AMERICAN CLINICAL LABORATORY ASSOCIATION

September 11, 2023

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

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure,

The American Clinical Laboratory Association (ACLA) is pleased to submit our written comments on the abovementioned rule ("Proposed Rule").[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

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

- Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment Reductions
- Medicare and Medicaid Provider and Supplier Enrollment
- Expand Diabetes Screening and Diabetes Definitions
- RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA
- Updates to the Definitions of CEHRT
- CY 2024 Conversion Factor

I. Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment Reductions

A. Phase-In of Payment Reductions

Section 1834A(b)(1)(A)[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 reduction in

[1] 88 Fed. Reg. 52262 (Aug. 7, 2023).
[2] 42 U.S.C. § 1395m-1(b)(1)(A).

payment amounts, as set forth in Sec. 1834A(b)(3).[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 conforming changes to the regulations implementing Secs. 1834A(a)(1)(B) and 1834A(b)(3)(B) to reflect changes made by Section 4114 of the Consolidated Appropriations Act, 2023 (CAA)[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, 2024 through March 31, 2024, and implementing a 0 percent payment reduction in CY 2023.[5]

ACLA agrees with CMS's proposed conforming changes, as Congress's action in the CAA was necessary to mitigate the harmful effects of the 2016 rule that are still impacting laboratories today. We have shared our point of view with CMS multiple times in the past: The definition of "applicable laboratory" in the 2016 PAMA final rule had the effect of excluding virtually all hospital outreach laboratories from reporting applicable information, which resulted in CLFS rates that were far lower than they would have been with all sectors of the clinical laboratory market having reported. Beginning in 2018, CLFS rates have been adversely impacted by the agency's choice in the 2016 rule. CMS did make a change to the definition of "applicable laboratory" in the CY 2019 Physician Fee Schedule final rule, to include hospital outreach laboratories that bill Medicare Part B on the CMS 1450 under bill type 14x.[6] Yet despite this change, many of the private payor rates that will be reported by applicable laboratories in future data reporting periods already have been "infected" by the faulty CLFS rates established after the 2017 data reporting period, as those private payor rates are derivative of the low Medicare rates.

Last year, the Court of Appeals for the D.C. Circuit validated ACLA's longstanding concerns about the effect of excluding hospital outreach laboratories' data from the CLFS rate calculations. In its decision in *ACLA v. Becerra*, the Court found that CMS's 2016 final rule was arbitrary and capricious because CMS failed to explain why it chose to define "applicable laboratory" in a way that effectively eliminated hospitals' private payor payment information from data reporting and CLFS rate calculations.[7] The Court found that ACLA members have been harmed by artificially low CLFS rates that were skewed by the absence of hospital data. The Court also agreed with ACLA that its claims were not mooted by subsequent rulemaking that amended the definition of "applicable laboratory" in a way that may result in more hospital laboratories reporting data to develop CLFS rates. (A year earlier, in its June 2021 report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that including representative data from hospital outreach laboratories would lessen the severity of CLFS rate reductions.[8])

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[3] 42 U.S.C. § 1395m-1(b)(3).
[4] Pub. L. 117-328 (December 2, 2022).
[5] 88 Fed. Reg. 52410.
[6] 83 Fed. Reg. 59452, 60074 (Nov. 23, 2018).
[7] *Am. Clinical Lab. Ass'n v. Becerra*, No. 21-5122, Opinion for the Court (D.C. Cir. July 15, 2022).
[8] *See* Report to the Congress: Medicare and the Healthcare Delivery System (Jun. 2021), Ch. 9, *available at* https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf.

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 beneficiaries.

B. Ensuring Complete Data Reporting

CMS should conduct aggressive outreach to hospital outreach laboratories and other applicable laboratories that need information and assistance to comply with Section 216 of PAMA. Hospital outreach laboratories in particular deserve the agency's attention, as they generally were not included in data reporting during the last reporting cycle. Prior to the COVID-19 pandemic, CMS deployed certain educational strategies to inform hospital outreach laboratories about their reporting obligations. If not reminded about their reporting obligations under Sec. 216 of PAMA now, hospital outreach laboratories would not know to seek out resources that CMS has created and to take advantage of them.

We ask CMS to take the following proactive steps as soon as possible to bolster its educational efforts directed at hospital outreach laboratories:

- Make available to national and state hospital associations multi-media materials and information to help raise awareness among their members about PAMA data reporting obligations (*e.g.*, links to webinars and videos that the association can push out, MLN matters articles, etc.).

- Send a letter with information about PAMA reporting to each hospital laboratory that submitted claims in the first six months of 2019 on a CMS-1450 using a 14X type of bill, as these are the hospital laboratories that most likely will qualify as "applicable laboratories" for the first time.

- Partner with ACLA, the American Medical Association, the American Hospital Association, and/or other similar organizations to produce a high-quality, informative presentation about Section 216 of PAMA, its purpose, and the responsibility of each applicable laboratory to report applicable information; the membership organizations can help distribute the presentation to their own members and affiliates.

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 civil monetary penalties. This would notify the other laboratories most likely to qualify as applicable laboratories about their reporting obligations.

CMS 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 where warranted, in order to signal to all applicable laboratories that reporting is not voluntary – it is mandatory. As demonstrated during the 2017 data reporting period, only 0.7 percent of labs paid under Medicare Part B in 2015 – 1,942 out of 261,524 – reported applicable information to CMS.[10] Just 658 independent labs reported applicable information – only twenty percent of all independent labs paid under Medicare Part B and less than half of the labs the HHS Office of Inspector General (OIG) estimated would report.[11] Only 1,106 physician office labs (POLs) reported applicable information to CMS – only one tenth of the POLs the OIG estimated would report information and just one half of one percent of all POLs paid for lab services under Medicare Part B in 2015. And just 21 hospital outreach labs reported data – representing one percent of all reporting entities and less than one half of one percent of all hospital labs paid under Medicare Part B for lab services in 2015. CMS took no action against the thousands of applicable laboratories that should have reported applicable information to the agency but did not. ACLA remains committed to ensuring that all applicable laboratories report applicable information to CMS during the next data reporting period and that the data that CMS uses to develop CLFS rates fairly and accurately represents the hospital outreach laboratories, physician office laboratories, and independent laboratories that receive Medicare payment under the CLFS.

II. Medicare and Medicaid Provider and Supplier Enrollment

A. Misdemeanor Convictions

CMS proposes edits to Section 42 CFR § 424.535(a) to include misdemeanor convictions as a reason to revoke a Medicare provider's or supplier's enrollment. CMS states that it is concerned about providers and suppliers convicted of misdemeanors for conduct that could endanger the Medicare Trust Funds' integrity and Medicare beneficiaries' health and safety. Therefore, CMS proposes in new § 424.535(a)(16)(i) that CMS may revoke a provider's or supplier's enrollment if they, or any owner, managing employee or organization, officer, or director thereof, have been convicted of a misdemeanor under Federal or State law within the previous 10 years that CMS considers "detrimental to the best interests of the Medicare program and its beneficiaries".[12]

ACLA requests additional clarity regarding the proposed new language in § 424.535(a)(16)(i). While ACLA understands the intent behind this proposed addition, we are concerned about the broad language giving CMS the authority to determine which misdemeanor convictions it considers detrimental to the best interests of the Medicare program and its beneficiaries. Beyond the examples included, it is unclear what CMS could consider "detrimental," and we recommend that this language be limited to specific types of healthcare-related offenses, such as the examples relating to fraudulent conduct in Federal or state health care program

[9] 42 U.S.C. § 1395m-1(a)(9).
[10] 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.
[11] *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.
[12] 88 Fed. Reg. 52516.

participation and to treatment of patients.

B. Timeframes for Reversing a Revocation Under § 424.535(e)

Section 424.535(e) currently states that if a revocation of Medicare provider enrollment was due to adverse activity (sanction, exclusion, felony) by one of the parties listed in § 424.535(e) (owner, managing employee, authorized or delegated official, supervising physician), the revocation can be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation notification. CMS has stated that it is concerned the 30-day period is too lengthy and proposes to revise § 424.535(e) to reduce the 30-day period therein to 15 days.[13]

CMS's proposal to revise the timeframe under § 424.535(e) would exacerbate existing challenges for complying with the current timelines. While oftentimes employment or contractual agreements include "for cause termination" clauses that include sanction or exclusion as a ground for termination, as a practical matter, at least 30 days would be required to terminate most agreements. It may take a number of weeks for a provider or supplier to learn of the revocation, conduct an internal investigation of the facts, and unwind the business relationship. For these reasons, ACLA recommends that CMS maintain the 30-day period.

C. Reporting Changes in Practice Location

42 CFR §§ 424.57(c)(2), 410.33(g)(2), and 424.516(d)(1)(iii) establish that the following provider and supplier types must report a change in practice location within 30 days of the change: (1) DMEPOS suppliers; (2) IDTFs; and (3) physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations. All other provider and supplier types are required per § 424.516(e)(2) to report practice location changes within 90 days of the change. CMS proposes to revise § 424.516(e)(1) to require location changes involving providers and suppliers (other than the categories previously described) to be reported within 30 days of the change.

ACLA is concerned that the shift from a 90-day to a 30-day notice period will exacerbate the current issues with reporting changes in practice location. Smaller managed care teams already have challenges completing the required Medicare and Medicaid updates within the 30-day notification timeline. Each form submission requires the signature of the Authorized or Delegated Official and must be done for each laboratory location separately. Each time a physical laboratory location changes, multiple of these forms need to be completed for each of the Medicare and State Medicaid programs.

As Medicare providers are already struggling to update their practice locations under the current timeline, ACLA is concerned that decreasing this timeline with further exacerbate this issue. ACLA recommends that CMS maintain the current reporting requirements for changes in practice location and not proceed with the proposed changes.

[13] *Id.* at 52519.

III. Expand Diabetes Screening and Diabetes Definitions

ACLA strongly supports CMS's proposal to add the Hemoglobin A1C (HbA1c) test to the diabetes screening tests covered under 42 CFR § 410.18(c).[14] While the glucose-based screening tests that are already covered are useful, HbA1c tests are important for identifying those with diabetes or pre-diabetes who present with glucose in the normal or pre-diabetes ranges at the time of a glucose test. Whereas a glucose test reflects the immediate level of glucose (glycemic) control, HbA1c reflects a time-averaged view of the past 2-3 months. Additionally, glucose and HbA1c levels can be discrepant when screening patients for diabetes, particularly in patients 60 years of age and older.[15] Coverage for the HbA1c test will be a great benefit to the Medicare population and ACLA applauds CMS on its proposal to expand coverage of diabetes screening tests.

IV. RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under CLIA

ACLA members are uniquely qualified to provide feedback on both the need for, and the practical impacts of, modernizing the CLIA regulations. ACLA appreciates the proactive steps that the Clinical Laboratory Improvement Amendments Committee (CLIAC) has taken to evaluate and make recommendations on modernizing the CLIA regulations to reflect the technologies and workflows of the 21st Century. We applaud CLIAC for establishing the CLIA Regulations Assessment Workgroup (CRA Workgroup), and we appreciate the substantive evaluation and assessment of the CLIA regulations that such group has undertaken. In addition to our comments on the RFI questions below, ACLA submitted detailed comments to CLIAC at the April 2023 meeting. ACLA agrees that advancements in laboratory technologies and non-traditional workflow models warrant modernization of the CLIA regulations, and we look forward to engaging proactively with both CMS and CLIAC.

A. Histopathology

1. Whether, and how, CLIA should provide oversight of histopathology preparation and processing of tissue samples for slide staining, specifically related to guidance for routine histopathology slide staining and complex IHC staining.

Specimen preparation facilities should be regulated when they conduct slide staining. The training requirements should remain the same for personnel participating in slide staining in regulated laboratories. Different levels of stain training should occur when an "outside laboratory" performs only rapid staining (rapid hematoxylin & eosin (H&E), Diff-Quik, Giemsa etc.) for specimen adequacy or intra-operative procedures for collection and preparing the residual tissue to be sent to laboratory for comparison diagnosis, verses all other H&E stains, immunohistochemistry (IHC) stains, and special stains.

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[14] *Id.* at 52527.

[15] Hillborne L et al. 2022. Contributions of Glucose and Hemoglobin A1c Measurements in Diabetes Screening. *Am J Clin Pathol* 2022;157:1-4. DOI: HTTPS://DOI.ORG/10.1093/AJCP/AQAB106.

At this point, while not explicitly included in CLIA, there are already College of American Pathologists (CAP) requirements regarding these processes.[16] ACLA encourages CMS to review the requirements that already exist in this space to determine if there are specific activities that require specific recommendations.

ACLA also underscores that these activities should be performed under the oversight of a board-certified pathologist.

2. What criteria (for example, training programs, on-the-job training, experience, or academic degree) would interested parties recommend for personnel performing high complexity automated IHC staining?

Across the country, clinical laboratories are grappling with a shortage of personnel. So as not to further exacerbate this issue, ACLA encourages CMS to identify basic knowledge areas that are necessary and state that there are multiple ways for an individual to obtain this knowledge, including relevant academic degrees, on-the-job training and experience.

IHC staining is already considered high complexity testing, and therefore it must be performed by personnel with the qualifications for performing high complexity testing. These existing qualifications already provide the most appropriate science background and demonstrate appropriate training and competency. ACLA encourages CMS to provide more clarity around the specific activities involving automation of IHC staining that would require more specific training beyond that already obtained by personnel qualified to perform high complexity testing (*e.g.*, diluting antibodies, buffer and other reagent preparation, equipment maintenance, any operation of the equipment).

3. How does the categorization of automated staining systems impact personnel who are currently performing this task but do not meet the qualifications for performing high complexity testing?

As answered above, IHC staining, in addition to other special staining, is already considered to be high complexity testing and therefore is currently being performed by personnel with the qualifications for performing high complexity testing, whether using an automated system or not.

Automated staining systems do exist for routine standardized staining procedures, such as H&E, which can even include ready-to-use reagents. ACLA anticipates that categorizing any automated staining system as high complexity testing will have a negative impact on staffing for laboratories who are currently utilizing these systems.

In laboratories utilizing automated staining systems, there are a variety of different tasks that can be performed by personnel with a range of experience and qualifications required. The categorization of automated staining systems and a specific requirement for personnel who engage with these platforms in any capacity has the potential to negatively impact staff and prevent individuals from performing specific tasks that are within their purview but happen to

[16] College of American Pathologists Accreditation Program Anatomic Pathology Checklist, 04.21.2014, *available here:* https://autopsypathology.net/wp-content/uploads/2016/02/CAP_APchecklist_2014.pdf

include these automated platforms. ACLA recommends that CMS define specific tasks that involve the utilization of automated staining systems (*e.g.*, maintenance, setting up the platform, simply transferring plates between machines), and then determine if specific requirements are needed for each task.

4. What is an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue?

These activities occur at the same time. It is unclear why these activities would be divided up and therefore it is difficult to determine a reasonable timeframe between reviews.

5. What education and experience or training requirements should be required for individuals to qualify as a general supervisor (GS) for histopathology? If qualified, what is an acceptable timeframe for the GS to review and evaluate gross examinations under the specialty of histopathology.

ACLA does not believe that any changes need to be made to the standards for a general supervisor (GS) for histopathology.

6. What education and professional experience, or training requirements should be required for individuals performing gross tissue examination that have an associate degree from a histotechnician program or a PA who has training from an accredited program and is certified as a PA?

ACLA believes CLIA's current qualifications for personnel performing high complexity testing are appropriate. These qualifications include "have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution." A Histotechnician Program Associates degree should qualify as a laboratory science and a PA who has trained from an accredited program should also qualify, if they have met the specific education/training semester hours and/or documented laboratory training detailed in the CLIA regulations.[17] As with all laboratory duties, competency must be demonstrated before performing independently.

B. Histopathology and Cytology Testing at Remote Locations

1. How should "remote testing location" be defined?

As shared in ACLA's comments for the April CLIAC 2023 meeting, ACLA proposes that remote review of all digital laboratory information, including digital histopathology and cytology information, should be allowed to be performed under a primary site's CLIA certificate. A "remote testing location" should be any location where testing activities are performed under a primary site's CLIA certificate and that does not hold its own CLIA certificate, such as those laboratory locations operating under an existing exception under 42 CFR §§ 493.43(b) and 493.55(b), *i.e.*, for mobile units and temporary testing sites, certain not-for-profit and

[17] 42 CFR § 493.1489

government laboratories, and laboratories within a hospital located at contiguous buildings and under common direction.

2. How should the CLIA regulations be revised to allow pathologists to examine histopathology and cytology slides/images at a remote testing location?

ACLA recommends that review of all patient-specific digital laboratory information—including histopathology and cytology images—should be permissible at a remote testing location that operates under a primary site CLIA certificate. Such practices remain subject to CLIA, but they are understood to be conducted under the oversight of the laboratory that holds the primary site CLIA certificate. In contrast, review of physical slides—or other specimens—should continue to be performed at a laboratory that holds its own CLIA certificate (unless subject to a different exception under sections 493.43(b) and 493.55(b)). Transport and analysis of physical slides presents different risks than review of digital laboratory information and requires more direct control by a CLIA-certified laboratory.[18]

To allow for review of images at a remote testing site, an exception from the requirement for each laboratory to hold its own CLIA certificate should be added to 42 CFR §§ 493.43(b) and 493.55(b) as follows:

> (4) Laboratories, from which a board-certified pathologist or other laboratory professional accesses the designated primary site system using a secure remote access protocol to retrieve, review, and analyze patient specific digital laboratory information.

We note that this recommendation is broader than histopathology and cytology specialties. However, it is consistent with CLIAC's Recommendation 3 at its November 2022 meeting:

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[18] ACLA acknowledges that this discrepancy between an exception for remote review of digital laboratory information and no exception for remote review of physical slides could place directors of such laboratories at a disadvantage because their home laboratory would count against the 5-laboratory limit specified in the CLIA regulations. Therefore, ACLA also proposes an exception to this five-laboratory limit to avoid this disadvantage under the following circumstances: activities at such additional laboratories are limited to the examination, but not preparation, of slides. This would maintain the level of oversight required for transport and analysis of physical specimens and provides flexibility for remote review of slides for laboratories without the ability for digitization. This could be accomplished by amending CLIA regulations as follows:

493.1359 Standard: PPM laboratory director responsibilities.
The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must –

(a) Direct no more than five laboratories**, except as described in sections 493.1407(d) and 493.1445(d) for laboratories certified to perform testing of moderate- or high-complexity**; and ....

493.1407 & 493.1455 Standard: Laboratory director responsibilities.

...

(d) Each individual may direct no more than five laboratories**, except that a laboratory director may direct additional laboratories that do not count toward the five laboratory limit if activities at such laboratories are limited to the examination, but not preparation, of slides.**

...

CLIAC recommends that the following guidelines be used when assessing the applicability of a site's CLIA certificate when evaluating whether remote testing requires an additional CLIA certificate for staff working at a remote location:

- *The CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty.*
- *If a laboratory employee works out of their home or at another remote location performing duties such as data analysis and interpretation associated with that laboratory, then those activities would be covered through an extension of that laboratory's CLIA certificate and do not require disclosure of the address of the remote location.*
- *A laboratory's CLIA certificate covers the qualified laboratory personnel when using a secured connection authorized and/or managed by that laboratory to review and report data for test processing remotely.*

To effectuate these changes for remote analysis of digital laboratory information, conforming edits to the regulations are required.[19] In particular, ACLA proposes defining the term "digital laboratory information" and amending the definition of "laboratory" at 42 CFR § 493.2 as follows:

Digital laboratory information:

(1) means any of the following:

(A) a digital image derived from a glass slide; or

(B) data including, but not limited to, flow cytometry plots; cytogenetic karyograms; chromatographic, mass spectrometric, clinical chemistry, immunological, and hematologic data; electropherograms; gel images; and genetic expression, array and sequencing data; and

(2) is patient-specific when it is accompanied by information that can be used to identify the individual from whose specimen the information was derived.

...

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body**, including patient-specific**

[19] In addition to updating the CLIA regulations, updates to guidance also may be necessary. In particular, if an individual reviews digital laboratory information on behalf of multiple laboratories from a single remote testing location, this could present tension with CMS's 2018 memo on the operation of multiple laboratories at the same location. *See* CMS Memo, Ref: QSO-18-20-CLIA, Clarification of the Operation of Multiple Laboratories at the Same Location and the Discontinued Use of the Term "Shared Laboratory" (July 20, 2018) ("Multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity."). CMS should clarify that a laboratory is "operating as a separate and distinct entity" when it operates an [LIS] that an individual may access only with credentials that are specific to that individual user, and that an individual being able to log into LISs of "separate and distinct entities" from the same location is not encompassed by "the operation of multiple laboratories at the same location."

> **digital laboratory information,** for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

This change to the definition of "laboratory" is necessary because digital laboratory information may not otherwise meet the definition of "materials derived from the human body." Moreover, the "patient-specific" modifier is important because only examination of patient-specific digital laboratory information should be subject to regulation under CLIA. Entities analyzing only deidentified information for the purpose of supporting a clinical laboratory's examination of a patient specimen, such as third parties that receive deidentified genetic variant information, should not be regulated as clinical laboratories under CLIA.[20]

Finally, to allow for remote review of cytology slides, the standard for cytology should be revised so that slides do not have to be evaluated at the same site at which they were prepared. This could be achieved with minor revisions to 42 CFR § 1274(a):

> (a) *Cytology slide~~s examination site~~.* All cytology slide**s** ~~preparations~~ must be ~~evaluated~~ **prepared** on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

3. What conditions (including, location(s)) should apply for a pathologist to examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification?

As detailed above, ACLA recommends that laboratories should not require a separate CLIA certification when they are "laboratories from which a board-certified pathologist or other laboratory professional accesses the designated primary site system using a secure remote access protocol to retrieve, review, and analyze patient specific digital laboratory information," which would include histopathology and/or cytology images. Rather, such laboratories would operate under a primary site's CLIA certificate, and any remote testing activities for the examination of such images would remain subject to the same conditions as to which they would be subject were they performed at the primary site.

4. Under what conditions should a primary location cease permitting testing at the remote location?

[20] In our comments to CLIAC at the April 2023 meeting, ACLA also recommended adding a new exception to 42 CFR § 493.3 to make clear that entities examining only deidentified information would not be regulated under CLIA. Specifically, we proposed that a new exception be added under section 493.3(b) for "(4) Any facility or component of a facility whose analysis is limited to digital laboratory information that is not patient-specific and is received from a clinical laboratory for purposes of providing information to support the clinical laboratory's examination of a patient specimen." Although such standalone entities would not be directly subject to CLIA, the laboratory requesting their services *is* subject to CLIA. Accordingly, that laboratory remains responsible for the quality of procured services as they relate to the laboratory's test system.

The remote testing location serves as an extension of the primary site. The primary site laboratory director is responsible for ensuring that the review quality performed at the remote site is equal to that performed in the primary site. Any conditions or concerns flagged within the remote testing location that would negatively impact the CLIA certificate of the primary location, such as lack of appropriate security to maintain confidentiality of patient information (42 CFR § 493.1231), concerns about the quality of test reports (42 CFR § 493.1291), or issues with the physical space (42 CFR § 493.1101), could lead the laboratory director to cease permitting review at the remote location.

In other words, a primary site should cease permitting testing at a remote location if any conditions exist at the remote location that, were they to exist at the primary site, would cause the primary site to cease testing. However, a remote testing location should be expected to comply only with those CLIA requirements that are applicable to the activities conducted at that remote site. For example, with regard to physical space requirements under 42 CFR § 493.1101, the "space, ventilation, and utilities necessary for conducting all phases of the testing process" are different for a laboratory handling human specimens than for a remote testing location that only analyzes digital laboratory information.

5. How should the remote location be included on the final patient report?

ACLA proposes that the remote location does not need to appear on a test report when the designated primary site is the certificate holder. Instead, CLIA should require only that the primary site address is included on the report. However, it could allow for some other designation indicating that the report was released from a remote testing location. 42 CFR § 493.1291 should be amended as follows:

(c) The test report must indicate the following: ...

(2) The name and address of the laboratory location where the test was performed**, or of the designated primary site for a laboratory described at § 493.43(b)(4) or 493.55(b)(4)**.[21]

6. How should CMS, SAs, or Accreditation Organizations perform onsite surveys at remote locations?

ACLA recommends that "remote testing locations" should not be subject to biennial inspections. Additionally, we recommend changes to 42 CFR §§ 493.1777 and 493.1780, as proposed below, to reflect that inspectors must acknowledge the different circumstances of a remote testing location operating under the CLIA certificate of the designated primary site, and inspections of such remote testing locations should not be unannounced.

493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance; **exception**.

...

[21] *See* response in section IV.B.2 *supra*, proposing a new exception for remote testing locations that retrieve, review, and analyze patient-specific digital laboratory information.

(e) *Exception*. The following standards apply to a laboratory described in § 493.43(b)(4)[22]:

(1) The laboratory is not subject to biennial inspections.

(2) If necessary, CMS or CMS agent may conduct an inspection of the laboratory during reasonable hours (after announcing the date and time of the inspection) to do the following:

(A) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(B) Evaluate a complaint from the public.

...

493.1780 Standard inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) *Validation inspection*. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation **(or in the case of a laboratory described at § 493.55(b)(4)[23], during reasonable hours and after announcing the date and time of the inspection).**

(b) *Complaint inspection.* CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation **(or in the case of a laboratory described at § 493.55(b)(4)[24], during reasonable hours and after announcing the date and time of the inspection)** upon receiving a complaint applicable to the requirements of this part.

...

C. Clinical Cytogenetics

1. Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?

As discussed in section IV.B.2 above, ACLA recommends that review of patient-specific digital laboratory information—including clinical cytogenetics images—should be permissible at a remote testing location that operates under a primary site CLIA certificate. Such practices remain subject to CLIA, but they are understood to be conducted under the oversight of a laboratory that holds the primary site CLIA certificate. We refer to our comments in section IV.B.2. above, which apply to this question, as well.

[22] *Id.*
[23] *Id.*
[24] *Id.*

2. Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?

We refer to our comments in section IV.B.4. above, which apply to this question as well.

3. What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?

The remote testing site is an extension of the primary site and should be maintained according to CLIA standards for the primary site as applicable to the remote review being performed. Consistent with this approach, the laboratory director would have the following responsibilities, among others, under 42 CFR § 493.1445 for in connection with any remote testing activities:

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

...

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

...

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

...

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

…

4. What conditions or criteria would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

As discussed in section IV.C.3. above, the remote site is an extension of the primary site. Accordingly, the remote location would be expected to comply with the CLIA regulations applicable to its testing activities. We also refer to our comments in section B.4. above, which apply to this question as well.

V. Updates to the Definitions of CEHRT

ACLA supports CMS's proposal to revise the definitions of CEHRT in 42 CFR §§ 495.4 and 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program so these definitions are consistent with the "edition-less" approach to health IT certification as proposed in the Office of the National Coordinator for Health Information Technology (ONC) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule.[25] Because multiple standards could be used during a transition period, it would allow for voluntary advancement to iterative certification criteria between updates, giving developers more flexibility. This approach also would allow for reasonable implementation timeliness for new standards and criteria.

ACLA also agrees with the proposal to replace the CMS references to the "2015 Edition health IT certification criteria" with "ONC health IT certification criteria" and add the regulatory citation for ONC health IT certification criteria in 45 CFR § 170.315. Finally, ACLA agrees with the CMS proposal to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR § 170.315 "as adopted and updated by ONC."

VI. CY 2024 Conversion Factor

CMS estimates that the CY 2024 PFS conversion factor will decrease to 32.7476 from the CY 2023 conversion factor of 33.0775, reflecting a budget neutrality adjustment, the zero percent update adjustment factor set forth in Sec. 1848(d)(19) of the Social Security Act, and the expiration of the 2.5 percent increase for services furnished in CY 2023, as provided in the Consolidated Appropriations Act, 2023.[26] CMS further states that the estimated impact on total allowed charges for pathology is -2 percent.

This cut is likely to have an adverse impact on recruitment and retention of qualified physicians in critical specialties. There is a dangerous shortage of pathologists, with an unprecedented number of unfilled pathologist openings.[27] Prior to 2020 the average number of job openings was between 200 and 300. In the past three years that number has averaged closer to 800 and experts believe this number is closer to 1,000 when including openings not publicly

[25] 88 Fed. Reg. 52546; *see also* 88 Fed. Reg. 23746-23917 (April 18, 2023).
[26] Pub. L. 117-328 (December 2, 2022).
[27] Edna Garcia, MPH and others, The American Society for Clinical Pathology 2020 Vacancy Survey of Medical Laboratories in the United States, American Journal of Clinical Pathology, Volume 157, Issue 6, June 2022, Pages 874–889, https://doi.org/10.1093/ajcp/aqab197.

advertised. This has left practices severely understaffed in a specialty that only graduates approximately 600 new pathologists each year, half of which require visa sponsorship (only about 1/3 of visa requests get accepted).

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, as set forth earlier in this letter, and cuts to the valuation of pathology services as a result of the decreased conversion factor will exacerbate those effects for many laboratories.

* * * * *

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

Sincerely,

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