Medicare Lab Test Payment: Preparing for the Upcoming PAMA Reporting Requirements

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Protecting Access to Medicare Act (PAMA)

- Comprehensive legislation signed into law on April 1, 2014,
  - revised Medicare physician payment
- Section 216 revised the Medicare payment system with the intent CLFS clinical diagnostic laboratory test (CDLT) to reflect private payor rates
  - Other impacts included the creation of ADLTs, the creation of the PAMA Advisory Panel, MAC consolidation, etc.
- **PAMA requires the collection and reporting of data from applicable laboratories** on payments that the laboratory receives from commercial payors for every unbundled test
- CMS then sets the CLFS rate for most CDLTs for the next 3-year period
  - Making payment the weighted median of the reported payment data

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Impact of First Reporting Round Significant

- PAMA caps Medicare payment cuts
- However, first round of data collection was very flawed, and the reduction in payments was greater than CMS estimated, with price cuts totaling $670 million (vs. pre-PAMA estimate of $390 million).
- Of the over 230 molecular tests (including oncology, inherited diseases, and infectious diseases) on the CLFS in 2017:
  - 57% received a decrease
  - 20% received an increase

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PAMA: What's Next?

- Congress has delayed the next reporting period and payment cuts several times
- **Latest Action:** Consolidated Appropriations Act signed into law February 3, 2026, changed requirements for CDLTs that are not ADLTs
  1. **Payment cuts delayed one more year**
     - Cuts resume for CY 2027-2029 and continue to be capped at no more than 15%
  2. **Reporting is back: All applicable labs must report this year**
  3. **Shifted data collection period from 2019 to 2025 data**

Data Collection Period	Data Reporting Period
January 1, 2025 – June 30, 2025	May 1, 2026 – July 31, 2026

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What is an Applicable Lab?

1. Bills Medicare Part B one of these ways:
   - Under its own NPI

     OR
   - If a hospital outreach laboratory, on the Form-1450 under type of bill (TOB) 14X.
2. Meets the "majority of Medicare revenues" threshold:
   - When you add your revenue from Medicare CLFS and Medicare Physician Fee Schedule (PFS), it's more than 50% of your total Medicare revenues.
3. Above the low expenditure threshold:
   - Labs that receive less than $12,500 in CLFS revenues during a data collection period do not need to report
   - MA plan payments are excluded for purposes of determining whether a laboratory meets the low expenditure threshold

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Additional Information on Applicable Lab

- **CMS Resources:**
  - CMS educational video on the definition of applicable lab: https://www.youtube.com/watch?v=c3eiPYeRA_U
  - Topic addressed in detail in CMS FAQs: https://edit.cms.gov/files/document/clinical-laboratory-fee-schedule-pama-reporting-frequently-asked-questions-faqs.pdf
- **Note:** *CMS is sending a letter by mail to entities that it believes are applicable laboratories*

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CMS Increased the Number of Labs that Need to Report

After 1st reporting period, CMS revised the definition based on stakeholder concerns that the CY2018 CLFS payments rates were based on applicable information from only a relatively small number of laboratories. (83 FR 60074)

CMS said, "We believe receiving additional applicable information from more laboratories of all laboratory types outweighs the additional reporting burden on laboratories."

Post-2018 Regulatory Changes
• **CMS excluded MA plan payments from total Medicare revenues** • **Impact:** An increase of 49% in the number of labs meeting the majority of Medicare revenues threshold, i.e., 951 additional labs will have to report
• **CMS changed definition to capture labs that bill Medicare Part B on the CMS 1450 under bill type 14x** • **Impact:** An increase of 39% in the total number of labs meeting the majority of Medicare revenues threshold, i.e., 757 additional lab will have to report

Grand total impact: ***An increase of 1,708 applicable labs reporting for a total of 3,650.***

TAKEAWAY: Labs that did not report in 2017 may now be required to report!

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What Needs to Be Reported?

Applicable labs must report applicable information:

1. Specific CLFS **HCPCS code** associated with the test
   - 2026 HCPCS code list: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Applicable-Information-HCPCS-Codes.zip

   (Note: Does not include certain codes like 81479)
2. Each **private payor rate for which final payment** has been made during the data collection period
3. The associated **volume** of tests performed corresponding to each private payor rate
4. NPI number

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What is a Private Payor?

- Health insurance issuer
- Group health plan
- Medicare Advantage Plan
- Medicaid Managed Care Organization

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Is It a Private-Payor Payment Rate That Needs to Be Reported?

Final claims only	• Must be a final claim paid during the data collection period • Date of service & date of claim submission not relevant
Do not report payments = $0	• Payments of $0.00/"zero dollars"/denied payments should not be reported
Only report if payment associated with specific HCPCS code	• If a laboratory cannot correlate a private payor payment amount to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information.
No encounter level payments	• If a private payor groups test-level payments into an encounter (claim-level) payment, instead of by individual HCPCS code, those rates would not be applicable information that need to be reported.
Factor in Discounts	• The private payor rates reported to CMS are required by statute to reflect all discounts, rebates, coupons, and other price concessions.

See examples of correct payment and whether the final claim needs to be reported: Page 3 of https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2019-CLFS-PrivatePayor-RateBased-Summary.pdf

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How Does a Laboratory Report?

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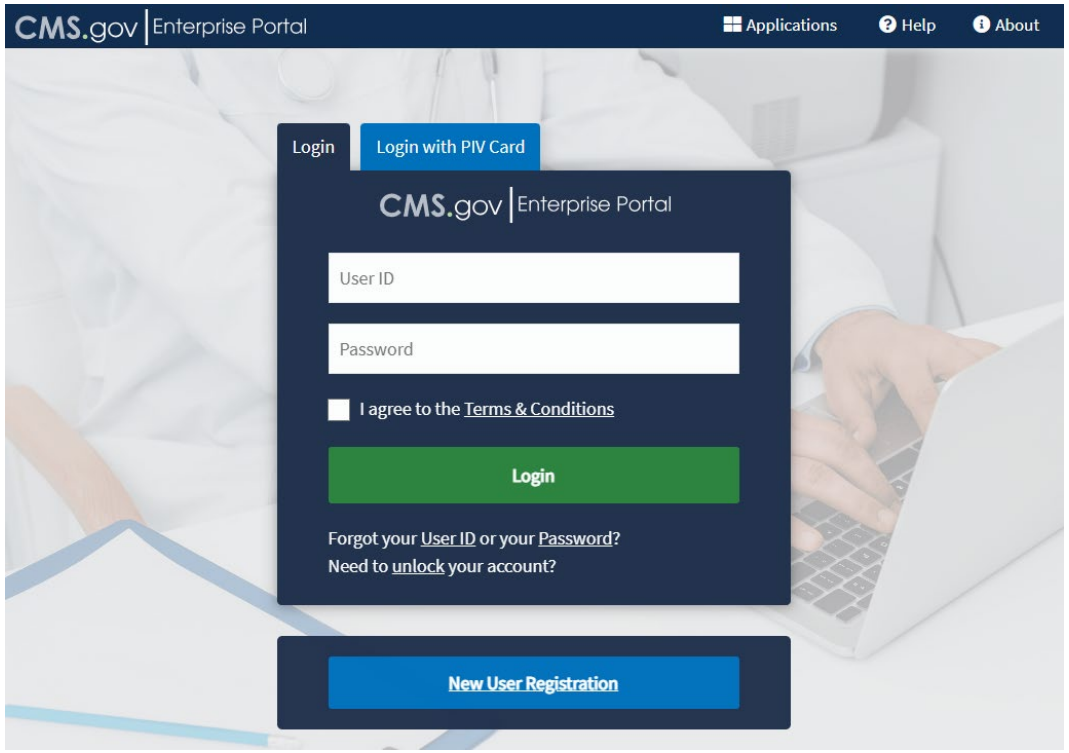
CLFS Module Reporting System

- To report, use the CLFS Data Collection Module within the Fee-for-Service Data Collection System (FFSDCS)
  - Accessed via the CMS Enterprise Portal
  - Same as 2017
- All FFSDCS Application users must complete the new user registration
- Users will either serve as a data "Submitter" or a data "Certifier"
- CMS has released guidance on registering and logging into the system
  - https://www.cms.gov/files/document/idm-registration-clfs.pdf



https://portal.cms.gov/portal/

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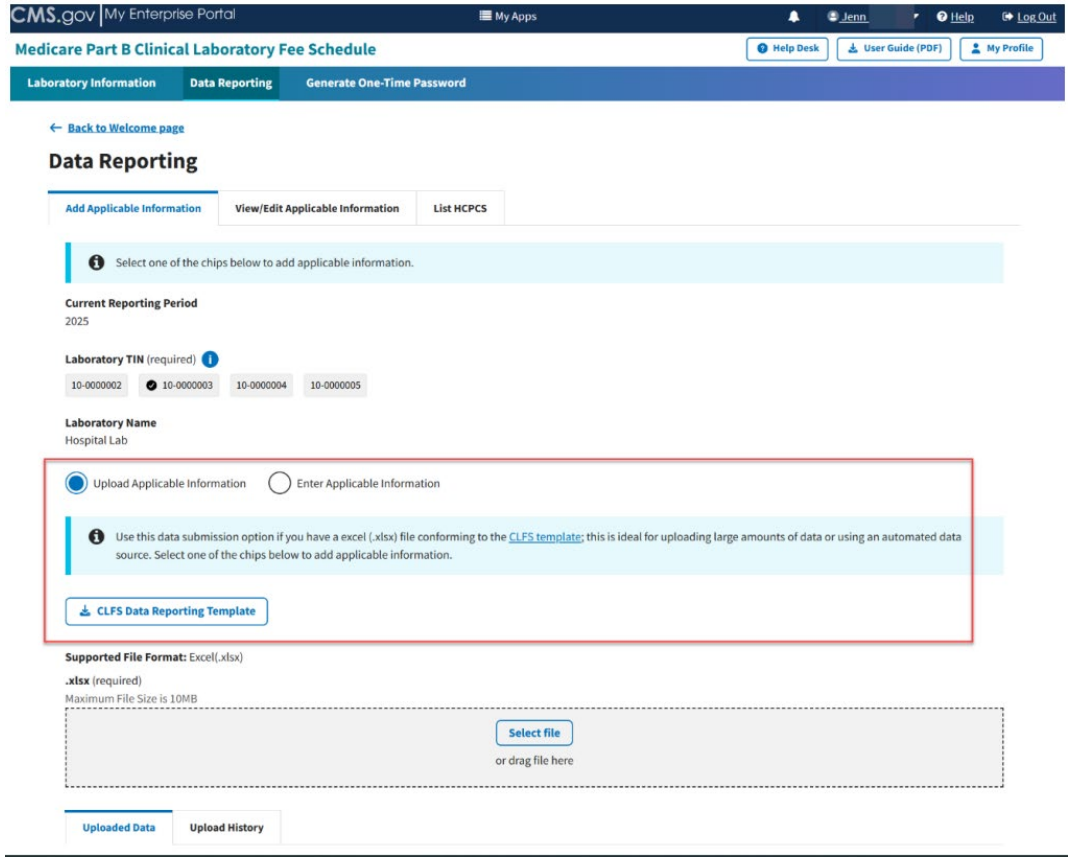
Submitting Data

- A **Submitter** is an individual at the applicable laboratory who submits its data via the CLFS module through **manual online data entry or by uploading a completed template file**

- CMS released updated, detailed data submission guidance: https://www.cms.gov/files/document/clfs-submitter-user-guide.pdf



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Using the Template for Reporting Applicable Information

- Do not add, remove, or otherwise change columns or column headings within the template
- Only one file per Tax Identification Number (TIN) can be uploaded, but this file may include multiple NPIs under that TIN.
- You must prepare one data file for each TIN on which you are reporting.
- Even if using the template, the CLFS module allows laboratories to edit data that has not been certified yet

The optional template can be found:
https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/downloads/clfs-data-collection-form.zip

HCPCS CODE (5-alpha numeric characters)	PAYMENT RATE (1-5 numeric characters and two decimal places)	VOLUME (1-6 numeric characters)	NATIONAL PROVIDER IDENTIFIER (10 numeric characters)

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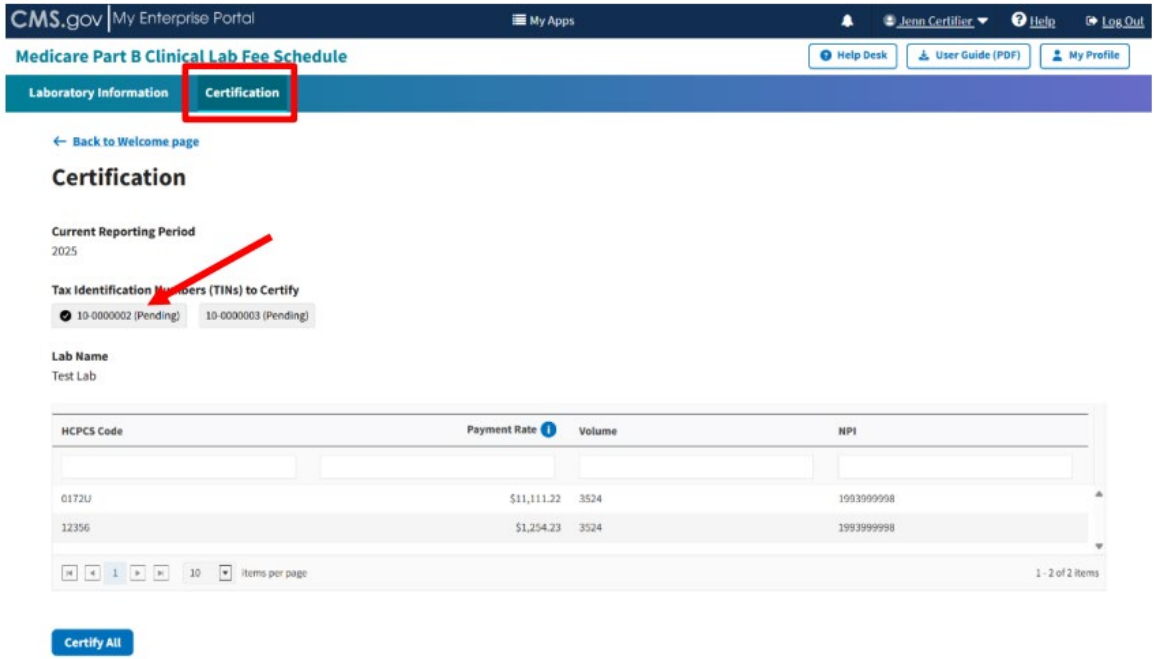
Certifying Data

- A **Certifier** is a President or Chief Financial Officer of the applicable laboratory, or an individual appointed as data certifier, who certifies the accuracy and completeness of applicable information submitted.
  - Cannot be the same person as the Submitter
- If any **errors** are found, they **must be corrected by the Submitter**.
- Once the Certifier has certified the data for the current period, submission closes and no more data can be entered for the TIN.
  - If corrections need to be made post certification, please contact the CLFS helpdesk: CLFSHelpDesk@dcca.com



CMS released detailed guidance for certifiers: https://www.cms.gov/files/document/clfs-certifier-user-guide.pdf

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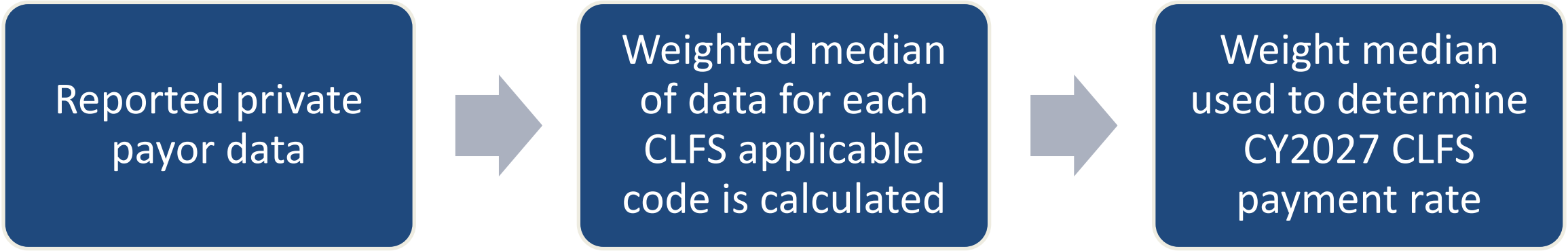
How is Reported Data Used?



- If the weighted median is greater than a 15% difference as compared to the current CLFS rate, then the **payment cut for CY 2027-2029 is capped at 15%**

- For all other situations, the weighted median = the new CY 2027-2029 payment rate

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Reminder: No Changes to the Process for ADLTs

Definition:	A type of CDLT that is furnished only by a single laboratory and is either FDA authorized or meets one of the following: 1. Is an analysis of multiple biomarkers of DNA, RNA, or proteins; 2. Uses an algorithm to predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy 3. Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests
Timeline:	• ADLT initial period = a period of 3 calendar quarters after ADLT status granted; payment = actual list charge • **After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median. Private payor data reported annually.**

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What is the Penalty for Non-Compliance?

- CMS has the authority to issue civil money penalties
- Up to **$10,000 per day (adjusted for inflation) for each failure** to report or each such misrepresentation or omission

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Preparing for the Next Reporting Period

- ✓ Visit the CMS CLFS website:
  - https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-reporting
  - CMS resources include:
    - Applicable HCPCS code list
    - Updated CLFS Data Reporting Template
    - Clinical Laboratory Fee Schedule: PAMA Reporting Frequently Asked Questions (FAQs)
    - CLFS Data Collection System User Guides - See under "How Do I Report?"
- ✓ Get Medicare Learning Network® (MLN) updates
  - https://www.cms.gov/training-education/medicare-learning-network/newsletter
- ✓ Contact help desk for info on the data collection system: clfshelpdesk@dcca.com

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Comprehensive PAMA Reform is Still Needed!

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AMP Joins Other Stakeholders in Calling for PAMA Reform

AMP is proud to join its advocacy partners in calling on Congress to pass the

Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act!

List of Provider Signatories

AdvaMed
ADVION
American Academy of Family Physicians
American Association of Bioanalysts
American Clinical Laboratory Association
American Hospital Association
American Medical Association
American Medical Group Association
American Medical Technologists
American Osteopathic Association
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Association for Molecular Pathology
American Society for Histocompatibility and Immunogenetics
Association of American Medical Colleges
Association for Academic Pathology
Association for Diagnostics & Laboratory Medicine
Association of Public Health Laboratories
California Clinical Laboratory Association
College of American Pathologists
COLA Inc.
GreatLakes Laboratory Network
Healthcare Leadership Council
Infectious Diseases Society of America
Medical Group Management Association
National Independent Laboratory Association
National Rural Health Association
New Jersey Association of Mental Health and Addiction Agencies Inc.
New York State Clinical Laboratory Association
Personalized Medicine Coalition
Point of Care Testing Association

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RESULTS Act Overview

- Introduced in both the House and Senate on September 10, 2025
- Sponsors: Reps. Richard Hudson (R-NC), Gus Bilirakis (R-FL), Scott Peters (D-CA), Brian Fitzpatrick (R-PA), and Raja Krishnamoorthi (D-IL), and Senators Thom Tillis (R-NC) and Raphael Warnock (D-GA)

	Current System	RESULTS Act
Data Collection Period:	Payment will be based on data from 1/1/2025-6/30/2025	Next data collection period begins 1/1/2027
Data Reporting Period:	5/1/2026 – 7/31/2026 (then every 3 years)	Delayed until 1/1/2028-3/31/2028 (then every 4 years)
Payment Cuts	Up to 15% each year 2027-2029	Up to 5% starting in 2029
Who Reports?	All applicable laboratories	Two differing data collection/reporting systems for “widely available CDLTs” versus “non-widely available CDLTs”

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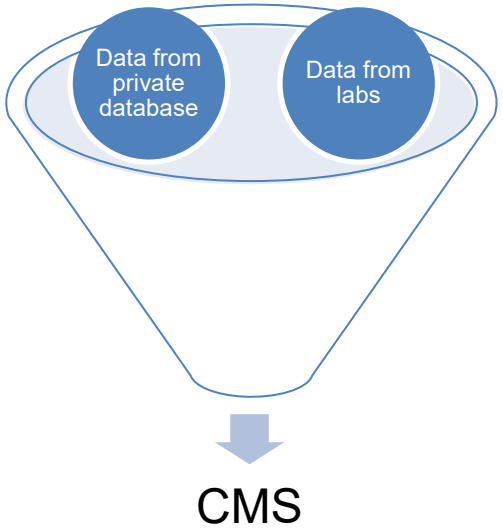
RESULTS Act Data Collection Systems

Widely Available CDLTs

- Number of providers receiving CLFS payments for the service **exceeds 100** during 11-month period immediately prior to data collection period
- **Labs do not report data to CMS**
- CMS will collect and use applicable information from a **qualifying comprehensive claims database** of a qualifying independent claims data
- Database must:
  - Be a "national nonprofit organization that is not affiliated with any governmental agency, insurance issuer, group health plan, provider of services or supplier, or other organization in the health care sector"
  - Have at least 50 billion claims from more than 50 private payors and claims administrators
- If no contract with database or no data, then payment = previous year payment adjusted for inflation

Non-Widely Available CDLTs

- Number of providers receiving CLFS payments for the service is **100 or below**
- **Individual labs continue to report data to CMS**
- If no data:
  - And previously crosswalked or gapfilled, then payment = previous year payment (not adjusted for inflation)
  - And not previously crosswalked or gapfilled, then code will go through the annual pricing exercise



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Act Now!

Scan the QR code to write to your elected officials and ask them to cosponsor and support passage of the RESULTS Act!

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