting and returning overpayments
- Proposed conversion factor for CY 2025
- Request for Information (RFI) on public health data reporting
- Continuing concerns regarding Opioid Treatment Program (OTP) bundles that include toxicology testing

## A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

Section 216 of the Protecting Access to Medicare Act (PAMA) made fundamental changes to the way that Medicare develops rates on the CLFS. Section 1834A(b)(2)[2] of the Social Security Act states that the payment amount for a clinical diagnostic laboratory test (CDLT) shall be equal to the weighted median of payment rates reported by applicable laboratories, subject to a limitation on the year-to-year reductions in payment amounts, as set forth in Sec. 1834(b)(3).[3]

[1] 89 Fed. Reg. 61596 (Jul. 31, 2024).
[2] 42 U.S.C. § 1395m-1(b)(2).
[3] 42 U.S.C. § 1395m-1(b)(3).

The applicable percent of a reduction in a given year is set forth in Sec. 1834A(b)(3)(B) and has been amended by Congress in recent years. CMS proposes to make confirming changes to 42 C.F.R. §§ 414.504 and 414.507 to reflect changes made by Sec. 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (FCAOEA)[4]: delaying by one year the next data reporting period for CDLTs that are not Advanced Diagnostic Laboratory Tests (ADLTs), so that data reporting would be required during the period of January 1, 2025 through March 31, 2025, and implementing a 0 percent payment reduction in CY 2024.[5]

ACLA agrees with CMS's proposed conforming changes, as Congress's action in the FCAOEA was necessary to mitigate the harmful effects of the 2016 rule that still impact laboratories today. ACLA will continue to work with CMS and with Congress to improve the Medicare payment system for CDLTs to ensure continued access to laboratory services for Medicare beneficiaries.

CMS itself has a critical role to play in improving implementation of PAMA to ensure that when applicable laboratories are required to report applicable information to CMS, the data is reflective of rates paid by private payors to all sectors of the clinical laboratory market serving Medicare beneficiaries. In the 2017 data reporting period, only 0.7 percent of laboratories paid under Medicare Part B in 2015 – 1,942 out of 261,524 – reported applicable information to CMS.[6] Just 658 independent laboratories reported applicable information – only twenty percent of all independent laboratories paid under Medicare Part B and less than half of the laboratories the HHS Office of Inspector General (OIG) estimated would be required to report.[7] Only 1,106 physician office laboratories (POLs) reported applicable information to CMS – one tenth of the POLs the OIG estimated would report information and just one half of one percent of all POLs paid for laboratory services under Medicare Part B in 2015. And just 21 hospital outreach laboratories reported data – representing one half of one percent of all hospital laboratories paid under Medicare Part B for laboratory services in 2015. CMS took no action against the thousands of applicable laboratories that should have reported applicable information but did not. Yet the law calls for all applicable laboratories to report applicable information to CMS during a data reporting period.

CMS should conduct aggressive outreach to hospital outreach laboratories and other applicable laboratories that need information and assistance to meet their obligation to report applicable information to CMS, per Sec. 1834A(a)(1)(A). Hospital outreach laboratories in particular deserve the agency's attention, as they generally were not included in data reporting during the last reporting cycle, but now are included under changes made by CMS in 2018 to the regulatory definition of "applicable laboratory".[8] Additionally, CMS should send a letter to each independent laboratory and physician office laboratory that qualified as an "applicable laboratory" in the 2016 data collection period but that failed to submit applicable information during the 2017 data reporting period, reminding each of its obligation to determine whether it meets the definition now and, if so, to report applicable information in the next data reporting period, or be subject to

[4] Pub. L. 118-22.
[5] 89 Fed. Reg. 61812.
[6] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary") at 3, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.
[7] See Office of Inspector General, Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040) at 7, available at https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.
[8] 83 Fed. Reg. 59452, 60074 (Nov. 23, 2018) (amending the definition of "applicable laboratory" at 42 C.F.R. § 414.502 to include hospital outreach laboratories that bill Medicare Part B on the CMS 1450 under bill type 14x).

civil monetary penalties. This would notify laboratories most likely to qualify as applicable laboratories about their reporting obligations. CMS also should use its authority to impose a civil monetary penalty of up to $10,000 per day on an applicable laboratory for each failure to report or each misrepresentation or omission of applicable information.[9] Furthermore, the agency should state publicly its intention to audit applicable laboratories and to impose penalties, when warranted, in order to signal to all applicable laboratories that reporting is not voluntary – it is mandatory.

## B. Expansion of Colorectal Cancer Screening

### 1. Definition of Complete Colorectal Cancer Screening

ACLA supports CMS's proposal to revise the regulatory text describing a complete colorectal cancer (CRC) screening at 42 C.F.R. § 410.37(k) to state that CRC screening tests include a follow-on screening colonoscopy after either a Medicare covered non-invasive stool-based CRC screening test or a Medicare covered blood-based biomarker CRC screening test returns a positive result.[10] At the time the Proposed Rule was issued, no blood-based biomarker tests for CRC screening met the coverage requirements described in National Coverage Determination (NCD) 210.3, Colorectal Cancer Screening Tests. However, on July 26, 2024, one such test received pre-market approval from the Food and Drug Administration,[11] potentially making it eligible for Medicare coverage under the NCD if other applicable requirements are met and making this policy timely and actionable.

This proposed revision would expand access to CRC screening, which serves important public health goals. When a patient has a positive blood-based biomarker CRC screening test, a colonoscopy is required to complete the screening process. CMS previously eliminated cost-sharing for the follow-up colonoscopy after a non-invasive stool-based test. However, under current policy a Medicare beneficiary is still liable for cost-sharing for the follow-up colonoscopy after a positive blood-based test. Individuals that did not get follow-up colonoscopies were about twice as likely to die of colorectal cancer compared to individuals who did get follow-up colonoscopies, and since the goal of screening is early detection and treatment and reduction of mortality, it is important to remove barriers to care. This proposal would remove beneficiary cost-sharing for a follow-on screening after a positive result from either a Medicare covered non-invasive stool-based CRC screening test or a Medicare covered blood-based biomarker CRC screening test, clearing away a potential deterrent for completing the screening process.

### 2. MIPS Quality Measure for Colorectal Cancer Screening

In order to make this expansion of a complete CRC screening meaningful, CMS also should update quality measures for CRC screening so that they include FDA-approved blood-based biomarker CRC screening tests and all FDA-approved non-invasive stool-based CRC screening tests. This is particularly important because MIPS quality measure Q113 (Colorectal Cancer Screening) would be included in the newly proposed MIPS Value Pathway (MVP) for gastroenterology care and beginning with the CY 2025 performance period/2027 MIPS payment year, it also would be included in the APM Performance Pathway (APP) Plus quality measure

[9] 42 U.S.C. § 1395m-1(a)(9).
[10] 89 Fed. Reg. 61996.
[11] PMA No. P230009, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230009.

set.[12] The MIPS quality measure Q113 includes screening modalities recommended by the United States Preventive Services Task Force (USPSTF) in its numerator. When USPSTF CRC screening recommendations last were updated in 2021, blood-based biomarker CRC screening tests were not widely available or currently available FDA approved RNA-based non-invasive stool-based CRC screening tests were not yet FDA approved, and it will be several years until USPSTF updates these screening recommendations. Physicians may be disincentivized to order a CRC screening test that is not included in the quality measure's numerator, even if the test could help remove barriers to CRC screening, particularly for underserved and rural communities.

## C. Medicare Parts A and B Overpayment Provisions in the Affordable Care Act

ACLA members believe strongly that health care providers should return funds to which they are not entitled and should do so as promptly as possible after discovering the existence of an overpayment and quantifying the overpayment. We support several of CMS's proposed revisions to regulations and policies regarding reporting and returning Medicare overpayments and urge CMS to clarify or modify other aspects of its proposals.

### 1. "Reasonable Diligence" Standard

A provider must report and return an overpayment within 60 days of when the overpayment is identified. ACLA supports CMS's proposal to remove the "reasonable diligence" standard from 42 C.F.R. § 401.305(a)(2) on identification of an overpayment, as initially proposed in the December 2022 overpayments proposed rule. Currently, the regulation reads:

> A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

If finalized, the regulation would state that a person has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. As ACLA stated in comments on the 2012 proposed rule to implement Sec. 6402(a) of the Affordable Care Act, the law imposes a requirement to report and return an overpayment only on a provider that identifies an overpayment, not on a provider who should have identified an overpayment. The regulation impermissibly introduced False Claims Act liability for mere negligence, and it should be revised as proposed.

### 2. Quantification of an Overpayment

It is not possible to return an overpayment that has not been quantified. Each of the Medicare Administrative Contractor's (MAC's) voluntary overpayment forms requests the amount of the overpayment. While we support the proposed change to 42 C.F.R. § 401.305(a)(2), it would remove the description of an identified overpayment as one that has been quantified. We agree with other commenters that a provider that has received an overpayment must be able to quantify it, after a thorough investigation of the facts and circumstances surrounding the overpayment,

[12] *Id.* at 62593.

and that the proposed revision of the regulation would remove quantification from the process of identifying an overpayment.

We appreciate that CMS has developed a proposal for retaining quantification as an aspect of reporting and returning an overpayment: it would include at 42 C.F.R. § 401.305(b)(3) an additional circumstance under which the deadline for reporting and returning an overpayment would be suspended, for a certain period of time, when a person has identified an overpayment but has not yet completed a "good faith investigation" to determine the existence of related overpayments from the same cause or reason.[13] We encourage CMS to describe the criteria it would apply to determine whether an investigation has been undertaken in "good faith" and therefore the deadline may be suspended. For example, would an overpayment recipient's "good faith" be evaluated based on the speed with which it initiated an investigation, the financial and personnel resources it allocates, the involvement of counsel, or other factors?

### 3. Suspension of Deadline for Reporting and Returning Overpayments

Under proposed 42 C.F.R. § 401.305(b)(3)(ii), the deadline for reporting and returning an overpayment would be suspended until the earlier of: (1) the date that the investigation is concluded and the overpayments are quantified, or (2) 180 days after the date on which the initial identified overpayment was identified.[14] Several years of experience with complying with the overpayments rule has shown that 180 days is not always sufficient to complete a thorough investigation of an overpayment. For example, overpayments may be received by a health care organization with multiple locations in different states that adhere to different billing and documentation procedures. Other times, overpayments involved multiple providers, as in the case of potential double-billing.

ACLA believes a health care provider should be able to request, and be granted, one 30-day extension of the deadline suspension when there are "extraordinary circumstances" that preclude completion of an investigation within 180 days. In the 2016 overpayments proposed rule, CMS acknowledged that there may be "extraordinary circumstances affecting the provider, supplier, or their community" that may warrant some additional time before lifting the suspension of the deadline, including "unusually complex investigations that the provider or supplier reasonably anticipates will require more than six months to investigate…".[15] To address this, CMS should include at the end of 42 C.F.R. § 401.305(b)(3)(ii)(B) the following: "Upon request from the person conducting the investigation, the deadline may remain suspended for an additional 30 days to account for extraordinary circumstances."

## D. Proposed Conversion Factor for CY 2025

CMS estimates that the CY 2025 PFS conversion factor will be 32.3562, a 2.8 percent decrease from the current conversion factor. We urge CMS to join ACLA and other stakeholders to ask Congress to address the impacts of this decrease, including inaccurate valuation of services and potential beneficiary access issues resulting from inadequate reimbursement. Laboratories that provide clinical laboratory services reimbursed under the CLFS already are facing steep reimbursement cuts as a result of the implementation of Sec. 216 of PAMA, and cuts

[13] *Id.* at 62006
[14] *Id.*
[15] 81 Fed. Reg. 7654, 7662 (Feb. 12, 2016).

to the valuation of pathology services will exacerbate those effects for many laboratories.

## E. RFI Regarding Public Health Reporting and Data Exchange

ACLA appreciates the attention that CMS is giving to improving interoperability and data reporting and exchange between health care providers and public health agencies (PHAs).[16] The existing patchwork system of public health data reporting is inefficient, resource-intensive, and time-consuming. During the COVID-19 public health emergency, ACLA member laboratories were subject to overlapping and duplicative requests for data from various entities, including local and state governments, health information exchanges, and federal exchanges. Establishing connections with multiple reporting systems and complying with each jurisdiction's ever-changing reporting requirements imposed significant costs on clinical laboratories. Oftentimes, ACLA members were tasked with reporting data to PHAs that they did not have in their possession (*e.g.*, demographic or clinical information in the patient's medical record).

CMS should give special consideration to how it can incentivize treating clinicians to report complete public health data to PHAs and how it can facilitate efficient, cost-effective public health data exchange between treating clinicians and PHAs. ACLA members take seriously their own responsibilities to report public health data to PHAs, yet oftentimes the types of information requested from laboratories is best requested from treating clinicians. Ordering clinicians are far better equipped to obtain and report complete patient information than laboratories are because they have face-to-face interactions with patients far more often than laboratories do and create and have access to patients' medical records. In most cases, clinical laboratories have only the information reported to them by ordering clinicians when they receive a specimen and requisition for testing, which often lacks information being requested by PHAs.

ACLA supports the creation of a centralized public health reporting mechanism to be deployed in a public health emergency, through which laboratories would report actionable test results that could be made available to federal, state, and local authorities simultaneously. A streamlined reporting system that decreases duplicative or overlapping requests has the potential to improve access to accurate and timely data to inform the nation's response efforts and provide a better understanding of health disparities among communities; however, clinical laboratories should be required to report only the data that they generate or possess, and not demographic or other clinical data that they do not possess but that treating clinicians have as a result of their face-to-face encounters with patients. Additionally, any data reporting requirements applicable to clinical laboratories should be established separately from CLIA regulations,[17] which are intended solely to regulate the quality of laboratory services and not public health data reporting.

A centralized public health reporting system also opens the possibility of standardizing data elements that must be reported and the format for reporting, alleviating burdens on treating clinicians and clinical laboratories alike and increasing the likelihood that ordering clinicians will report the information in their possession that PHAs need. Upfront federal investment in a modernized public health reporting platform would provide vital infrastructure to help prevent and prepare for future public health emergencies. ACLA member laboratories will be ready to play a key role in implementation of any new public health data reporting system, and we appreciate the opportunity to work collaboratively with CMS, the Centers for Disease Control and Prevention,

[16] 89 Fed. Reg. 62072.
[17] 42 C.F.R. Part 493.

the Office of the National Coordinator, and other agencies on development of the system.

## F. Continuing Concerns Regarding Opioid Treatment Program (OTP) Bundles That Include Toxicology Testing

Beyond ACLA's comments on items included in the proposed rule above, we also wanted to provide updated recommendations on a topic included in the CY 2020 Physician Fee Schedule Rule. In our comments on the CY 2020 Physician Fee Schedule Proposed Rule (CMS-1715-P), ACLA raised concerns with the Opioid Treatment Program (OTP) bundle structure and the proposed inclusion of more resource-intensive toxicology testing. At that time, we agreed that simple point-of-care tests could appropriately be included in the bundle, but presumptive testing using an instrumented chemistry analyzer and definitive testing, both of which would rarely be provided by an OTP at the point-of-care[18], should be excluded from the bundle, and we recommended these types of testing should be paid separately. We were concerned the inclusion of more complex drug tests in the OTP bundles, wherein the costs for those tests would dominate the bundled payment of the non-drug component, could lead to an incentive to forgo medically necessary testing.

Since that time, the opioid and substance abuse epidemics have worsened, and there has been a proliferation of substances that require higher complexity of testing to ensure adequate detection (*e.g.*, many benzodiazepines, xylazine, and numerous fentanyl analogs.). Further, ACLA members have reported cases of reduction in testing by OTPs that may be indicative of testing avoidance. We are concerned that incentives may be misaligned in a paradigm of expanded drug abuse, overdose, and overdose deaths, including within the Medicare population.

Given these concerns, we continue to believe that medically necessary presumptive testing using an instrumented chemistry analyzer and definitive testing for a patient being treated by an OTP should be removed from the non-drug component of the OTP bundle and to be billed directly by the performing laboratory (or another appropriate entity). We urge CMS to take action to modify the OTP bundles to ensure all Medicare beneficiaries have consistent access to the standard-of-care in drug testing, including the use of instrumented chemistry analyzers and definitive testing when medically necessary.

* * * * *

[18] Testing for drugs of abuse typically includes presumptive testing and/or definitive testing. Presumptive testing allows for an initial determination of whether a patient may have certain drugs in his or her system. When results are needed immediately, the testing can be performed by an Opioid Treatment Program (OTP) at the point-of-care with a CLIA-waived presumptive test readable by optical observation only (e.g., cup, dipstick, cassette). It also can be performed in a CLIA-certified laboratory using instrumented chemistry analyzers, when a lower substance detection cut-off is necessary and test results are not needed immediately. The clinical setting and the treating clinician's risk assessment for the patient determines whether the simpler CLIA-waived presumptive test is medically appropriate, or whether it is necessary for a sample to be sent to an outside laboratory for testing. In addition to presumptive testing, a CLIA-certified laboratory may perform definitive testing when it is medically necessary for a treating clinician to be able to identify specific medications, illicit substances, and metabolites in a patient sample. It also is used when several opioids are present in the urine of a patient prescribed a single opioid and the clinician needs to know whether the presence of other opioids is consistent with metabolism of the prescribed opioid or if the patient is using more than one drug class. Definitive testing methods include gas chromatography coupled with mass spectrometry (GC-MS) and liquid chromatography coupled with mass spectrometry (LC-MS).

Thank you very much for your consideration of ACLA's comments on the Proposed Rule.

Sincerely,

Sarah Thibault-Sennett
Senior Director of Reimbursement Policy
American Clinical Laboratory Association