ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

STOP LAB CUTS

Summary of The RESULTS Act
H.R. 5269 / S. 2761

Reforming and Enhancing Sustainable Updates to Laboratory Testing Services

The Protecting Access to Medicare Act (PAMA), which describes the process for establishment of rates on the Medicare Clinical Laboratory Fee Schedule (CLFS), was passed in 2014 and is set forth in section 1834 of the Social Security Act.[1] Under current law, every three years, during a reporting period, applicable laboratories are to report applicable information (private payor rates and associated volumes) to the Centers for Medicare & Medicaid Services (CMS). CMS develops a weighted median of the private payor rates reported about a test code, which becomes the CLFS rate until after the next reporting period. CLFS rates were reduced up to 10% in each of 2018, 2019, and 2020, and they can be reduced up to 15% in each of 2026, 2027, and 2028, until a fully-implemented weighted median is reached. For tests that have been designated as Advanced Diagnostic Laboratory Tests (ADLTs), applicable laboratories initially are paid at list price, and thereafter they report applicable information annually. Currently, 18 tests are considered ADLTs. New tests that are not ADLTs are crosswalked or gapfilled, and those rates stay in place until after the next reporting period.

Current rates are based on applicable information from the first six months of 2016 that was reported in 2017. Congress has delayed the reporting period that was scheduled for 2020 six times. Without Congressional action, starting on January 31, 2026, applicable laboratories will report applicable information from the first six months of 2019; resulting rates would be effective January 1, 2027. Further, absent congressional action, a cut of up to 15% will be imposed on rates for nearly 800 tests on the CLFS in January 2026 and again in 2027 and 2028. There is no limit on cuts thereafter.

In 2022, the Court of Appeals for the D.C. Circuit ruled that CMS's definition of "applicable laboratory", which had the effect of removing hospital outreach laboratories from those reporting private payor rates to CMS, was arbitrary and capricious.[2] Nevertheless, the court was unable to recalculate past Medicare rates, due to PAMA's provision stripping jurisdiction to review Medicare payment amounts.

Long term PAMA reform must address PAMA's main flaws:

- Overrepresentation of independent laboratories in data reporting, anemic reporting by hospital outreach laboratories and physician office laboratories, and lack of penalties for failure to report
- Use of pre-pandemic private payor rates and volumes to establish current CLFS rates
- Inclusion of Medicaid managed care organization (MMCO) rates in data used to develop CLFS rates
- Year-over-year CLFS rate cuts of up to 15%

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[1] Protecting Access to Medicare Act, Sec. 216, Pub.L. 113-93; 42 U.S.C. § 1395m-1.
[2] American Clinical Laboratory Association v. Becerra, No. 21-5122 (D.C. Cir. 2022).

- Lack of a mechanism for an interested party to challenge a CLFS rate

ACLA has developed a legislative redline proposal that addresses these flaws but would not change the way that CMS sets CLFS rates for ADLTs or change the definition of ADLT. For tests for which 100 or fewer laboratories are paid under the CLFS, applicable information reporting and rate-setting would be largely unchanged.

For each subsection of Sec. 216 of PAMA, the following summary of the PAMA reform legislative redline proposal addresses current law, issues that need to be addressed (if any), and how the proposal would address the issues. Note that this is a summary of current law and the legislative proposal, and it does not summarize regulations or CMS's interpretation of current law.

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(a) Reporting of private sector payment rates for clinical diagnostic laboratory tests

- Current law:
  - Every three years (annually for an ADLT), an applicable laboratory reports applicable information during a reporting period for a data collection period for each clinical diagnostic laboratory test (CDLT). The current data collection period is Jan. 1 – Jun. 30, 2019, and the reporting period is Jan. 1 – Mar. 31, 2026 (in general, a data collection period can be any period of time specified by the Secretary).
  - An "applicable laboratory" is a laboratory that receives a majority of its Medicare revenue under the CLFS and/or Medicare Physician Fee Schedule (PFS); the Secretary may establish a low volume or low expenditure threshold.
  - "Applicable information" is the payment rate paid by each "private payor" and the associated volume (does not include capitated or bundled payments, but does include discounts, rebates, coupons). A "private payor" is a health insurance issuer, group health plan, Medicare Advantage plan, or MMCO.
  - If the Secretary determines that an applicable laboratory has failed to report or has made a misrepresentation or omission in reporting, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.
- Issues:
  - In 2017, fewer than 1% of all laboratories paid by Medicare reported applicable information. Data from independent labs (ILs) comprised 90% of the data CMS used to develop CLFS rates, yet they account for just 50% of CLFS volume. Physician office labs (POLs) contributed only 7.5% of the data, but they account for 23% of CLFS volume. Only 21 hospitals reported data, while hospitals account for 27% of CLFS volume. Both POLs and hospitals tend to have private payor rates that are higher than those of ILs.
  - CMS has no intention of penalizing any applicable laboratory for failure to report, having never established a penalty program as permitted under the statute, and hospitals and POLs have more pressing data reporting priorities (because they are incentivized for reporting or penalized for failure to report for more significant aspects of Medicare payment systems that govern payment for those settings).
  - MMCO rates are not market-based. These rates are always lower than CLFS rates and can only bring Medicare rates down.

- Private payor rates and volumes from 2019 do not reflect current market rates.

- Summary of new policy:
  - Information would be reported for the data collection period of Jan. 1 to Jun. 30, 2027, and the reporting period would be Jan. 1 – Mar. 31, 2028. Reporting would happen every four years thereafter.
  - The definition of "applicable laboratory" would reflect the definition at 42 C.F.R. § 414.502[3], without the "majority of Medicare revenues" test.
  - The definition of "applicable information" would specify that it includes only final payment rates, and the definition of "private payor" would not include MMCOs.
  - For test codes for which 100 or fewer entities received CLFS payments during the data collection period ("non-widely available non-ADLT CDLTs"), applicable laboratories would report to the secretary information on final private payor rates and the associated volume of tests at each rate for which payment was made during the data collection period. CMS will publish a list of such test codes prior to the reporting period.
  - For ADLTs, applicable laboratories would report applicable information annually, as is the case under current law.
  - For purposes of determining weighted medians for "widely-available non-ADLT CDLTs" (non-ADLTs for which more than 100 entities received CLFS payments in the first six months of the calendar year prior to the data collection period[4]), CMS would contract with a "qualifying independent claims data entity" to provide information about private payor rates and volumes from a "qualifying comprehensive claims database". Applicable information would be reported about the final rates paid (and associated volumes at each rate) through the end of the calendar year for tests furnished during the data collection period; this would allow for a six-month "run out" period after the conclusion of the data collection period, during which initial payments for the tests that were appealed or disputed would be finalized for the overwhelming majority of all claims.
    - A "qualifying independent claims data entity" is a non-profit not associated with any governmental agency, health insurance issuer, group health plan, provider or supplier, or other organization in the health care section that: (1) maintains a qualifying comprehensive claims database; (2) is certified by CMS to be a "qualified entity";[5] (3) complies with all federal and state privacy and security requirements; and (4) applies a quality assurance process to validate all data included in the qualifying comprehensive claims database, including comprehensive statistical testing.
    - A "qualifying comprehensive claims database" is an independent database of private payor claims data that: (1) includes at least 50 billion claims from more than 50 private payors and claims administrators; (2) is a statistically significant repository of claims data that is representative for all 50 states and DC; (3) includes only data that is validated by a quality assurance process; (4) complies with all federal and state privacy and security requirements; (5)

[3] 42 C.F.R. § 414.502.
[4] The total volume of tests billed and paid under the CLFS in 2023 was approximately 398 million. 99.5% of this volume was for codes for which more than 100 labs billed and were paid under the CLFS.
[5] 42 U.S.C § 1395kk(e)(2).

provides version control of claims to enable the collation and submission of only claims representative of final payment amounts; and (6) includes claims data with respect to widely-available non-ADLT CDLTs.

(b) Payment for clinical diagnostic laboratory tests

- Current law:
    - The CLFS payment amount is equal to the weighted median for the most recent data collection period.
    - In 2026-2028, a CLFS rate may be reduced up to 15% per year; thereafter, there would be no limit on year-to-year rate reductions.
    - CLFS rates remain in place until after the next reporting period.
- Issues:
    - Unlimited year-over-year cuts are unsustainable.
- Summary of new policy:
    - Rates would be frozen at 2025 levels for 2026-2028.
    - For 2029 and subsequent years, CMS would calculate weighted medians for CLFS test codes, and the most that a rate could be reduced from year to year beginning in 2029 would be 5%. For non-widely-available non-ADLT CDLTs, the data would be from applicable laboratories only.
        - For non-widely-available non-ADLT CDLTs, the data would be from applicable laboratories only.
        - For widely-available non-ADLT CDLTs, the data would be from the qualifying comprehensive claims database only.
        - For ADLTs, the data would be from the ADLT "owner" only.
    - If CMS does not enter into a contract with a qualifying independent claims data entity, CLFS rates for all widely-available non-ADLT CDLTs would be updated annually by CPI-U.
    - If the qualifying comprehensive claims database does not have claims data about a widely-available non-ADLT CDLT, the CLFS rate for such widely-available non-ADLT CDLTs would be updated annually by CPI-U.
    - If CMS does not receive applicable information about a non-widely-available non-ADLT CDLT, the code will be crosswalked or gapfilled (unless it was crosswalked or gapfilled in the last 2 years, in which case the current crosswalked/gapfilled rate would remain in effect).
    - Prior to the new 2029 rates' implementation, CMS would make available to the public an explanation of the CLFS rates it developed, including such supporting data it may provide (*e.g.*, aggregated volume information, low and high payments, etc.).

(c) Payment for new tests that are not ADLTs

- Current law: Tests are crosswalked or gapfilled.
- Issues: None.

- Summary of new policy: No changes.

(d) Payment for new ADLTs

- Current law: ADLTs are paid at actual list charge for the first three calendar quarters, then applicable laboratories report applicable information annually and the CLFS rate is the weighted median.
- Issues: None
- Summary of new policy: No changes

(e) Coding

- Current law: Allows for temporary HCPCS codes for new ADLTs and FDA-cleared or FDA-approved tests and unique identifiers for such existing tests.
- Issues: None.
- Summary of new policy: No changes.

(f) Input from clinicians and technical experts

- Current law: Establishes the CDLT Advisory Panel and sets forth its responsibilities.
- Issues: None
- Summary of new policy: No changes.

(g) Coverage

- Current law:
    - Specifies that a Medicare Administrative Contractor (MAC) can make a coverage determination for a laboratory test only in accordance with the process set forth in 42 C.F.R. part 426.
    - Allows the Secretary to designate one or more (not to exceed four) MACs to establish coverage policies and process claims for laboratory tests.
- Issues: None.
- Summary of new policy: No changes.

(h) Implementation

- Current law: There shall be no administrative or judicial review of the establishment of payment rates.
- Issues: Although ACLA prevailed in its legal challenge against CMS regarding its definition of "applicable laboratory" and the effective exclusion of hospitals from the definition, because of this policy, the court was unable to require any meaningful remedy and the rates remain in place to this day.
- Summary of new policy: The policy would remain in place for payment amounts prior to January 1, 2029, after which time the establishment of payment rates would be subject to administrative or judicial review.

(i) Transitional rule

- Current law: The previous method for establishing CLFS rates stays in effect until December 31, 2016.
- Issues: None
- Summary of new policy: No changes