POCTA
POINT OF CARE TESTING ASSOCIATION

September 6, 2022

VIA Electronic Submission to http://www.regulations.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1770–P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: [CMS–1770–P]: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule – Phase-in of PAMA Payment Reductions

Dear Administrator Brooks-LaSure:

On behalf of the Point of Care Testing Association (POCTA), we are pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Proposed Rule entitled, "Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts" (the "Proposed Rule") to address certain of CMS's payment policies, which impact Point of Care (POC) testing services.[1]

POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. POC laboratory testing, such as testing conducted in a physician's office, offers benefits to patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients. POCTA works to develop reimbursement policies that can improve health outcomes by supporting access to POC testing.

In response to CMS's Proposed Rule, POCTA offers the following comments on **section III.C.** regarding the Clinical Laboratory Fee Schedule (CLFS), and particularly on phased-in payment reductions under the Protecting Access to Medicare Act of 2014 ("PAMA"), 87 *Fed. Reg.* 46,068:

[1] CMS, U.S. Department of Health and Human (HHS), *Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts*, 87 FED. REG. 45860 (July 29, 2022).

I. <u>We urge CMS to extend the 0% payment reduction to ensure sound data collection and rate setting methodologies</u>.

As currently proposed, CLFS rates for certain tests are expected to decrease by as much as 15%, effective January 1, 2023. Because implementation of this payment reduction phase-in will have a significant impact on payment rates—and will likely disproportionately impact tests offered in POC settings—we respectfully request that the 0% reduction that has been in place for the last two years (2021 and 2022) be extended until the Agency evaluates whether its existing data collection methodologies under PAMA facilitate the development of Medicare rates that accurately reflect private payer rates.

Section 1834A of the Social Security Act, as established by § 216 of PAMA, revises Medicare's payment methodology for CLFS services to reflect rates paid by third-party payers. Under PAMA, certain "applicable laborator[ies]" are required to report rates paid by private payors to the U.S. Department of Health and Human Services ("HHS").[2] The Secretary calculates the weighted median of the reported private payor data to determine Medicare payment.[3] In recognition of the fact that such rates may be substantially lower than historical CLFS rates, PAMA imposes statutory phase-in payment guardrails to transition rates. These reductions have been delayed in 2021 and 2022,[4] but it is anticipated that future reductions will have a substantial impact on patient access to testing, particularly insofar as the rate arrays used by CMS to calculate the weighted median do not appropriately reflect current costs of furnishing testing services across a representative subset of sites of services.

POCTA and others have long-asserted that the initial data collection methodology did not capture a representative sample of laboratory rates. The "applicable laboratory" definition imposed limitations that blocked certain labs, namely physician office labs, from reporting private payer data. Omitting physician office laboratory data, as well as data from hospital laboratories, skewed data in favor of lower rates that are negotiated by (and only financially feasible for) high-volume reference laboratories. While we credit the Agency for revising the "applicable laboratory" definition in subsequent rulemaking to partially address this issue,[5] the current data collection and rate-setting methodologies are not sound.

A recent case agreed with this conclusion.[6] In *ACLA v. Becerra*, the court found that the 2016 PAMA Rule was arbitrary and capricious because "the 2016 Rule result[ed] in inaccurate marketplace data and depress[ed] Medicare reimbursement rates." The court found that the "[A]gency failed to consider an important aspect of the problem," and "without adequate explanation, exempted a sizable portion of the laboratories covered by the statute from data reporting requirements."[7]

The court in *ACLA v. Becerra* not only agreed that stakeholders have been harmed by low CLFS rates that were not representative, but it also agreed that subsequent amendment of the "applicable laboratory"

[2] The statute provides the "Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory . . . as the Secretary determines appropriate." Social Security Act, §1834A(a)(2); however, the statue prescribes how rates may be set (i.e., 10% through 2020, and 15% through 2023; Social Security Act, §1834A(b)(3)). Rate reductions were delayed until 2023.
[3] Social Security Act, §1834A(b)(1)(A).
[4] *See* Protecting Medicare and American Farmers from Sequester Cuts Act (Dec. 2021) (delaying the reporting requirement under Section 1834A of the Social Security Act and the application of the 15% phase-in reduction).
[5] The definition of "applicable laboratory" was revised to add hospital outreach laboratories (i.e., adding those that "bill[ ] Medicare Part B on the CMS 1450 under bill type 14" to the definition. *See* 42 C.F.R. § 414.502 (defining "applicable laboratory")).
[6] *See Am. Clinical Lab. Ass'n v. Becerra*, No. 21-5122, Opinion for the Court (D.C. Cir. July 15, 2022) [hereinafter *ACLA v. Becerra*].
[7] *Id.* at 11-13.

definition to include certain hospital laboratories' reporting data to develop CLFS rates was not sufficient to render the case moot.[8]

POCTA urges CMS to extend the 0% phase-in while the Agency further analyzes the potential impact of this recent case and payment reductions more generally. Reimbursement reductions disproportionally impact laboratories and tests offered in POC settings. If these settings are unable to sustain POC testing, then Medicare beneficiaries could suffer reduced access and delayed results.

II. <u>Extending the 0% payment reduction will allow laboratories to continue to efficiently and cost-effectively assist with services directly impacting the COVID-19 pandemic response</u>.

Laboratories have served as the backbone of the COVID-19 pandemic response, and laboratories with limited resources— as compared to those equipped to perform high-volume testing—will carry a substantial burden if Medicare rates continue to be reduced because the underlying data is skewed towards lower rates. While POC laboratories are not able to utilize the same cost efficiencies as high-volume laboratories, they play a key role in facilitating timely access to important diagnostic tests that allow for the faster identification of infectious disease(s) and appropriate medical management for the same.

POC testing allows providers to make important treatment decisions in real time based on test results. Rapid results have a direct impact on prescribing decisions and implementation of appropriate infection control measures, as providers work hard to manage contagious diseases, such as COVID-19.

We urge CMS to consider the potential impact implementation of the currently-scheduled payment reduction will have on beneficiary access to accurate, reliable, and timely testing performed at POC laboratories, including which such rates will give POC laboratories access to the resources needed to make medically necessary testing services available to beneficiaries to mitigate the impact of infectious diseases, such as COVID-19.

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We appreciate the opportunity to comment on the Proposed Rule. Please contact Eric Zimmerman at ezimmerman@mcdermottplus.com or 202.204.1457 if you have any questions or would like to discuss the points raised in this comment letter.

Sincerely,

[8] *Id.* at 3-4; 7.