

PAMA-Mandated Reporting Rules for Clinical Laboratory Services

Welcome

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- **Vice Chair, CAP Economic Affairs Committee**
- **Chair, CAP Economic Affairs Payment Policy Subcommittee**



CLFS and PAMA

- **Clinical laboratory fee schedule (CLFS) first developed in 1984**
- **CMS planned to overhaul the system in 2015**
- **Protecting Access to Medicare Act of 2014 (PAMA) enacted:**
 - **Institutes various Medicare payment changes to offset a temporary SGR fix**
 - **Including changing the Medicare CLFS**
 - **Setting CLFS rates at the weighted median of private payer payments effective 2018**
 - **Setting annual cap for reductions**

PAMA Caps CLFS Cuts

- **Medicare CLFS provides payment on roughly 1,300 tests, pays \$8 billion a year**
- **PAMA reductions phased, in limiting cuts to:**
 - 10% per year for 2018-2020
 - 15% per year for 2021-2023
- **Advanced Diagnostic Laboratory Tests (ADLTs) undergo a different reporting and pricing process**

Basic Components of PAMA

Collection

- Applicable laboratories collect and compile private payor reimbursement for clinical laboratory services

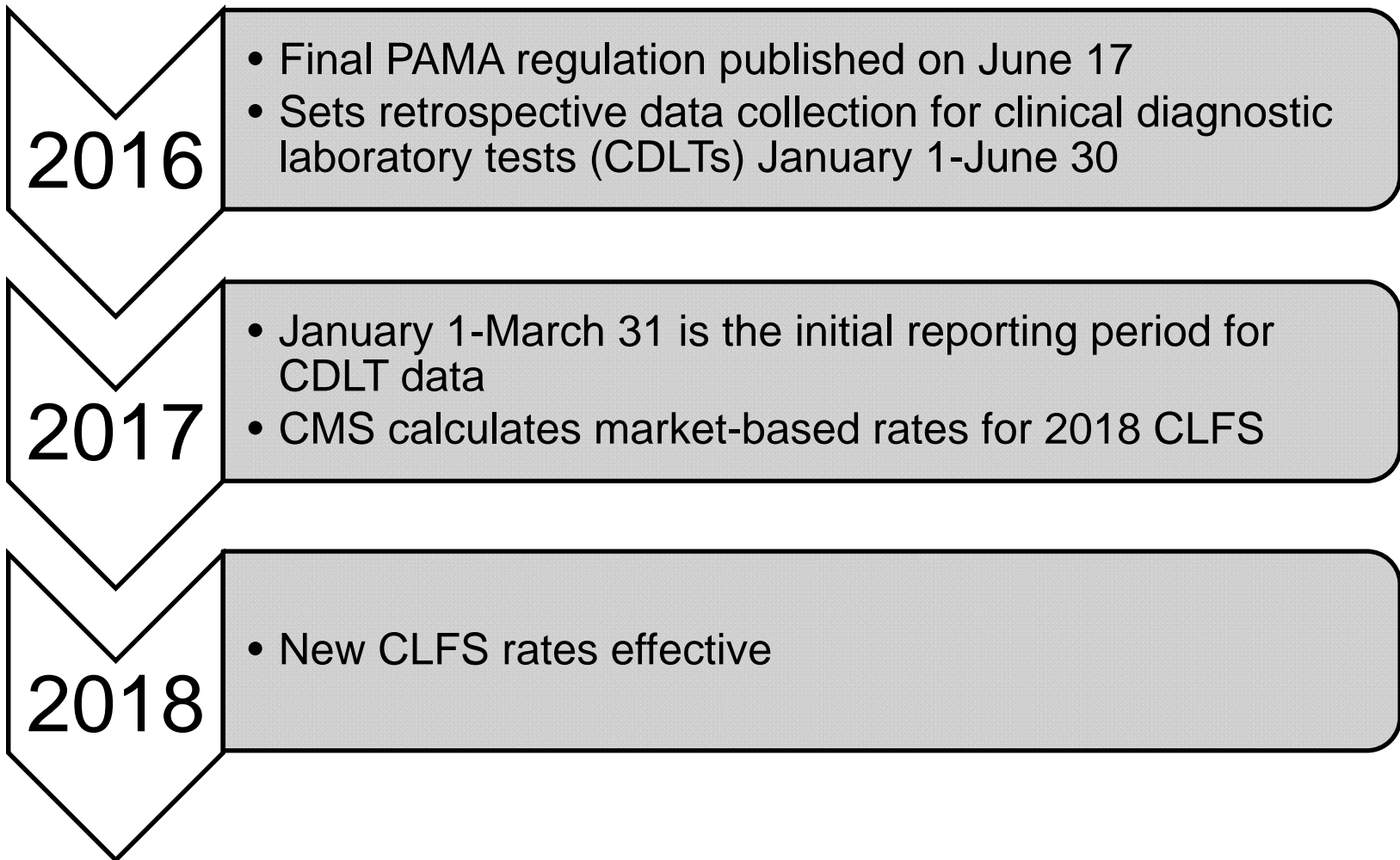
Reporting

- Applicable laboratories report private payor reimbursement to CMS

Calculation

- CMS will use the “weighted median” to determine new CLFS rates

PAMA Timeline



An Applicable Laboratory that is Required to Submit Data has ...

- 1. A CLIA Certificate**
- 2. An NPI**
- 3. Meets the Majority of Medicare Revenues Threshold**
- 4. Exceeds the Low Expenditure Threshold**

Applicable Laboratories Subject to Reporting

- **Majority (>50%) of total Medicare revenues from the CLFS and physician fee schedule (PFS) of an organization as defined by national provider identifier (NPI)**
 - **Effect: Exclude most hospital laboratories**
- **Low Expenditure Exclusion:**
 - **Laboratories paid < \$12,500 on the CLFS during 6-month collection period, not required to report**
 - **≥ \$12,500 required to report**
 - **Effect: Exclude most physician office laboratories**

Calculating the Majority of Medicare Revenue Threshold

- Medicare revenues are based on the final paid claims received by the laboratory's billing NPI the PFS and CLFS
- $[\text{CLFS revenues (for billing NPI)} + \text{PFS revenues (for billing NPI)}] \div \text{total Medicare revenues (for billing NPI)} > 50\%$

Calculating Low Expenditure Exclusion Threshold

- **CLFS revenues (for billing NPI) \geq \$12,500**
 - **Based on final paid claims received by billing NPI during the data collection period**
 - **Applies to CLFS services only**

What Must Be Reported

- More than **1,300 CDLTs** subject to first collection period
 - Includes codes not currently payable under CLFS
- **CMS data collection template includes:**
 - HCPCS Code
 - Private Payor Payment Rate (based on final payment)
 - with Associated Volume for Each Test
 - and National Provider Identifier
- **Data can be submitted via Excel or text file; or by manual entry on CMS' website**

Applicable Information: What's Included?

- **Final Amounts paid by private payors:**
 - **Payments from secondary insurers**
 - **Patient cost sharing amounts**
 - **Multiple payment rates for the same test**
 - **Resolved appeals**
 - **Non-contracted out-of-network laboratory payments including any patient cost sharing amounts**

Applicable Information: What's Excluded?

- **Test codes paid only under the PFS**
- **\$0.00 (denied) payments**
- **Unresolved appeals**
- **Capitated payments**
- **Payments where the associated test volume cannot be determined**

Example of HCPCS Codes Subject to Reporting

- **Pap codes on the CLFS for cytotechnologist performance and screening (ie P3000 for screening Papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision)**
 - **Codes on the physician fee schedule, such as 88141—for cytopathology, cervical or vaginal requiring physician interpretation—do not require reporting**

How to Report Data: FFS Data Collection System (FFDCS)

- **CMS requires:**
 - Use of enterprise portal, <https://portal.cms.gov>
 - FFDCS access and role designation
 - CLFS submitter or certifier
 - **Must be two individuals: a submitter and a certifier**
- **CMS November 2, 2016 presentation provided [guidance on how to access the system](#)**

Data Certification

- **Certification of accuracy and completeness of applicable information by:**
 - **President, CEO, or CFO of an applicable laboratory**
 - **Or a direct report to whom the individual above has delegated authority**
- **Under statute, PAMA provides for civil monetary penalties (CMPs) of up to \$10,000 per day for each failure to report, misrepresentation, or omission**

Private Payor-Based CLFS

- **For transparency, CMS will release aggregate private payer rate and volume data**
- **Proposed 2018 CLFS amounts will be published in September 2017; finalized in November 2017**

Additional Resources

- **CAP Protecting Access to Medicare Act (PAMA) for Laboratories webpage**
 - <http://www.cap.org/web/home/involved/advocacy/pama-requirements-for-laboratories>
- **CMS PAMA webpage**
 - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>

Questions

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