COLLEGE of AMERICAN PATHOLOGISTS

Get Ready for New PAMA Requirements for Laboratories

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Welcome

Jonathan L. Myles, MD, FCAP

- **Chair, CAP Economic Affairs Committee**
- **Pathology Advisor to the AMA-RUC**

Welcome

W. Stephen Black-Schaffer, MD, FCAP

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

Welcome

Ronald W. McLawhon, MD, PhD, FCAP

- **CAP Representative to AMA-CPT Advisory Committee**
- **Chair, AMA/CAP Pathology Coding Caucus**
- **Member, CAP Economic Affairs CPT/RUC Subcommittee**

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Agenda

- **Background**
- **Data Collection and Reporting**
- **Coding and Coverage**
- **What's Next**
- **Questions?**

Background

CLFS and PAMA

- **Clinical laboratory fee schedule (CLFS) first developed in 1984**
- **CMS planned to overhaul the system starting in 2015**
- **2014: Protecting Access to Medicare Act (PAMA) enacted**
  - **Postponed Medicare sustainable growth rate (SGR) cut**
  - **Reformed the Medicare CLFS and sets cap for reductions**
  - **Instituted other Medicare payment changes to offset temporary SGR fix**
- **CAP opposed PAMA**
- **CAP now advocates minimizing disruption and burdens to laboratories and patients.**

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PAMA Proving Difficult for CMS to Implement

Since enactment, the CMS has indicated the law and downstream implications for implementation are complex. As a result, CMS implementation deadlines were missed and stakeholders are now calling for delays.

Basic PAMA Timeline

2015

CMS required by statute to implement through final regulation by June 30
(Late, proposed rule issued September 25, final rule expected January 2016)

2016

Laboratories report to CMS private market data on payment rates
(proposed submission deadline to be delayed until March 2016)

2017

New prices set and in effect for CLFS

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PAMA Caps CLFS Cuts

- **Medicare CLFS currently provides payment on 1,300 tests, pays $8 billion a year**
- **Before PAMA, CLFS faced major cuts**
- **PAMA now phases in those reductions, but sets limits to cuts at 10% per year for 2017-2019 and 15% per year for 2020-2022**

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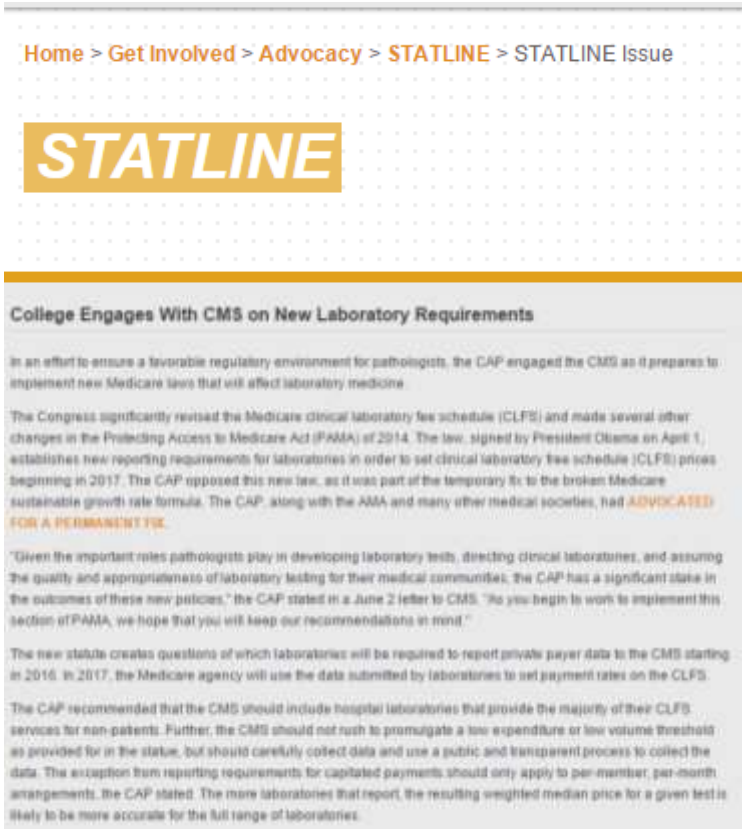
CAP Advocacy on PAMA Implementation

- **CAP engaged CMS after the law was enacted**
- **June 2014 comment letter detailed CAP's positions**
- **Nominated two members that now serve on a newly created advisory board**
- **November 2015 comments on proposed regulation**



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STATLINE

College Engages With CMS on New Laboratory Requirements

In an effort to ensure a favorable regulatory environment for pathologists, the CAP engaged the CMS as it prepares to implement new Medicare laws that will affect laboratory medicine.

The Congress significantly revised the Medicare clinical laboratory fee schedule (CLFS) and made several other changes in the Protecting Access to Medicare Act (PAMA) of 2014. The law, signed by President Obama on April 1, establishes new reporting requirements for laboratories in order to set clinical laboratory fee schedule (CLFS) prices beginning in 2017. The CAP opposed this new law, as it was part of the temporary fix to the broken Medicare sustainable growth rate formula. The CAP, along with the AMA and many other medical societies, had ADVOCATED FOR A PERMANENT FIX.

"Given the important roles pathologists play in developing laboratory tests, directing clinical laboratories, and assuring the quality and appropriateness of laboratory testing for their medical communities, the CAP has a significant stake in the outcomes of these new policies," the CAP stated in a June 2 letter to CMS. "As you begin to work to implement this section of PAMA, we hope that you will keep our recommendations in mind."

The new statute creates questions of which laboratories will be required to report private payer data to the CMS starting in 2016. In 2017, the Medicare agency will use the data submitted by laboratories to set payment rates on the CLFS.

The CAP recommended that the CMS should include hospital laboratories that provide the majority of their CLFS services for non-patients. Further, the CMS should not rush to promulgate a low expenditure or low volume threshold as provided for in the statue, but should carefully collect data and use a public and transparent process to collect the data. The exception from reporting requirements for capitated payments should only apply to per-member, per-month arrangements, the CAP stated. The more laboratories that report, the resulting weighted median price for a given test is likely to be more accurate for the full range of laboratories.

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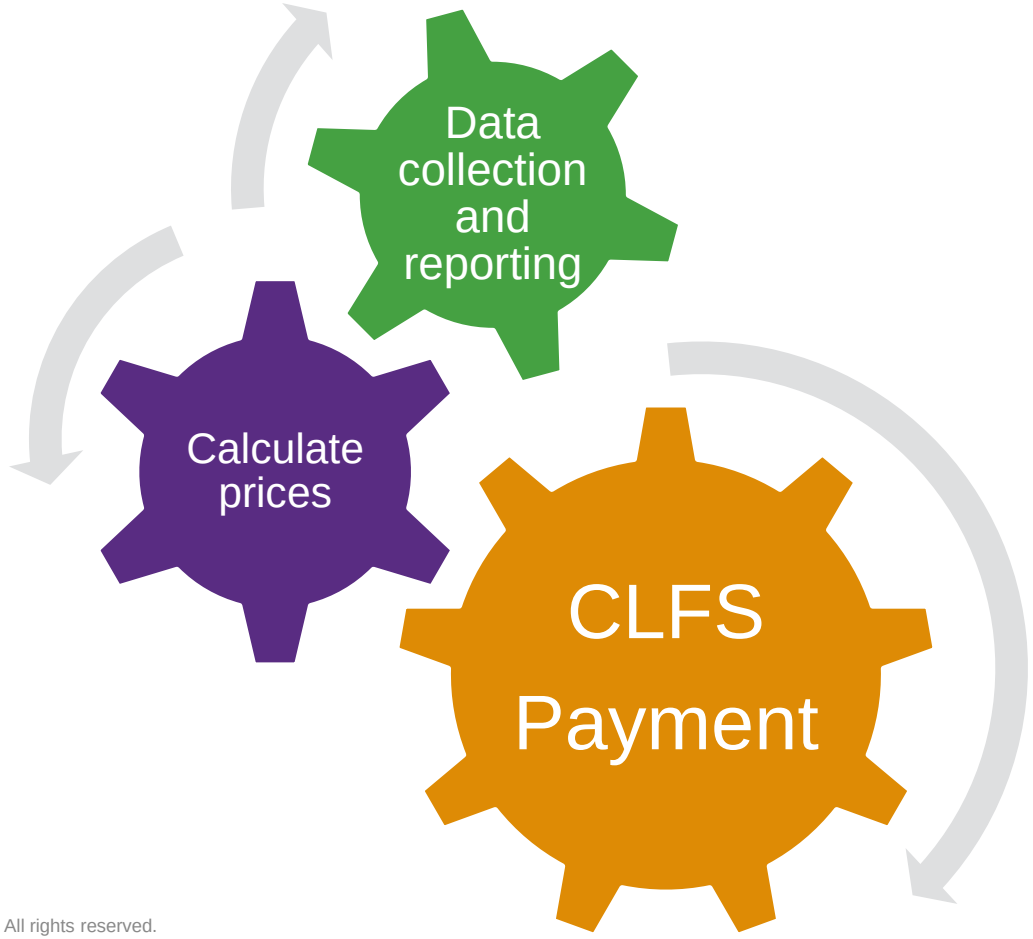
Data Collection and Reporting

How will CMS make the system work?



What Must Be Reported

- **Statute requires reporting of "applicable information" on the payment rate paid**
  - **For each clinical diagnostic laboratory diagnostic test (CDLT) during the reporting period**
  - **By each private payor**
    - **Health insurance issuer and group health plan**
    - **Medicare Advantage plan**
    - **Medicaid managed care organization**
  - **With the volume of tests by each payor at each rate**
- **But how is "the payment rate paid" defined?**

CDLT and ADLT Reporting

Test	Data Reporting
CDLT	Every 3 years
Advanced Diagnostic Laboratory Tests (ADLTs)	Annually

ADLTs = Tests furnished by only one laboratory that meets one of the following:

- **analysis of RNA or DNA, or proteins combined with a unique algorithm**
- **cleared or approved by the FDA**

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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 a single TIN.**
  - **Effect: Exclude hospital laboratories**
- **Low Expenditure Exclusion:**
  - **Laboratories paid < $50,000 on the CLFS per year, not required to report; ≥ $50,000, required to report**
  - **Effect: Exclude most physician office laboratories**

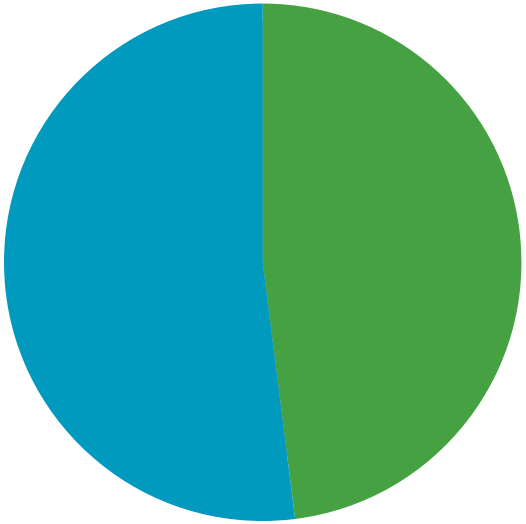
Applicable Laboratories Subject to Reporting

- **CAP believes the criteria for reporting are too narrow and will skew CLFS reimbursement**
- **American Hospital Association (AHA), laboratory community, and others express similar concerns**

Which Laboratories Will Report?

Most large laboratories except hospitals would submit data

Independent Laboratories



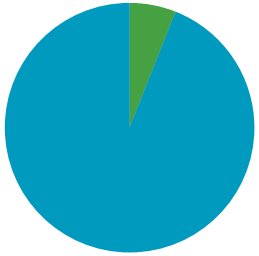
48%

Independent laboratories will report

52%

Independent laboratories will not report

Physician Office Laboratories



6%

Physician office laboratories would report

Overall CLFS Payments

CMS estimates those reporting account for 99% of CLFS reimbursements

If CMS Does Not Broaden Laboratories Required to Report…

- **CAP encourages CMS to publicly report the weighted average payment for each test stratified by laboratory size in order to:**
  - **Document a likely trend toward lower payments correlated with higher volumes**
  - **Allow CMS to adjust requirements as needed prospectively so that data collected mirrors true market rates (potentially including smaller laboratories should this trend be validated)**

Data Collection Period

- **CMS Proposed Rule: Initial collection period**
  - **Collection period: all private payor payments from July 1 – December 31, 2015**
  - **Submission deadline: Delayed until March 31, 2016**
- **CAP recommendation:**
  - **Collection period: January 1 – June 30, 2016**
  - **Submission deadline: September 30, 2016**
- **AHA, laboratory community and others also call for delays**

Administrative burden, cost?

- **To date, CMS has specified only that rate and volume is to be reported. Specifics to be provided in subsequent guidance.**
- **CAP concerns:**
  - **Insufficient detail and time to implement**
  - **Substantial costs and burdens**
  - **Ability to comply with reporting requirements**
  - **Penalties for failure to comply with reporting requirements**
- **Reporting will be by web-based portal/reporting system.**
  - **Based on previous experience with similar CMS systems, this could prove cumbersome.**

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Penalties for noncompliance

- **Under statute, PAMA provides for civil monetary penalties (CMPs) of up to $10,000 per day for each failure to report, misrepresentation, or omission.**
- **CAP proposed:**
  - **Leniency for laboratories especially during initial reporting period**
  - **Penalties only for material and/or willful violations**
  - **Opportunity to correct reported data and to address disputed information before being penalized**
  - **Calibration of any penalty to complexity and impact**

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Data Certification

- **Certification of accuracy and completeness of applicable information by:**
  - **President, CEO, or CFO of an applicable laboratory**
  - **Direct report to the whom the individual above has delegated authority**
- **CMP implications for those who certify**
  - **OIG will enforce/implement**
- **Part B drug reporting = model for PAMA CMPs**
  - **Not analogous and volume significantly lower**

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Calculating payments

- **Statute: CMS will use a "weighted median."**
  - **Median of array of volume and reimbursements**
- **CAP Recommendation: Independent review of CLFS calculations and publication of review's findings**

Coverage and Coding

Coverage

- **PAMA gives CMS the authority to consolidate Medicare coverage policies and/or claims processing for laboratory tests**
  - **CAP pleased the CMS did not exercise this authority with regard to payment processing**
- **CMS requested comment on pros and cons of consolidating coverage policies to one to four MACs**
  - **CAP pointed out the disadvantages based on recent experiences**

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Consolidating MACs?

Advantages

- None

Disadvantages

- Exacerbates current problems
- Process/evidentiary issues
- Beneficiary access to care
- No savings from processing

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Coding

- **CMS proposes to use its current coding processes to meet its statutory obligation to assign codes to certain new tests**
  - **CAP seeks to ensure CMS uses HCPCS Level 1 (CPT) codes when available**
- **PAMA permits HHS to use temporary HCPCS codes for new:**
  - **ADLTs**
  - **CDLTs cleared or approved by the FDA**

Coding: ADLTs

- **CAP strongly recommends the timely establishment of permanent codes for ADLTs through CPT**
  - **Sunset temporary codes after two years despite Secretary authority to extend**
- **Importance of use of HIPAA-designated code sets, identifiers and modifiers, especially in assigning codes for new tests**
- **CPT codes and CPT gene identifiers already cover many new tests**

ADLTs: Payment and Coding

- **Under PAMA, the initial payment rate for ADLTs is set at the actual list charge until private payer rates are established.**
- **CMS proposes to use current temporary coding process to meet its statutory obligation.**

ADLTs: Proposed Definition

- **Statute: Tests furnished by only one laboratory that meets one of the following:**
  - **Analysis of RNA or DNA, or proteins combined with a unique algorithm**
  - **Cleared or approved by the FDA**
  - **Other similar criteria established by CMS**
- **Proposed Rule:**
  - **Must include RNA or DNA; analysis of proteins alone does not meet definition**
  - **No additional criteria established**

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Other Coding Considerations

- **Gapfilling lack of transparency and full disclosure**
  - **Crosswalking or gapfilling for initial payment for new/substantially revised HCPCS codes on or after April 1, 2014**
- **Issuance of different codes for FDA-approved and non-FDA approved version of an existing CDLT**
- **AMA establishment of new section in CPT code set:**
  - **Requests to more specifically identify tests under PAMA**

PAMA Advisory Panel

- **CMS required to consult an advisory panel on PAMA requirements**
- **CAP nominated two members who serve on the panel**
  - **Dr. Stephen Bauer**
  - **Dr. Stanley Hamilton**
- **Panel is charged to work on CLFS rates and coverage of new tests.**
- **CAP has provided testimony to, and will remain engaged with, the advisory panel**

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What’s Next?

What's Next?

- **Expect the final rule to be published in January**
  - **CAP will issue a STATLINE Special Report**
- **CAP will analyze and keep members informed on content and advocacy on this issue**

What's Next?

- **CMS indicated it will issue regulatory guidance for:**
  - **Information to be reported**
  - **How to apply for ADLTs**
  - **CMP guidance**
- **CAP will analyze and continue to keep members informed**

Questions?

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