PAMA-Mandated Reporting Rules for Clinical Laboratory Services

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December 2016
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

2016
- Final PAMA regulation published on June 17
- Sets retrospective data collection for clinical diagnostic laboratory tests (CDLTs) January 1-June 30

2017
- January 1-March 31 is the initial reporting period for CDLT data
- CMS calculates market-based rates for 2018 CLFS

2018
- New CLFS rates effective
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

• \[
\frac{\text{CLFS revenues (for billing NPI)} + \text{PFS revenues (for billing NPI)}}{\text{total Medicare revenues (for billing NPI)}} > 50\%
\]
Calculating Low Expenditure Exclusion Threshold

• CLFS revenues (for billing NPI) $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 (i.e., 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:
  – 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](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](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html)
Questions

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