January 18, 2016

Delivered electronically to: marc.hartstein@cms.hhs.gov

Marc Hartstein
Director, Hospital and Ambulatory Payment Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Timeline for New ADLT Designation, Coding and Payment

Dear Mr. Hartstein:

We are writing to follow up on our meeting on January 4, 2016 regarding the timeline for the designation, coding and payment of New Advanced Diagnostic Laboratory Tests (ADLTs). The Coalition members appreciate your time and found the meeting very productive. As the agency is in the final stage of the rulemaking process, we want to respond to several of the points that were raised at the meeting.

Given that the statutory timeline for a New ADLT to report private payor payment rate data is very tight, we think it is critical that the date of the "New ADLT Initial Period" start the first day of the first full calendar quarter following Medicare coverage and designation of a test as an ADLT. As we explained in the meeting, the establishment of Medicare coverage for a new advanced diagnostic test can take 12 to 18 months or longer following commercial launch.

Below we have summarized the key points we discussed at the meeting which reflect the points addressed in the C21 comment letter submitted November 24th during the PAMA comment period. We also prepared the attached chart to illustrate the sequence of steps through ADLT designation and payment at Actual List Charge (ALC) for New ADLTs after January 1, 2017.

1. "New ADLT Initial Period" should start on the first day of the first full quarter following Medicare coverage and ADLT designation

PAMA provides that for new ADLTs after January 1, 2017 "during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test." CMS's Proposed Rule defines the New ADLT Initial Period as beginning on the "first day of the first full calendar quarter following the first day on which a new ADLT is performed." The date of first performance of a New ADLT is often months or even years before Medicare coverage. We are concerned that the use of the date of first performance would result in commencing the New ADLT Initial Period before a test is even

covered by the Medicare program. Further, the date of first performance does not account for the prerequisite that an ADLT designation be made by the Agency for the test.

As we discussed, we believe a more appropriate trigger for the start of the New ADLT Initial Period should be the date of Medicare coverage and ADLT designation by the Agency. Nearly all New ADLTs undergo review through the MAC Local Coverage Determination (LCD) process before the test receives payment. Many contractors rely on the MolDX program which has a non-coverage policy for new tests until evaluation through their technology assessment process. CMS should clarify the definition of "New ADLT initial period" in § 414.502 to mean "***a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the first day on which a new ADLT is performed following the date on which Medicare implements coverage and confers ADLT status upon the test***."

2. ADLT application and designation must be completed prior to start of the New ADLT Initial Period

The Proposed Rule does not specify a timeframe for a laboratory to request designation as an ADLT, or the timeframe to receive such a determination. The ADLT application and designation period should occur in advance of the New ADLT Initial Period. Laboratories should submit the ADLT application and receive a designation in advance of the initial period while they are working with commercial payors and Medicare contractors on coverage. This allows for synchronization of Medicare coverage and ADLT designation. The application process should be on a quarterly basis to align with the reporting periods.

3. ADLT codes should be assigned prior to start of New ADLT Initial Period

A critical element of the Medicare Clinical Diagnostic Laboratory Tests Payment System is the assignment of new codes for ADLTs in order to facilitate private payors data collection and reporting. We recommend that a permanent Level I HCPCS test-specific code set process be adopted that would allow for a singular code set to be used by private payors and Medicare and that would avoid disruption on switching from a temporary to a permanent code. The permanent ADLT code should be assigned in advance of the New ADLT Initial Period so the laboratories can start to use the codes with private payors.

4. New ADLT codes do not go through annual July Public Meeting

Under the PAMA market-based payment system the statute clearly establishes that New ADLTs after January 1, 2017 do not go through the annual gapfill or crosswalk process. Therefore it is important that any New ADLT codes are not put on the agenda for the July public meeting for gapfill or crosswalk. C21 has been in discussions with the AMA CPT Editorial Panel concerning their new Proprietary Laboratory Analyses (PLA) proposal. Based on the new coding proposal, it is possible in some cases that a new code maybe assigned prior to designation of an ADLT. We recommend that a new code for any test that is under review for ADLT designation or has already received ADLT designation should not be placed on the July public meeting agenda.

5. Initial data reporting period for a new ADLT code can include private payer data paid under a NOC code

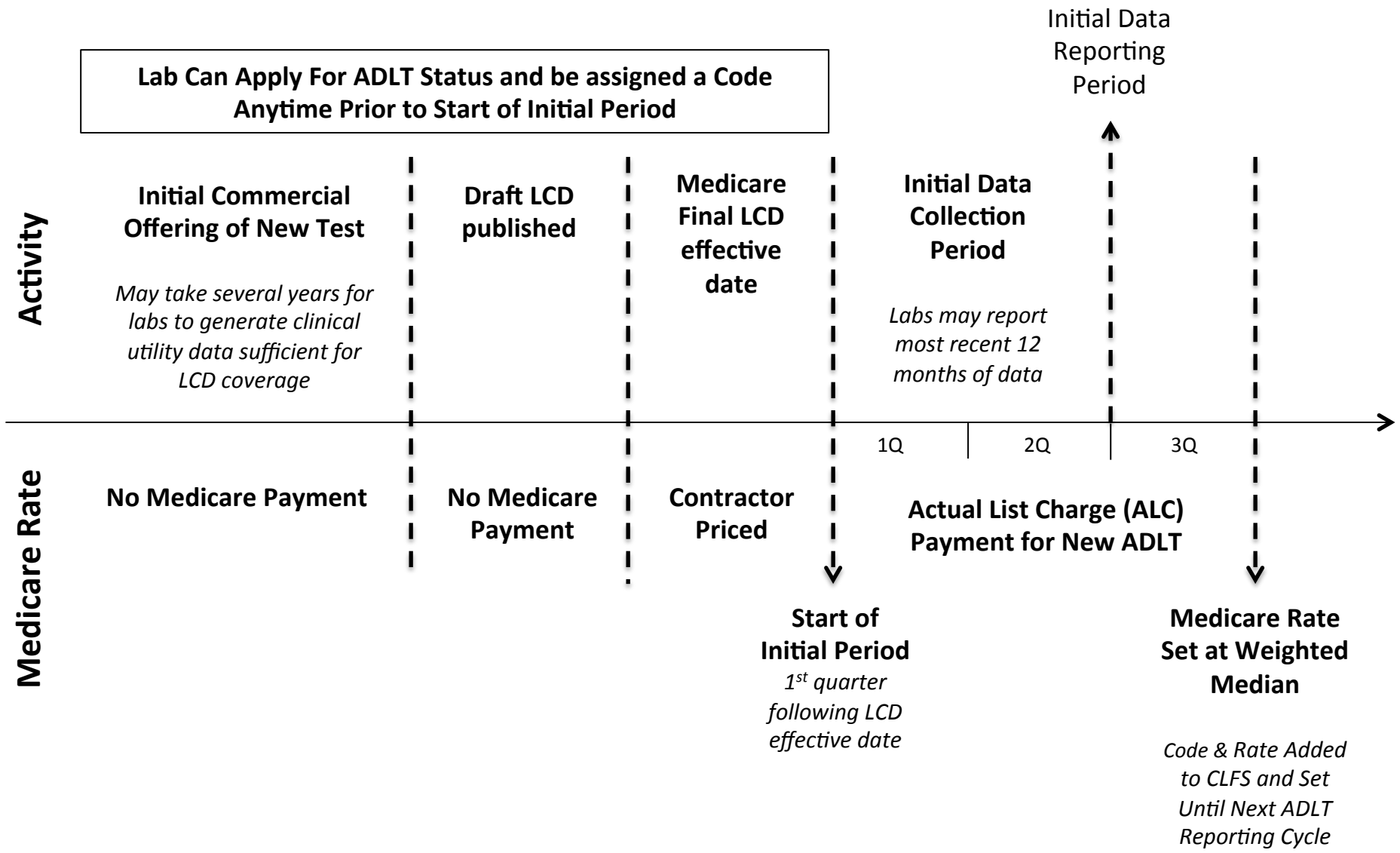
From the start of the New ADLT Initial Period, laboratories will have to report private payor data within just six months. Based on this short timeframe it is possible that some of this private payor data would be identified through payments made using unlisted codes prior to private payers adoption of a unique HCPCS code for the New ADLT. We understand that in order for CMS to set a national fee schedule price for a test, there must be a specific HCPCS code for the test. It may be necessary, however, for some tests to report data for a New ADLT test code that was paid by commercial payors under an unlisted code.

In addition, we recommend that for New ADLTs the Initial Data Collection Period not exceed the time frame of the annual Data Collection Period for ADLTs (i.e. 12 months). As a result, the Initial Data Collection Period may include applicable information from the two quarters prior to the Initial Period if available, and the first two quarters of the Initial Period.

Thank you again for the opportunity to meet and discuss these issues. We appreciate all of your work to finalize the Medicare Clinical Diagnostic Laboratory Tests Payment System rulemaking. The Coalition urges CMS to implement the New ADLT payment methodology and assignment of specific codes on January 1, 2017, as specified in the statute. Please contact us with any additional questions on these topics or other issues related to ADLTs.

Sincerely,

John W. Hanna
Chair, Reimbursement Workgroup
Coalition for 21st Century Medicine


Lab Can Apply For ADLT Status and be assigned a Code Anytime Prior to Start of Initial Period
Initial Data Reporting Period
Activity
Initial Commercial Offering of New Test
May take several years for labs to generate clinical utility data sufficient for LCD coverage
Draft LCD published
Medicare Final LCD effective date
Initial Data Collection Period
Labs may report most recent 12 months of data
1Q
2Q
3Q
Medicare Rate
No Medicare Payment
No Medicare Payment
Contractor Priced
Actual List Charge (ALC) Payment for New ADLT
Start of Initial Period
1st quarter following LCD effective date
Medicare Rate Set at Weighted Median
Code & Rate Added to CLFS and Set Until Next ADLT Reporting Cycle