AMERICAN CLINICAL LABORATORY ASSOCIATION

The Honorable Russell T. Vought
Director
Office of Management and Budget
Executive Office of the President
1650 Pennsylvania Ave, NW
Washington, D.C. 20503

April 10 2025

Re: Response to the President's Deregulatory Initiative, Executive Orders 14192, 14219

Dear Director Vought:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide recommendations on the Administration's implementation of the President's deregulatory initiative, as set forth in Executive Order 14192, "Unleashing Prosperity Through Deregulation" and Executive Order 14219, "Ensuring Lawful Governance and Implementing the President's Department of Government Efficiency Deregulatory Initiative." ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers in all 50 states, informing increasingly personalized care. Clinical laboratory testing services provide enormous value to patients and clinicians, informing 70% of medical decisions but comprising less than 1 percent of total Medicare spending.

In the enclosure, ACLA offers recommendations for specific actions federal agencies can take to deregulate, alleviate administrative burdens, and reduce inefficiencies, including the following:

1. Medicare Clinical Laboratory Fee Schedule (CLFS): Take concrete steps immediately to address flaws with the CLFS payment system, the only Medicare fee schedule based on commercial payor rates.

2. Medical Documentation: Streamline medical documentation requirements for prior authorization of clinical laboratory tests to reduce inefficiencies and administrative burdens for clinical laboratories and ordering providers.

3. Prior Authorization Policies: Remove "date of service" roadblocks to prior approval and payment for laboratory testing services.

4. CMS National Coverage Determination Process: Improve the efficiency of CMS's National Coverage Determination process to more swiftly bring innovative laboratory services to Medicare beneficiaries.

5. National Correct Coding Initiative: Strike language in the NCCI Medicare Policy Manual that results in conflicting coding guidance for providers and resulting in inappropriate denials of medically necessary services.

6. E-signature Policies for Laboratory Tests: Modernize policies to recognize electronic signatures on laboratory test orders as evidence of a physician's intent to order, as is permitted for pharmaceutical and imaging services.

AMERICAN CLINICAL LABORATORY ASSOCIATION

7. ICD-10 Guidelines for Clinical Laboratory Tests: Modify ICD-10 guidelines to remove Excludes notes to prevent unnecessary administrative burdens on ordering providers and clinical laboratories and inappropriate claim denials for testing services.

8. Costs to Use CPT® Codes: Remove cost barriers to clinical laboratory compliance with Health Insurance Portability and Accountability Act (HIPAA) coding requirements.

Enclosed are detailed descriptions of the problems to be addressed, ACLA's recommendations, supporting information about the negative impact of the regulation or burden, and the anticipated positive outcomes of addressing these issues.

ACLA appreciates your consideration of our recommendations as the Administration implements the President's deregulatory initiative. ACLA and our member laboratories remain committed to serving patients and providers and serving as a resource for you and your staff. To discuss these recommendations, please contact Mary Lee Watts, ACLA Vice President of Government Affairs and Policy at mlwatts@acla.com.

Sincerely,

Susan Van Meter
President, American Clinical Laboratory Association

Enclosure

American Clinical Laboratory Association

Recommendations to Reduce Administrative Burden, Protect Patient Access, and Foster Innovation: Response to Executive Orders 14192 and 14219

Centers for Medicare & Medicaid Services, Department of Health and Human Services

I. Problem: The current methodology for setting Medicare Clinical Laboratory Fee Schedule (CLFS) rates was included in Sec. 216 of the Protecting Access to Medicare Act (PAMA), which passed in 2014. It calls for Medicare CLFS rates to be based on commercial payor rates for laboratory services – the only fee schedule to be based on market rates.

Unfortunately, CMS's implementation of the law in 2016 resulted in CLFS rates that do not reflect rates paid in the commercial market. Whereas the majority of clinical laboratories should have reported data to CMS for CLFS rate-setting, fewer than one percent of all laboratories reported data, and the data reported was not representative of the full laboratory market. Ninety percent of the data was reported by independent laboratories (which submit only about half of all claims paid under the CLFS), and only 21 hospitals nationwide reported any data to CMS, despite thousands of hospitals receiving payments under the Medicare CLFS each year.

Cuts of almost $4 billion to CLFS rates in just the first three years of PAMA implementation far exceeded the Congressional Budget Office's (CBO's) ten-year savings projections of $2.5 billion, harming investment in the next generation of diagnostics and jeopardizing patient access to innovative testing services.

Currently, commercial payor rates and volumes from the first half of 2019 are to be reported to CMS beginning January 1, 2026, for rates that would take effect on January 1, 2027. Originally, this data was supposed to have been reported in 2020, but Congress has delayed further implementation of the law for many years, owing to its concerns about how it was implemented, so the intended triennial data collection and reporting cycle has become illusory. Using 2019 to set today's rates is not the intent of the law and will not result in accurate or fair rates.

There are concrete steps that CMS can take now to ameliorate some of the flaws with the CLFS payment system while Congress considers improvements to the law to yield a Medicare payment system that is truly reflective of the commercial payor market.

Recommended Actions:

A. **In the Medicare Physician Fee Schedule (PFS) Proposed Rule or another vehicle, CMS should maintain current CLFS rates in 2026, using flexibility in the statute to hold off on further reductions of up to 15% on 800 tests scheduled to begin January 1, 2026.**

B. **In the PFS Proposed Rule or another vehicle, CMS should change the next PAMA data collection period from January 1 – June 30, 2019, to January 1 – June 30, 2025.**

C. CMS should conduct an aggressive education campaign to ensure that all applicable laboratories – physician office, hospital outreach, and independent – know about their obligations under PAMA to report information to CMS for purposes of rate-setting.

Class of Regulation per E.O. 14219:

- Regulation that harms the national interest by significantly and unjustifiably impeding technological innovation, infrastructure development, disaster response, research and development
- Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition
- Regulations that impose significant costs upon private parties that are not outweighed by public benefits

Background and Rationale:

- Since the implementation of PAMA, Medicare CLFS rates have failed to reflect the commercial market. CMS based CLFS rates on private payor rates reported by fewer than 1% of applicable clinical laboratories; nearly all reported rates came from independent laboratories, with modest reporting from physician-office labs and reporting from only 21 hospital outreach labs.
- The PAMA statute says: "Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2028 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year." The "applicable percent" of reductions set to resume for some tests effective January 1, 2026 is 15%, as the rate reductions calculated by CMS in 2017 were so large that they have still not been fully phased in.
- The law does not require CMS to reduce the payment for a test code by exactly the applicable percent; rather, it prohibits a rate reduction that **exceeds** the applicable percent.
- CMS should not reduce rates in 2026 given that annual cuts of up to 10% to the CLFS in each of the first three years of PAMA implementation already far exceeded the Congressional Budget Office's (CBO) estimated reduction of $2.5 billion over 10 years. Instead, nearly $4 billion in reductions were taken in just three years.
- Put into context, the CLFS accounts for only $8 billion a year in Medicare spending, less than 1% of total Medicare spend in 2023.[1]
- Specifically, for those test codes whose weighted medians have not been fully implemented, CMS should use its authority to hold CLFS rates constant and not reduce rates by the maximum amount allowed in the law.

[1] https://oig.hhs.gov/reports/all/2024/total-medicare-part-b-spending-on-lab-tests-decreased-in-2023-driven-in-part-by-less-spending-on-covid-19-tests/.

- Updating the data collection period, as CMS has previously done using its administrative authority, would ensure data more accurately reflects current commercial market rates and help support more robust data reporting by applicable laboratories.
- No rates should be reduced until at least after the next data collection and data reporting cycle has been completed.

II. **Problem: Clinical laboratories and other providers face significant administrative burden due to discrepancies in medical documentation requirements between Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) Plans, among other payors.**

Recommended Actions: CMS should clarify that a test requisition form (TRF) is valid medical documentation and may be sufficient to determine that the service is reasonable and necessary for Medicare beneficiaries without the need for other medical information from the ordering provider.

A. CMS should update the Program Integrity Manual, Pub. No. 100-08 Ch. 3, Sec. 3.3.2.1, Documents on Which to Base a Determination. Specifically, CMS should add the following text to Pub. No. 100-08 Ch. 3, Sec. 3.3.2.1: *When requisition forms include complete information validating medical necessity, such as qualifying clinical information that demonstrates test coverage criteria are met, the test requisition form may be sufficient to determine if the service is reasonable and necessary for Medicare beneficiaries without other medical information from the ordering provider.*

B. Additionally, CMS should communicate this update to the MACs through written communication and to Medicare Advantage plans through a Health Plan Management System (HPMS) memo.

Class of Regulation per E.O. 14219:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits
- Regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship

Background and Rationale:

- Some MACs and MA plans do not accept the types of documentation submitted with a test order, such as a test requisition form (TRF) or a physician attestation, to support the medical necessity of a test. A TRF includes valuable information, including current diagnosis codes.
- Payors' refusal to accept TRFs as medical documentation creates additional administrative burdens on the ordering provider and laboratory, as they are forced to identify and submit additional documentation to reiterate the information previously submitted with the test order.

- A recent Office of Inspector General (OIG) report found that in some cases, despite MA organizations' requests for additional documentation, the information already provided was sufficient to demonstrate medical necessity.
- The need for agency-wide consensus on the topic of TRF acceptance was elevated in 2024 when the MolDX program, which is utilized by multiple MACs, released a policy stating that the TRF may be sufficient to determine if a service is reasonable and necessary. There is now a discrepancy in policy between the medical documentation requirements between MACs that utilize the MolDX program and those that do not, which must be resolved by the agency.
- Providing agency-wide clarity around these documentation requirements will reduce paperwork burdens and administrative complications for ordering providers, clinical laboratories, the Medicare program itself, and the Medicare Advantage plans that follow Medicare policies.

III. <u>Problem</u>: The CMS date of service policy is a roadblock to prior authorization approvals for clinical diagnostic laboratory tests.

<u>Recommended Actions</u>: CMS should prohibit Medicare Advantage organizations from denying a request for prior authorization on the basis that the request was made after the date of service of the clinical diagnostic laboratory test, i.e., the date of specimen collection, by amending 42 C.F.R. § 422.122, Prior Authorization Requirements, to add a subsection (d). Specifically, CMS should add the following subsection:

A. ***(d) Date of Service:***

1. ***In the case of a clinical diagnostic laboratory test that requires prior authorization, an MA organization must accept a prior authorization request from the provider who ordered the test or the clinical laboratory that furnished the test at any time before a timely claim for reimbursement is submitted.***
2. ***An MA organization may not deny a request for prior authorization for a clinical diagnostic laboratory test because the request was made after the date of service of the test.***

B. CMS should amend 42 C.F.R. § 414.510, the Laboratory Date of Service definition, to clarify the purpose of the definition and clearly state that the laboratory date of service is not intended to be used to deny appropriate coverage or restrict beneficiary access to appropriate services. CMS should provide a written update of this change to all applicable plans.

1. **Specifically, CMS should amend the front language in 42 C.F.R. § 414.510 to read:**
   a. ***"The date of service for either a clinical laboratory test or the technical component of physician pathology service determines which provider should bill for the service and is as follows…"***
2. **CMS also should add the following to the CMS Laboratory Date of Service webpage**

a. The laboratory date of service definition is used to determine which provider should bill Medicare for a specific service. The laboratory date of service cannot be used as a reason to deny appropriate coverage or restrict beneficiary access to appropriate services.

C. Report the update to Laboratory Date of Service (detailed above) in a Health Plan Management System (HPMS) memo to Medicare Advantage plans and memos to other applicable plans.

D. CMS should notify States and Managed Medicaid organizations of these changes to Medicare Advantage regulations to encourage parallel changes to Medicaid program guidelines.

Class of Regulation per E.O. 14219:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits
- Regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship.

Background and Rationale:

- The concept of "prior authorization" oftentimes is not compatible with how lab tests are used to guide patient care. In practice, a physician or other clinician orders a specific laboratory service and collects a patient sample, such as blood or tissue, and the physician sends the order and sample to a clinical laboratory. Invoking the "date of service" rule is one way some MA plans leverage prior authorization processes to deny payment to laboratories. MA plans often adopt the Medicare Part B "date of service rule" at 42 CFR § 414.510(a), such that the date of service is generally the date of specimen collection, not the date when the test is performed.
- The "date of service" – the date of specimen collection - often has passed by the time the laboratory even receives the specimen for testing. If a health care practitioner does not get prior authorization before ordering the test or before the date that the sample is collected—which is often the case—the laboratory will attempt to get prior authorization once it receives the order. However, this frequently results in a denial because the date of service has passed by the time the request is made, resulting in further issues with the appeal process and creating an unnecessary burden for all parties involved.
- The Administration can address the misuse of the date of service for laboratory tests as a reason to deny coverage through small updates to existing policies. Providing clarity and guardrails around the use of the date of service for laboratory tests will remove administrative burdens for patients, providers, and the payers themselves.
- Medicaid programs are designed with guidelines that often reflect the regulatory framework established by Medicare, particularly concerning the date of service for laboratory tests. By amending 42 CFR §414.510(a) to address the misuse of date of service for laboratory tests, CMS can significantly alleviate the burden on providers delivering services to Medicaid beneficiaries, improving patient access.

IV. <u>Problem</u>: CMS's National Coverage Determination (NCD) process lacks efficiency and prevents timely review of innovative services for Medicare beneficiaries.

<u>Recommended Action</u>: The Administration and the CMS Office of General Counsel should provide guidance that the agency can use a streamlined process for reconsiderations or updates to existing National Coverage Determinations (NCDs) that expand coverage for new and innovative technologies and/or update the coverage to be consistent with the covered service's expanded intended use.

***Note*:** Large-scale reconsideration requests to NCDs or reconsideration requests that would narrow existing coverage should not be eligible for this streamlined reconsideration pathway and should be considered under the existing NCD consideration pathway.

<u>Class of Regulation per E.O. 14219</u>:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits
- Regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship
- Regulations that harm the national interest by significantly and unjustifiably impeding technological innovation, infrastructure development, disaster response, inflation reduction, research and development, economic development, energy production, land use, and foreign policy objectives

<u>Background and Rationale</u>:

- The process to develop or reconsider an NCD through CMS is extremely burdensome and has a backlog spanning years, resulting in a delay for Medicare beneficiaries to receive appropriate services. This backlog is due in part to an internal CMS decision to consider small reconsiderations or updates to previous NCDs as novel NCD requests, which then must go into the queue and require extensive agency resources to consider the request and perform the required research and analysis anew.
- Taking action will reduce the backlog of NCD requests, decrease CMS agency resources needed to review and process these requests, and improve Medicare beneficiary access to new and innovative services more quickly.

V. <u>Problem</u>: Conflicting medical procedure coding guidance from the National Correct Coding Initiative (NCCI) Medicare Policy Manual and the American Medical Association (AMA) leads to compliance issues and reimbursement denials for clinical laboratories and other medical service providers.

<u>Recommended Actions</u>: CMS should make the following changes to the NCCI Medicare Policy Manual:

A. Chapter X: Pathology/Laboratory Services[2] Introduction, Section A: CMS should remove the paragraph below in its entirety.

- ***If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service.*** **[Ch. X, X-4.]**

B. Molecular Pathology [Ch. X, Section, F.8]: CMS should delete this section in its entirety.

C. Medically Unlikely Edits (MUE) [Ch. X, Section M.15]: CMS should delete this section in its entirety.

D. In the General Coding Policies [Chapter 1, page I-22][3] CMS should modify the language where CMS provides guidance that they may adopt NCCI edits that are not consistent with the American Medical Association's CPT Assistant publication. This places an immense burden on laboratory providers as they must use the AMA HIPAA compliant code set and AMA guidance.

- **Modifying the language that states, *"CMS may adopt NCCI edits that are not consistent with CPT Assistant" to "CMS shall not adopt NCCI edits that are not consistent with CPT instructions and guidance, including CPT Assistant"* would reduce the burden on laboratory and other providers as they must follow AMA CPT guidance and instructions.**

Class of Regulation per E.O. 14219:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits

Background and Rationale:

- Coding guidance provided in the Medicare NCCI Policy Manual is not consistent with the American Medical Association (AMA) Current Procedural Terminology (CPT) code set for laboratory services. This discord places an immense burden on laboratory providers, as they must use the AMA HIPAA-compliant code set and AMA guidance.
- NCCI should define correct coding, and it is imperative that the Manuals and other established NCCI methodologies (i.e. MUE and PTP edits) not include information that contradicts AMA CPT coding structure or guidance.
- Laboratories must code claims correctly to avoid false claims liability, and reimbursement for medically necessary services provided to Medicare and Medicaid beneficiaries should be

[2] https://www.cms.gov/files/document/10-chapter10-ncci-medicare-policy-manual-2025finalcleanpdf.pdf.
[3] https://www.cms.gov/files/document/01-chapter1-ncci-medicare-policy-manual-2025finalcleanpdf.pdf

tied to correct coding, not to coding inconsistent with AMA CPT guidance. It is critical that this conflict is resolved.

VI. **<u>Problem</u>: CMS has failed to modernize its policies to reduce administrative burden by allowing a physician's electronic signature to demonstrate intent to order a clinical diagnostic laboratory test, like a physician's orders for a pharmaceutical or imaging services.**

<u>Recommendation</u>: CMS should work with the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP) to establish standards for electronic signatures for laboratory tests, making clear that an electronic signature on an order submitted through a certified electronic health record (EHR) is a signed laboratory order and is evidence of the physician's intent to order to the test.

<u>Class of Regulation per E.O. 14219</u>:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits
- Regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship

<u>Background</u>:

- Currently, there is no practical way for a laboratory to obtain an electronic signature on an electronic test order. A laboratory cannot include a signature on an order in an X12 275 health care attachment because a clinical laboratory order does not contain a signature.
- Electronic Health Records (EHRs) and Laboratory Information Systems (LISs) do not support the Health Level Seven (HL7) Clinical Documentation Architecture (CDA) to exchange orders and results; they predominantly use HL7v2, which is a "transactional" standard that has been used for many years that can handle the data necessary to support high-volume clinical laboratory ordering and resulting. CDA, on the other hand, is a document-based standard, suitable for messaging a final laboratory result, but not suitable for the high-volume transactional exchange necessary for clinical laboratory orders.
- An HL7v2 message used to communicate a laboratory order includes data that identifies the ordering practitioner, and it is possible to determine if that ordering practitioner was authorized to place the order. This type of process has been in place for more than a decade without concerns raised about the validity of such electronic orders, or clinicians' intent to submit such orders.
- CMS should convene a stakeholder meeting that includes the ASTP, the CLIA office, Health Level Seven (HL7), Electronic Health Records Association (EHRA), ACLA, and other stakeholders to resolve the critical issue of clarifying standards for electronic signatures as evidence of a physician's intent to order a laboratory test.

Centers for Disease Control and Prevention and Centers for Medicare & Medicaid Services, Department of Health and Human Services

VII. Problem: ICD-10 coding guidelines are used as unnecessary administrative barriers to medical care.

Recommended Action: Require the CDC National Center for Health Statistics (NCHS) and CMS to modify the ICD-10 guidelines[4] to remove the Excludes Notes from the guidelines (Section I.A.12) to prevent undue burden on ordering providers and performing laboratories and inappropriate claims denials for necessary services.

Class of Regulation per E.O. 14219:

- Regulations that impose significant costs upon private parties that are not outweighed by public benefits
- Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition

Background and Rationale:

- Ordering providers, not clinical laboratory providers, select ICD-10 codes for the laboratory requests, and laboratories cannot determine ICD-10 codes, including Excludes Notes code pairs that appear on a claim. Laboratory providers are not reimbursed for performing and reporting clinically appropriate testing because of ICD-10 Excludes Notes guidance. Payors use front-end claim edits to deny coverage and payment for laboratory services, using the Excludes Notes section in the ICD-10 guidelines as rationale.
- Patients broadly may require multiple diagnostic laboratory services based on their clinical presentation. In these cases, the ordering provider may place multiple ICD-10 diagnosis codes on a requisition for testing based on the patient's clinical presentation.
- **Example:** A patient with a history of obesity reports to his primary care provider for an abnormal weight gain. The provider then orders testing to determine the reason for the abnormal weight gain, such as fluid excess in the setting of congestive heart failure, and to determine the necessary treatment. In this scenario, the ICD-10 codes for both obesity and abnormal weight gain would be appropriately supported and reported, but based on Excludes Type Notes, the claim for these appropriate services would be denied in total and not processed due to administrative reasons.
- This creates an extreme burden on the performing laboratory, as it would not receive payment for services performed and reported.

[4] International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Official Guidelines for Coding and Reporting "Excludes Notes" (ICD-10-CM Guidelines).

Department of Health and Human Services

VIII. <u>Problem</u>: HIPAA code set regulations require covered entities to use a privately-owned code set for submitting health care claims to third party payors without regulating the royalties that the owner can charge covered entities to use the mandated code set.

<u>Recommended Action</u>: HHS should either purchase a single, unlimited license to allow all covered entities conducting HIPAA standard transactions to use the mandated American Medical Association (AMA) Current Procedural Terminology (CPT®) code set without charge or establish through rulemaking a reasonable limit on licensing fees for use of the code set—preferably at cost.

<u>Class of Regulation per E.O. 14219</u>:

- Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition
- Regulations that impose significant costs upon private parties that are not outweighed by public benefits

<u>Background and Rationale</u>:

- HIPAA covered entities, including clinical laboratories, are required by law to use the AMA CPT® code set to bill third parties such as Medicare, Medicaid, or private insurers for laboratory services.[5]
- The CPT® code set is copyrighted by the AMA; there is no other source for these codes.
- When enacting HIPAA, Congress recognized that by directing the Secretary to establish standard code sets for mandatory use, monopolies could be created that needed to be regulated.
- While the Secretary of HHS is required by law to ensure efficient and low-cost distribution of all code sets used for billing, including the CPT® code set,[6] HHS has not taken any action to regulate the royalties that AMA can charge for use of the code set that HHS has required covered entities to use, contrary to the best reading of the underlying statute.
    - As a result, AMA has proposed to charge laboratories exorbitant royalties for the mandatory use of the CPT® code set based on an excessive rate applied to a unit of measure unrelated to the CPT® code set. This threatens patient access to innovative laboratory tests, increases healthcare costs, and outweighs the public benefits of standardized coding.

[5] 42 USC §1320d-2(c)(1); 45 CFR §§162.1000, 162.1002.
[6] 42 USC §1320-2(c)(2).