Implications of Clinical Laboratory Fee Schedule Reforms

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Agenda

1. What is “PAMA” and how does it reform clinical lab reimbursement?
2. Timeline for PAMA implementation: what happens and when?
3. Intersection with FDA LDT regulation
4. Implications for launch of new molecular diagnostic tests and commercial payer negotiations

PAMA CLFS Reform

- The enactment of Protecting Access to Medicare Act of 2014 (PAMA) includes landmark CLFS payment reform
  - First major reform to the CLFS since 1984
  - Establishes transparent, predictable payment methodology
- Legislation was designed to encourage continued advanced diagnostic innovation
  - Reporting of all private payor rates will set market rates as the benchmark for Medicare prices

Timetable for CLFS Reform Implementation

Date	Rule
January 1, 2015	CMS precluded from price adjustments to the CLFS under prior “technology change” statute
	MACs must make lab test coverage policy through LCDs
June 30, 2015	CMS will publish final rule for CLFS market price reporting
July 1, 2015	CMS will establish expert outside advisory panel
January 1, 2016	Laboratories must begin price reporting at some point in 2016
	CMS must assign HCPCS code to existing ADLTs that were paid in April, 2014 by miscellaneous codes
January 1, 2017	Market based pricing for all CLFS tests; Actual List Charge pricing for new ADLT tests

Key PAMA Implementation Issues

1. **Rulemaking.**
   - How will CMS (through rulemaking) implement its rules, timelines, and data elements for price reporting?
2. **Classification.**
   - What process will designate tests that are eligible for ADLT classification and special payment?
3. **Coding.**
   - What process will assign new and sometimes temporary HCPCS codes and unique identifiers?
4. **Price Reporting.**
   - Which labs have to report data?

Making the Rules: Implementation Process

CMS must establish rules
To implement the CLFS changes

Annual PFS Rulemaking

Publication ~ July 1
60 days public comment
Finalize ~ Nov 1
Effective Jan 1

- ✓ CMS proposed to implement a new LCD framework designed for clinical laboratory tests

Special PAMA/CLFS Rulemaking

CMS plans to release a stand alone data collection and price reporting proposed rule

Likely: December/January

Would allow additional proposals, comments, with final regs by July 2015

Subregulatory Guidance

CLFS and ASP processes are often “subregulatory” – almost none of the RVU rules are in formal regulations

CMS can issue guidance via websites or other transmittals

Example: Detailed rules & instructions that are found only on HCPCS website

1. LCD Reform

In the proposed PFS rulemaking, July 2014, CMS implemented PAMA's requirements for the LCD process for clinical lab tests. Statute requires January 1, 2015 implementation.

Key changes include:

- ✓ All new lab test coverage policies must be done through LCD
- ✓ Draft LCD can be released at any time (not on a CAC schedule)
  - CAC meeting is optional
- ✓ Public comment period shortened to 30 days
- ✓ Final LCD becomes effective on the issue date

- *Example: A new draft LCD could be released at the same time in all ten MACs on March 1, and implemented in all MACs (all states) shortly after March 30.*

Impact of LCD Reform on MolDX?

- Will the Palmetto pilot MolDX program continue to determine non-coverage based on articles?
- PAMA allows CMS to consolidate lab tests into one-to-four regional special MACs
  - Analogous to the four DME MACs
  - PFS proposed rulemaking does not mention MAC consolidation

2. Data Reporting Proposed Rulemaking

- Stakeholders need substantive guidance for price reporting requirements, to ensure that implementation proceeds smoothly
  - Very short timeframe for laboratories to implement data collection procedures
  - Many technical factors that will impact laboratory compliance
  - Information technology challenges to collect, organize, and transmit data and for CMS to calculate accurate payment rates
- Next Steps: Look for CMS proposed rulemaking by January, 2015

Price Reporting: Who will report and When

Data for CY2017 Payment rates

Who will report?

Labs with over half of Medicare revenue from Part B Physician and Part B CLFS fee schedule

- May be ambiguous re hospital outpatient labs (where nearly all CMS lab payments are now packaged to services)
- Exemptions for physician and small labs?

When will reporting period be?

Rates must be effective by 1/1/2017, so reporting period will probably close by early 2016

What period will be reported? (E.g. 6 months of data?)

Ideally labs will know all the rules before the reporting period starts, to ensure correct data collection

Rules for the reported price

Market price includes both insurance payment and copay (add up to the "allowed amount")

Issues related to timing of payment, in-network and out-of-network labs

Advanced Diagnostics: Annual reporting and rate setting (rather than 3 years)

Rate Setting Details Left to CMS

- **Beginning in 2017:**
  - Weighted median by arraying test rates weighted by volume and lab
  - Statute requires “payment rate” paid by private payers times test volume at each rate
  - The specific data collection period is not defined

- **Also beginning in 2017:**
  - Advanced diagnostics paid at Actual List Charge for 3 quarters
    - Subject to recoupment if market price proves substantially lower

- **For 2020 and Future Cycles:**
  - CMS may make additional rules, e.g. exemptions for small labs

Defining Data Elements for Submission

- PAMA is intended to capture the market based rate paid for a laboratory test
- Labs will report test volume by payer at each rate during the initial and annual data collection periods
- To ensure consistent and accurate reporting laboratories should report the allowed amount which represents the total market based payment rate for lab tests

Definition of Applicable Laboratory

PAMA requires reporting for:

- In this section, the term ‘applicable laboratory’ means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.
- The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

Who has to Report?

- Will a hospital lab performing outreach testing be considered an “applicable laboratory”?
  - Hospital lab services provided to inpatients or outpatients do not result in separately identifiable revenue.
  - Hospital lab services provided to non-patients do result in separately identifiable revenue.
- Will a physician office labs be considered an “applicable laboratory”?
  - Physician office labs appear to meet the definition.
  - Volume of labs may make it impractical to include every physician office lab.
  - Important for Point of Care testing.

3. HCPCS Coding and Unique Identifiers

Existing Tests	Temporary HCPCS	Unique Identifiers
Required by January 1, 2016 CMS must assign specific codes to ADLTs paid as of 4/1/2014 CMS may poll contractors for “ADLT” paid by unlisted code as of 2014	For: 1) Advanced Diagnostics 2) OR FDA cleared/approved tests CMS assigns temporary code while CPT codes are pending 1-2 years	For: 1) Advanced Diagnostics 2) OR FDA cleared/approved tests CMS must issue “identifier” on request For “Tracking” by CMS May be an “identifier or modifier such as HCPCS code”

Identifiers for FDA tests; need not be “sole source” or new; May apply to FDA based lab tests on PFS or CLFS

Unique Codes for Existing ADLTs

- PAMA requires CMS to assign certain existing ADLTs a unique HCPCS code and publicly post rates if:
  - Paid by Medicare as of the date of enactment
  - Not yet assigned a unique HCPCS code
- Issuing unique codes will facilitate private payer data collection in the 2016 reporting period
- Next Steps: CMS must assign unique HCPCS codes and publish the payment rates for these tests
  - Statute requires codes by January 1, 2016

Temporary Code Assignment For New Tests

- PAMA requires CMS to assign temporary HCPCS codes to identify new ADLTs and/or any FDA approved or cleared tests on a rolling basis
- Nest Steps: CMS must adopt new codes
  - Unclear how fast “new temporary codes” need be assigned
  - Potential model: quarterly applications for HOPPS pass-through codes

AMA Coding Proposal

- AMA plans to propose an expedited code establishment process to be consistent with PAMA
- AMA proposal would allow for new category of administrative codes
- Unclear whether the proposal would also address unique identifiers

4. ADLT Definition

- PAMA creates a new test category called Advanced Diagnostic Laboratory Test (ADLT).
- By statute an ADLT is a lab test offered and *furnished by only the original developing laboratory* when the test is:
  - multi biomarker test with a unique algorithm; or
  - Sole source FDA cleared or approved; or
  - Meets similar criteria

Definition of Advanced Diagnostics

"Advanced diagnostic laboratory test" is defined as:

- –a clinical diagnostic laboratory test that is
- –offered and furnished by a single laboratory and
- –not sold for use by a laboratory other than the original developing laboratory (or a successor owner).

In addition, the test must [also] meet at least one of the following three criteria:

1) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; or
2) the test is cleared or approved by the FDA; or
3) the test meets other similar criteria established by CMS.

Impact of FDA LDT Guidance

For the Purpose of Notification to Congress Only

Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories

Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)

This document provides the anticipated details of the *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* that FDA intends to issue in 60 days, and is being provided to Congress pursuant to section 1143 of the Food and Drug Administration Safety and Innovation Act of 2012

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Center for Biologics Evaluation and Research

Would appear to greatly increased the number of sole source ADLTs approved or cleared by FDA

These might all qualify as PAMA ADLTs for special pricing rules

*FDA would view each LDT (e.g. KRAS) as a unique clearance – would CMS also view as a "unique KRAS test" for PAMA***?**

ADLT Classification

- Next Steps: CMS should establish a two step process for the determination of whether a test meets any of the three statutory criteria:

  1. Labs should have the option to apply to a MAC to be classified as an ADLT at the time of submission of clinical evidence for Medicare coverage

  2. MACs should make this determination during the review for Medicare coverage and payment

5. Launch of New Tests in 2017

- "Actual List Charge" Methodology
  - Under PAMA new ADLTs in 2017 will be paid for three quarters at Actual List Charge
- How will it work:
  - reported by a lab to the MAC who processes claims for the test
  - started once a MAC determines that an ADLT is covered by Medicare
  - linked to a temporary HCPCS code to identify the test
  - Continued for three full calendar quarters

Reporting for New ADLTs

- Initial Reporting Period:
  - New ADLTs must report private payor rates for no later than the “last day of the second quarter” of the initial period

Annual Reporting for ADLTs

- The statute does not specify a process for annual lab reporting for ADLTs
- ADLTs may require different reporting specifications from the three year cycle

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