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Implementation of CLFS Reforms: Key Considerations

BIO-PMC-NVCA Roundtable

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Timetable for CLFS Reform Implementation

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

Making the Rules: Implementation Process Options

CMS must establish rules
To implement the CLFS changes

Annual PFS Rulemaking

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

Most CMS Part B rules follow this process, e.g. last summer's CLFS tech change proposal; 14 Day DOS, etc.

Unlikely full depth of CLFS issues could be drafted by CMS by June

Special PAMA/CLFS Rulemaking

Some rules are published and finalized on an ad hoc schedule

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 were in formal regulations

CMS can issue guidance via websites or other transmittals

Example: Detailed rules & instructions found only on HCPCS website

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

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 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

HCPCS Coding and Unique Identifiers

Existing Tests	Temporary HCPCS	Unique Identifiers
Required by January 1, 2016 Applies to Advanced Diagnostics and FDA cleared/reviewed tests 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"

For FDA tests; does not require "sole source" rule or a new test; may apply to FDA CLFS and PFS lab tests

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.

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