American Clinical Laboratory Association

# Hospital Reporting Under PAMA Sec. 216

## What you Need to Know to Comply with CMS's New Data Collection and Reporting Requirements for Hospitals

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# Structuring our discussion

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1. **Statutory Background of PAMA Sec. 216**
2. **How to Know Whether You Are Required to Report**
3. **How to Report**
4. **New Legislative Proposal to Delay the Upcoming Data Reporting Period**
5. **Q&A**

# Questions addressed

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**WHO** needs to report private payor rates to CMS?

**WHAT** needs to be reported?

**WHEN** does reporting happen?

**HOW** is reporting done?

**WHAT** are possible penalties for failure to report?

**WHERE** can hospitals find answers to questions about PAMA reporting?

# Sec. 216 of PAMA

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- Sec. 216 of the Protecting Access to Medicare Act (PAMA) became law in April 2014
- **Changed the way that rates are set** on the Clinical Laboratory Fee Schedule (CLFS) for the **first time in 30 years**
- Intended to create a **market-based system** under which CLFS rates are derived from information reported by labs about their private payor rates and volumes
- **All entities that are reimbursed under the CLFS** for laboratory services **are subject to the rates** – hospitals, physician office laboratories, independent laboratories – regardless if they report data to CMS

# Sec. 216 of PAMA – the basics

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- Requires **"applicable labs"** to report **"applicable information"** to CMS (private payor rates and volumes)
- Establishes **data collection periods** and **data reporting periods**
- Authority for CMS to impose **Civil Monetary Penalties** for non-reporting, omissions, misrepresentations
- Creates a new category of test – **"advanced diagnostic laboratory test"** – with its own data reporting and payment rules
- Sets forth **coding requirements** for certain new and existing tests
- Creates **Advisory Panel on Clinical Diagnostic Laboratory Tests** to assist CMS with technical aspects of implementation

# PAMA rulemaking

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- CMS issued a proposed rule about **three months after the deadline for issuing a final rule**
- Statute calls for first data reporting period in 2016 and new CLFS rates in 2017; **final rule pushed everything back one year**
- The first data collection period was Jan. 1 – June 30, 2016
- The first data reporting period was scheduled to be Jan. 1 – Mar. 31, 2017 – extended two months because of technical difficulties
- Preliminary rates released Sept. 2017; final rates released Nov. 2017
- **New CLFS rates went into effect Jan. 1, 2018**
- Some regulations were amended in the CY 2019 Physician Fee Schedule Final Rule, applicable to future data collection and reporting cycles

# Timeline

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| 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | Repeat… |
|---|---|---|---|---|---|---|
| **JUN. 16:** Final rule released | **JAN. 1 – MAY 31:** First data reporting period | **JAN. 1:** New rates effective | **JAN. 1 – JUN. 30:** Second data collection period | **JAN. 1 – MAR. 31:** Second data reporting period | **JAN. 1:** New rates effective | |
| **JAN. 1 – JUN. 30:** First data collection period | **SEPT. 22:** CMS releases preliminary payment rates, followed by 30 day comment period | | | **SEPT.:** CMS releases preliminary payment rates, followed by 30 day comment period | | |
| | **NOV. 17:** CMS releases final payment rates | | | **NOV.:** CMS releases final payment rates | | |

# Who reports data to CMS?

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In other words, what is an **applicable laboratory**?

- An entity that:
  - Is a **laboratory**, as defined in §493.2 of this chapter;
  - Bills Medicare Part B under its own National Provider Identifier (NPI);
    - **For hospital outreach laboratories—bills Medicare Part B on the CMS-1450 under bill type 14x;**
  - In a data collection period, **receives more than 50 percent of its Medicare revenues**, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period **from one or a combination of the following sources**:
    - This subpart G (**Clinical Laboratory Fee Schedule**)
    - Subpart B of this part (**Physician Fee Schedule**)
  - [During a data collection period] **receives at least $12,500 of its Medicare revenues from [the CLFS]**. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—
    - Does not apply with respect to the ADLTs it offers and furnishes; and
    - Applies with respect to all the other CDLTs it furnishes.

# Who reports data to CMS?

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**IF** A hospital laboratory has its **own NPI or** the hospital bills Medicare using a **14x type of bill** for services furnished to non-hospital patient

**AND** The **majority of** the laboratory's **Medicare revenues** are from the **CLFS and/or PFS**

**AND** The hospital laboratory receives **more than $12,500 in CLFS revenue** in the first six months of 2019

**THEN** The hospital laboratory **qualifies as an applicable laboratory** and **must report applicable information** to CMS in the **first three months of 2020**

# Who reports data to CMS?

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**Majority of Medicare revenues equation:**

$$\frac{\textbf{CLFS + PFS revenue}}{\textbf{Medicare Part A, B, and D revenue}}$$

**Hospital outreach laboratory** = "A hospital laboratory that furnishes laboratory tests to patients other than inpatients or registered outpatients of a hospital."

**Examples of applying the equation:**

- Hospital outreach laboratory bills under its own NPI for its non-patient services:
  - **Uses only its own revenue** to determine whether CLFS + PFS revenue > 50% of NPI's Medicare revenue, and it received > $12,500 in CLFS revenue in data collection period

# Who reports data to CMS?

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## Examples continued:

- Hospital outreach laboratory and two other outreach laboratories bill under another hospital outreach laboratory's NPI for non-patient services:
  - **Uses combined revenue from all outreach labs** to determine whether CLFS + PFS revenue > 50% of NPI's Medicare revenue, and together they received > $12,500 in CLFS revenue in data collection period

- Hospital has three outreach labs; one bills Medicare for non-patient services under its own NPI, and the other two bill Medicare for non-patient services under the hospital's NPI:
  - Laboratory with its own NPI **uses only its own revenue** to determine whether CLFS + PFS revenue > 50% of NPI's Medicare revenue, and it received > $12,500 in CLFS revenue in data collection period
  - Laboratories billing under the hospital's NPI **use only 14x TOB revenue** to determine whether CLFS + PFS revenue > 50% of NPI's Medicare revenue, and it received > $12,500 in CLFS revenue in data collection period

# Applicable Information: What's In and What's Out?

# What data is reported?

## In other words, what is **applicable information**?

- **HCPCS** code for each test
- **Private payor rate** for each test for which **final payment** has been made **during the data collection period**
- **Volume** for each test at **each** private payor rate

## What is a **private payor**?

- A **health insurance issuer**
- A **group health plan**
- **Medicare Advantage plan**
- **Medicaid Managed Care organization**

# What data is reported?

- **Final payments made during** a data collection period (DCP)
  - Initial claim paid in error before DCP and final correct amount paid during DCP = IN
  - Initial claim paid in error during DCP and final correct amount paid after DCP = OUT
  - Appeals resolved during the DCP = IN
- Payments from **secondary insurers** made during a DCP
  - Reported rate = 100% of the primary payor's fee schedule amount (final payment from primary payor + any patient cost-sharing amounts + payment from secondary insurer)
  - DO NOT report payments from secondary insurers separately
- **Patient cost-sharing amounts**
  - Rate reported should be 100% percent of payor's fee schedule (which includes patient cost-sharing, if applicable)
  - Report whether cost-sharing amounts collected during DCP or not
- **Multiple payment rates** for same test from same payor
  - Report each unique payment rate with the associated volume at that rate
- **Manual remittances**
  - Sorry, folks, these are included, too…

# What data is NOT reported?

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- Rates for tests paid only under the **PFS**
- **Price concessions** applied by a laboratory
- **Denied payments** and **zeroes**
- **Unresolved appeals**
- Payments made on a **capitated** basis
- Payments where the **associated test volume isn't clear** from the remittance
- Remittances where a payor has grouped individual HCPCS code payments into an **encounter- or claim-level payment**
- **Estimated payments**

**General rule:** If you cannot correlate a payment amount and volume to a specific HCPCS code, *it is not applicable information* and it's not reported.

# Hospital outreach laboratories, take note:

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**Q** **Do hospital outreach laboratories that are applicable laboratories based on the revenues attributed to the 14x TOB only need to collect and report the private payor data that is billed using a 14x TOB, or would hospital outreach laboratories need to collect and report private payor data that is billed in other ways, as well?**

**A** Reporting applicable information is not discretionary. If the hospital outreach laboratory is an applicable laboratory it would be responsible for collecting and reporting all applicable information attributed to its applicable laboratory. When a hospital outreach laboratory is an applicable laboratory as defined by revenues attributed to the 14x TOB, **applicable information for all non-patient laboratory test services must be reported, regardless of the TOB required by the private payor for laboratory tests furnished to non-patients**.

# Hospital outreach laboratories, take note:

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**Q** **What if the private payor does not use the form CMS-1450 14x TOB for laboratory tests furnished to non-hospital patients?**

**A** **In circumstances in which a private payor does not require a hospital outreach laboratory to use the form CMS-1450 14x TOB**, the hospital must distinguish between private payor fee-for-service payments (and the associated volume) for laboratory tests furnished to non-patients (the applicable laboratory) from private payor fee-for-service payments (an associated volume) for laboratory tests furnished to hospital patients. For example, if a private payor requires a hospital laboratory to use the CMS-1450 13x TOB for laboratory tests furnished to hospital outpatients and non-hospital patients (instead of the 13x TOB for hospital outpatients and the 14x TOB for non-hospital patients), **the hospital must develop a mechanism to identify the private payor rates and corresponding volume furnished to non-hospital patients**.

# When does reporting happen?

| Data Collection Period | Review and Validation Period | Data Reporting Period | Used for CLFS Rate Years |
|---|---|---|---|
| Jan. 1 – Jun. 30, 2019 | Jul. 1 – Dec. 31, 2019 | Jan. 1 – Mar. 31, 2020 | 2021 – 2023 |
| Continues every third subsequent calendar year | Continues every third subsequent calendar year | Continues every third subsequent calendar year | New CLFS rate every three years |

- Rates that are reported are final payments received during the Data Collection Period
- Use the six months between the Data Collection Period and the Data Reporting Period to collect, review, organize, and validate the data that will be reported
- Data Reporting can happen any time during the Data Reporting Period

# How is reporting done?

- The **reporting entity** is the TIN-level entity that reports for all component applicable laboratories.
- The reporting entity and the applicable laboratory may be the same entity.

**Examples:**

- A TIN-level entity reports on behalf of its five laboratories, each with their own NPIs and each that qualify as applicable laboratories. The TIN-level entity reports separately on behalf of five applicable laboratories.
- A TIN-level entity consists of five laboratories, each with their own NPIs but only three of which qualify as applicable laboratories; it reports on behalf of the three that are applicable laboratories.
- A TIN-level entity consists of five laboratories that all bill under one NPI and that collectively qualify as an applicable laboratory; the TIN-level entity reports applicable information for one applicable laboratory, consisting of all laboratories associated with the NPI.
- A TIN-level entity includes one hospital outreach laboratory that qualifies as an applicable laboratory; the TIN-level entity reports applicable information attributable to the hospital outreach laboratory only.
- A TIN-level entity includes two laboratories that use the hospital's NPI (collectively they qualify as an applicable laboratory) and one laboratory that uses its own NPI to bill for non-hospital patients and qualifies as an applicable laboratory. The TIN-level entity reports on behalf of two applicable laboratories: (1) the labs that bill under the hospital's NPI, and (2) the lab that bills under its own NPI.

# More on reporting…

- The reporting entity must **ensure accurate collection and reporting** of applicable information on behalf of its applicable laboratories.
  - The **President, CEO, or CFO of a reporting entity**, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, has to **certify the accuracy and completeness** of the data reported.
- **Voluntary** reporting is **not permitted**.
  - Not an applicable laboratory? Don't report.
- **Reporting** applicable information is **not discretionary**.
  - An applicable laboratory? Report.
  - And report all data that qualifies as applicable information.
- The Secretary may impose a **Civil Monetary Penalty** of up to $10,000 per day for **each misrepresentation or omission** in reporting applicable information.

# Registration for Clinical Laboratory Data System

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- For each TIN-level "applicable lab" that will be reporting data in this data reporting period, **a CLFS Submitter and a CLFS Certifier must register** for an account in the CMS Enterprise Portal: https://portal.cms.gov
  - Submitter and Certifier cannot be the same person for a TIN-level entity
  - Same person can act as a Submitter for more than one TIN-level entity, and same person can act as a Certifier for more than one TIN-level entity
- After registration, must **request access to the CLFS Data Collection System** (one of many reporting systems in the CMS Enterprise Portal)
  - Involves a "soft credit check" to verify identity
  - Approval may take up to 72 hours
- Registration is a multi-step process and a registration has to be approved before data can be submitted – **do not wait until the last minute to register**!

# Registration for Clinical Laboratory Data System

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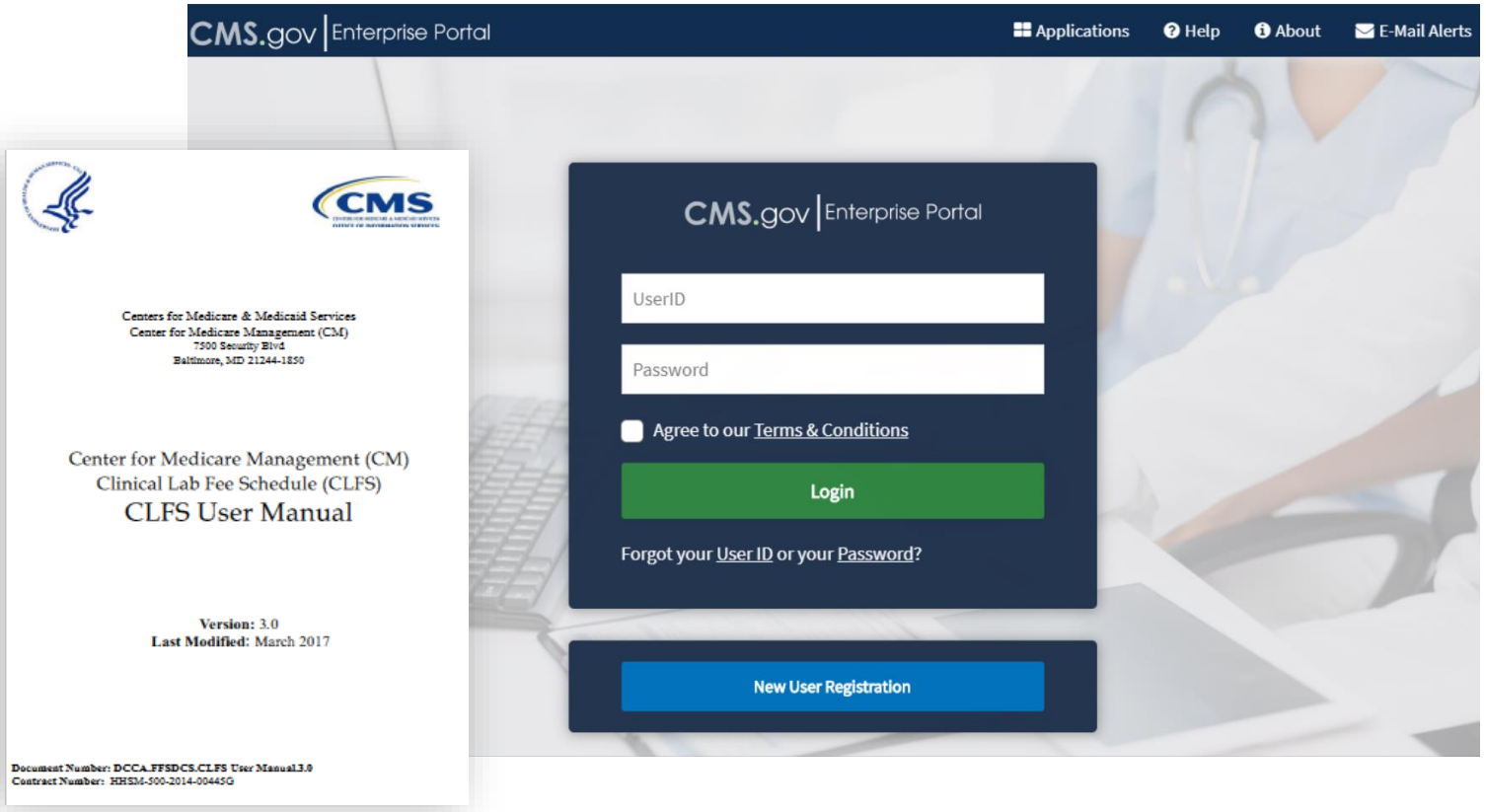


CLFS User Manual available on the PAMA website:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Data-Collection-System-User-Guide.pdf.

# Data submission and certification

- Link to reporting template for uploading data is online at:
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html
- Can change the file name of the reporting template, but **not** the column names, column numbers, values
- Duplicate data is allowed
- Payors **do not** have to be separated out by line
- Validation errors:
  - No data are saved until all data are correct
  - If there are errors (*e.g.*, HCPCS code with 6 digits, or a private payor rate with a letter in it), you will get an error message at the line level
  - **When all errors are corrected, data can be uploaded and saved**

# Where can you find more info?

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- 42 U.S.C. § 1395m-1 (added by PAMA Sec. 216)
- PAMA Final Rule: 81 Fed. Reg. 41036 (Jun. 23, 2016)
- CY 2019 Physician Fee Schedule Final Rule: 83 Fed. Reg. 59452 (Nov. 23, 2018)
- 42 C.F.R. §§ 414.500 – 414.504 (Payment for Clinical Diagnostic Laboratory Tests)
- CMS Website, PAMA Regulations, Guidance, FAQs:
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html
- ACLA Website, PAMA:
  - https://www.acla.com/pama/

# Increased reporting is critical!

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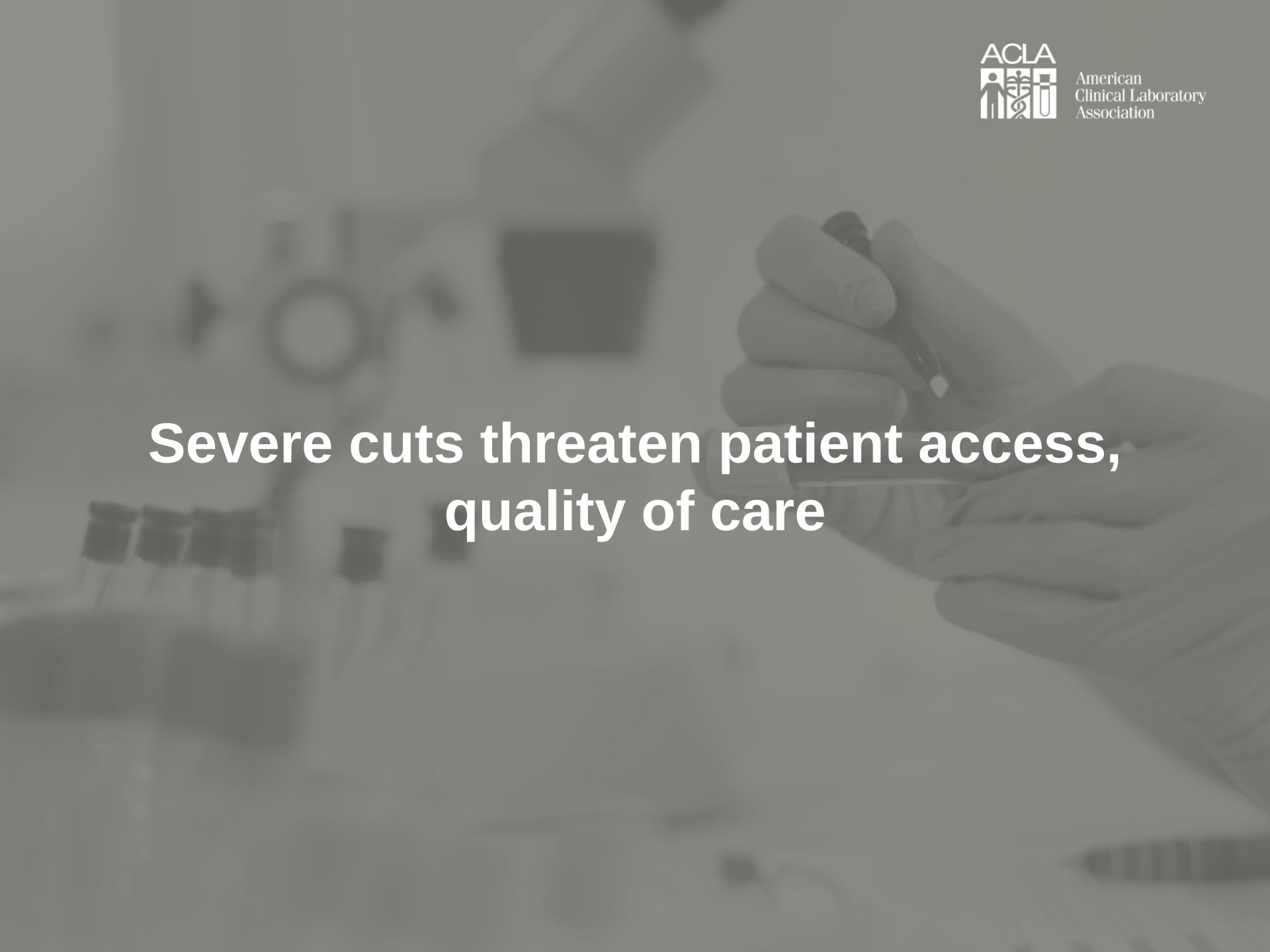
- **Less than 1%** of all labs reported data in 2017
- Hospitals **contributed 1% of data** in first reporting period, even though **hospital labs make up approximately 26% of CLFS spending**
- **Physician office labs made up 7.5% of data** submitted, despite **representing approximately 20% of CLFS spending**
- **All labs are subject to PAMA rates**
- Commonly ordered tests **subject to cuts of greater than 30%**



# Severe cuts threaten patient access, quality of care

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# PAMA slashes top 10 lab tests

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| HCPCS | Description | Annual Test Volume | 2017 Effective Rate | Weighted Median | Percent Change |
|---|---|---|---|---|---|
| 84443 | Assay thyroid stim hormone | 21,168,378 | $23.00 | $14.87 | -35% |
| 80053 | Comprehensive metabolic panel | 40,644,516 | $14.01 | $9.08 | -35% |
| 85025 | Complete cbc w/auto diff wbc | 41,047,544 | $10.56 | $6.88 | -35% |
| 80061 | Lipid panel | 27,250,027 | $17.86 | $11.23 | -37% |
| 82306 | Vitamin d 25 hydroxy | 8,836,881 | $40.35 | $26.37 | -35% |
| 83036 | Glycosylated hemoglobin test | 18,999,605 | $13.29 | $8.50 | -36% |
| G0483 | Drug test def 22+ classes | 1,175,501 | $246.53 | $193.71 | -21% |
| 80048 | Metabolic panel total ca | 13,320,608 | $11.19 | $8.06 | -28% |
| G0482 | Drug test def 15-21 classes | 774,326 | $202.15 | $132.00 | -35% |
| 83970 | Assay of parathormone | 2,123,536 | $56.62 | $36.76 | -35% |

# What YOU can do to #ProtectLabAccess

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Congress needs to hear from labs in their districts

**ACLA has the tools to help make your voice heard!**

**Letters:** Letters to Congress from Laboratory and Hospital Leadership

**Emails and Calls:** Lab and hospital employee emails and calls to Congress

**Real Stories:** We need REAL stories from labs and patients about the harm and risk of the Medicare lab cuts

# LAB Act of 2019

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- H.R. 3584 was introduced June 27, 2019 by Rep. Scott Peters (D-CA), Rep. Bill Pascrell (D-NJ), Rep. Kurt Schrader (D-OR), Rep. Richard Hudson (R-NC) and Rep. George Holding (R-NC).
- Would **delay the upcoming data reporting period** until 2021 so that applicable laboratories would **not have to report applicable information to CMS in 2020**
- Would call for a **study on how to implement a less burdensome data reporting process** that still would result in market-based rates on the CLFS and would be representative of the entire laboratory market
- **Visit ACLA's website to send an email to your member of Congress**, urging him or her to support the LAB Act: https://www.acla.com/take-action/
- **Call your member of Congress** at (202) 224-3121 and urge him or her to support the LAB Act
  - Don't know who your member of Congress is? Go to https://www.house.gov/representatives/find-your-representative and enter your zip code – it's that easy!


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Questions?