Protecting Access to Medicare Act Implementation of Section 216: Improving Policies for Clinical Diagnostic Laboratory Tests

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Coalition Mission

The Coalition represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission: to develop and commercialize state-of-the-art diagnostics that improve patient health.

The Coalition is committed to working collaboratively and in an open and transparent manner with CMS and other stakeholders

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Coalition Members

Allegro Diagnostics *(Maynard, MA)*
Biodesix *(Boulder, CO)*
Castle Biosciences *(Friendswood, TX)*
CardioDx *(Palo Alto, CA)*
CareDx *(Brisbane, CA)*
Crescendo Bioscience *(So San Francisco, CA)*
Domain Associates (*Princeton, NJ*)
Foundation Medicine *(Cambridge, MA)*
GE healthymagination (Palo Alto, CA)
Genetic Alliance *(Washington, DC)*
Genomic Health (Redwood City, CA)
Kleiner Perkins Caufield & Byers (Menlo Park, CA)
Myriad Genetic Laboratories (Salt Lake City, UT)
Precision Therapeutics (Pittsburgh, PA)
Prometheus (San Diego, CA)
Sera Prognostics (Salt Lake City, UT)
Sequenta (So San Francisco, CA)
Target Discovery (Palo Alto, CA)
Veracyte (So San Francisco, CA)

C21 Support for CLFS Reform

- C21 strongly supported the enactment of CLFS reform provisions in PAMA
  - First major reform to CLFS since 1984
  - Establishes transparent, predictable payment methodology
- Legislation designed to encourage continued advanced diagnostic innovation
  - Private payment reporting will ensure market rates are captured by Medicare
- C21 supports the public comments of ACLA and AdvaMedDX

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Key PAMA Implementation Recommendations

C21 recommends that CMS:

1. Issue a proposed rulemaking as soon as possible in 2014 so labs can prepare to comply with the data reporting
2. Establish a sub-regulatory process to designate tests eligible for ADLT classification
3. Assign unique HCPCS codes for Existing ADLTs in 2014 so that these tests can be included in the initial reporting period
4. Clearly define the lab reporting data elements and timelines for ADLTs

1. Issue Proposed Rulemaking in 2014

- Stakeholders need substantive guidance for 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 challenge to collect, organize, and transmit data and for CMS to calculate accurate payment rates
- **Recommendation:** CMS issue a propose regulation as soon as possible in 2014

2. 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
  - FDA cleared or approved; or
  - Meets similar criteria

2. ADLT Classification

- **<u>Recommendation</u>:** 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

3. Existing ADLTs – Assign Unique Codes

- PAMA requires CMS to assign certain existing ADLTs 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
- **Recommendation:** CMS should assign unique HCPCS codes and publish the payment rates for these tests during 2014
  - Statute requires codes by January 1, 2016

3. New ADLTs – Coding Process Needed

- PAMA requires CMS to assign temporary HCPCS codes to identify new ADLTs on a rolling basis
- CMS should establish for 2015 an expedited code assignment process
- **Recommendation:** CMS should allow laboratories to submit applications for new ADLTs on a quarterly basis for new codes
  - Consistent with the timeframe CMS evaluates applications for HOPPS pass-through codes

4. Payment for New ADLTs in 2017

- "Actual List Charge" Methodology
  - Under PAMA new ADLTs in 2017 will be paid for three quarters at Actual List Charge
- **Recommendation:** Actual List Charge payment should be:
  - 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

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4. 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

- **<u>Recommendation</u>:** Initial reporting period should include at a minimum private payor rate data from the first quarter after Medicare coverage and payment commences

4. Annual Reporting for ADLTs

- Statute does not specify process for annual lab reporting for ADLTs
- ADLTs may require different reporting specifications from the three-year cycle for other non-ADLT test
- **Recommendation:** Establish separate parameters for annual ADLT reporting; scope of data and timeline may need to be adjusted based on experience in 2017

4. Defining Data Elements for Submission

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

Thank you