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Client Alert

FDA & Life Sciences Practice Group

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CMS Proposes Sweeping Changes to Medicare Reimbursement for Clinical Diagnostic Laboratory Tests

First Data Collection Period for Clinical Laboratories Is July 1, 2015 to December 31, 2015

In the October 1, 2015 Federal Register, the Centers for Medicare & Medicaid Services (CMS) published a **proposed rule** outlining extensive revisions to Medicare reimbursement for clinical diagnostic laboratory tests (CDLTs) that are paid based on the Medicare Clinical Laboratory Fee Schedule (CLFS). A related CMS factsheet is available **here**, and a CMS FAQ is available **here**. A **National Provider Call** on the proposed rule is scheduled for November 10, 2015 from 2-3 pm ET. Interested parties may submit comments on the proposed rule on or before ***November 24, 2015***.

The proposed rule implements a portion of the Protecting Access to Medicare Act of 2014 (PAMA), which requires that CMS set CLFS payment rates based on the weighted median of private payor rates for CDLTs as reported by clinical laboratories to CMS. In order to set CLFS payment rates effective on January 1, 2017 using this new methodology, CMS proposes that clinical laboratories collect private payor payment data for the period from July 1, 2015 through December 31, 2015, and report this data to CMS by March 31, 2016. Thus, clinical laboratories must ***immediately*** take steps to interpret the provisions of the proposed rule, assess their CDLT revenues and prepare to implement applicable data collection and reporting processes, without the benefit of final regulations to establish the parameters of these requirements.

The King & Spalding Reimbursement and Government Pricing Teams have extensive experience with coverage, coding and payment for clinical laboratory tests, as well as advising clients on data collection and reporting requirements in other, similar contexts, such as pharmaceutical price reporting. We welcome the opportunity to assist clinical laboratories with analyzing the provisions of the proposed rule, submitting comments, and preparing for compliance with this new reimbursement regime.

CMS Requires That "Applicable Laboratories" Collect and Report Private Payor Payment Information

CMS proposes that only "applicable laboratories" are required to collect and report private payor payment information. An "applicable laboratory" is

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defined as an entity that receives more than 50 percent of its total Medicare revenues from payments under the Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule (PFS) in a data collection period.[1] An applicable laboratory is either an entity that is a laboratory itself (as defined in 42 C.F.R. § 493.2), or an entity that has at least one component that qualifies as a laboratory (for example, a health care system that is comprised of one or more hospitals, physician offices, and reference laboratories). The entity is defined as one that reports tax-related information to the Internal Revenue Service under a single Tax Identification Number (TIN), but that may have multiple National Provider Identifier (NPI) numbers. As such, Medicare revenues for purposes of this analysis would be calculated across the entire entity, including all component NPI entities, and not just those NPI entities that are laboratories. CMS welcomes comments on this approach, including whether a corporate entity with multiple TINs should be able to report applicable information for all of its TINs that have a particular private payor rate.

CMS also proposes a low revenue threshold,[2] under which an entity that otherwise qualifies as an "applicable laboratory" would not be required to report private payor rates to CMS. For the first data collection period from July 1, 2015 through December 1, 2015 (for purposes of calculating payment rates effective in 2017), a laboratory is not required to submit a report if it receives, collectively with its associated NPI entities, at least $25,000 of its Medicare revenues from the CLFS. For all subsequent data collection periods, a laboratory is not required to submit a report if it receives at least $50,000 of its Medicare revenues from the CLFS.[3] Because some entities will not know whether they exceed the threshold until after the data collection period is over, CMS acknowledges that these entities will need to retroactively assess their Medicare revenues during the data reporting period immediately following the data collection period.

Proposed Parameters for Data Collection and Data Reporting for CDLTs

The proposed rule requires that an applicable laboratory must collect and report to CMS "applicable information" with respect to each CDLT it performs during a data collection period. This "applicable information" includes each private payor rate, the associated volume of tests performed corresponding to each private payor rate, and the specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

A "private payor" is a health plan insurance issuer, a group health plan, a Medicare Advantage plan or a Medicaid managed care organization. The "private payor rate" is the amount that was paid by a private payor for a CDLT net of all price concessions,[4] but including any patient cost sharing amounts, if applicable. Where an applicable laboratory has more than one payment rate for the same payor for the same test, or more than one payment rate for different payors for the same test, the applicable laboratory must report each such payment rate and the volume for the test at each such rate. Applicable laboratories are not required to report any information regarding CDLTs paid on a capitated or similar basis.

Applicable clinical laboratories are required to collect applicable information during a "data collection period" and then report the information to CMS during a "data reporting period." CMS proposes that, for most CDLTs, the first data collection period started on July 1, 2015 and ends on December 31, 2015, and the first data reporting period begins on January 1, 2016 and ends on March 31, 2016. This would provide CMS with enough time to process the information and publish payment rates before they become effective on January 1, 2017. For most CDLTs, these payment rates will be in effect for three calendar years (i.e., through 2019). Subsequent data collection periods will consist of a full calendar year, and occur once every three years.

CMS will issue guidance by January 1, 2016 specifying the form and manner of reporting applicable information.[5]

CMS Proposes Unique Data Collection and Data Reporting Requirements for ADLTs

An advanced diagnostic laboratory test (ADLT) is a CDLT covered under Medicare Part B that is marketed and performed only by a "single laboratory" and is not sold for use by a laboratory other than the laboratory that designed the test, or a successor owner of that laboratory. CMS defines a "single laboratory" as a facility with a single CLIA certificate, with certain narrow exceptions for laboratories with multiple locations.[6] Thus, only one laboratory may design, market, perform and sell the test—if more than one laboratory (not including a successor owner[7]) engages in any one of those activities, the test would not meet be eligible to be considered an ADLT.

An ADLT must also meet one of the following two criteria[8]:

(1) The test must be a molecular pathology analysis of multiple biomarkers of DNA or RNA that, when combined with an empirically derived algorithm, yields a result that predicts the probability a specific patient will develop a certain condition or respond to a particular therapy. The test must also provide new clinical diagnostic information that cannot be obtained from any other tests, and may include other assays.

(2) The test must be cleared or approved by FDA (and not be exempt from FDA approval or clearance).

CMS will establish guidelines for laboratories to apply for ADLT status and submit documentation to support their application. In the proposed rule, CMS highlights that information submitted in such applications is not explicitly protected from disclosure under the confidentiality provisions of PAMA, and would need to meet an existing Freedom of Information Act (FOIA) exemption in order to be exempt from disclosure under FOIA.

The first data collection period for each ADLT is the first and second full calendar quarters after an ADLT is first performed. The data must be reported to CMS by the last day of the second quarter. Subsequent data collection periods occur annually on a calendar year basis.

Payment Amounts for CDLTs and ADLTs under the New Methodology

In general, the payment amount for a CDLT (except for new ADLTs and new CDLTs) furnished on or after January 1, 2017, will be equal to the weighted median of private payor rates for the test reported during the most recent data collection period. These payment rates will be applicable until the year following the next data collection period, which means that they will be in effect for a period of three calendar years for CDLTs and one calendar year for ADLTs. The payment amounts will not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update or other adjustment).

For CDLTs (except for ADLTs and new CDLTs) that are paid on the CLFS prior to implementation of PAMA, however, any reduction in Medicare payment resulting from the new methodology must be phased in over the first six years of payment under the new system. Specifically, calendar year payment amounts for a CDLT cannot be reduced by more than 10% from the preceding year during each of 2017 through 2019, and cannot be reduced by more than 15% from the preceding year during each of 2020 through 2022. For purposes of applying the 10% reduction limitation to CY 2017 payment amounts, because current Medicare payments for a particular test vary and PAMA intends payment amounts to be uniform nationwide, CMS would establish a payment amount for CY 2017 that is not less than 90% of the National Limitation Amount (NLA) for the test.[9]

For new ADLTs, which are ADLTs for which payment has not been made prior to January 1, 2017, initial payment will be based on the "actual list charge" of the test for three calendar quarters. "Actual list charge" is the lowest publicly available rate on the first day at which the test is available for purchase by a private payor for a laboratory test.[10] After

that, the payment rate will be determined using the weighted median of private payor rates reported each year. Notably, if the difference between the Medicare payment amounts for an ADLT during the new ADLT initial period based on actual list charge and the subsequent period based on weighted median rate exceeds 130 percent, CMS proposes to recoup the entire amount of the difference between the Medicare payment amounts.

For the following tests, CMS proposes to use crosswalking and gapfilling methods to establish payment amounts until payment rates under the new methodology can be established:[11]

- Existing ADLTs, which are ADLTs furnished between April 1, 2014 and December 31, 2016;
- New CDLTs that are not ADLTs and are assigned a new or substantially revised HCPCS code on or after April 1, 2014; and
- New and existing tests where CMS receives no applicable information in the relevant data collection period to calculate a weighted median.

PAMA requires CMS to consult with an expert outside advisory panel regarding the establishment of payment rates for new CDLTs, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test, and the factors to be used in determining coverage and payment processes for new CDLTs. A notice announcing the establishment of the Advisory Panel on CDLTs and soliciting nominations for members was published in the October 27, 2014 Federal Register and the panel's first public meeting was held on August 26, 2015.

CMS Will Assign Unique HCPCS G Codes to Certain Tests

CMS proposes to use HCPCS G codes to temporarily identify new ADLTs and new CDLTs that are FDA cleared or approved. These G codes would be effective for up to 2 years or until a permanent HCPCS code is established.

Also, no later than January 1, 2016, CMS must ensure that a unique HCPCS code is assigned to each existing ADLT and each CDLT that is cleared or approved by the FDA for which Medicare payment has been made as of April 1, 2014. CMS must also publicly report the payment rate for these tests by January 1, 2016.

Potential Changes to Medicare Coverage for CDLTs

PAMA requires that coverage policies for CDLTs issued by a local Medicare Administrative Contractor (MAC) must be issued in accordance with formal processes for Local Coverage Determinations (LCDs) outlined in Chapter 13 of the Medicare Program Integrity Manual, and appeals of LCDs shall follow regulatory requirements at 42 C.F.R. Part 426.

PAMA also provides CMS with discretionary authority to designate one or more (not to exceed four) MACs to establish coverage policies and process claims for all CDLTs nationwide. Given the administrative complexities with consolidating MAC jurisdiction, CMS is requesting public comment on this topic before making any specific proposals.

Significant Penalties May Be Imposed for Non-Compliance with Reporting Requirements

CMS proposes to apply a civil monetary penalty of up to $10,000 per day to an applicable laboratory that fails to report or that makes a misrepresentation or omission in reporting applicable information, as such penalties are currently applied in other similar processes, such as pharmaceutical price reporting and reporting under the Physician Payments Sunshine Act. Notably, the proposed rule requires that all reported data be certified by an applicable laboratory's

President, Chief Executive Officer or Chief Financial Officer (or a designee) as "accurate, complete, and truthful, and meets all the reporting parameters" prior to submission to CMS.

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King & Spalding is ready to advise you in the preparation of thoughtful, coherent and persuasive comments to this proposed rule, as well as compliance with the new data collection and reporting requirements. Please contact us if we may be of assistance.

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[1] Payments for tests furnished to hospital inpatients or hospital outpatients would not be included because these tests are paid under the Hospital Inpatient Prospective Payment System or the Hospital Outpatient Prospective Payment System.
[2] CMS is not proposing a low testing volume threshold at this time.
[3] CMS estimates that this revenue threshold will exclude approximately 50 percent of independent laboratories and 90 percent of physician offices from the reporting requirements.
[4] These price concessions include all discounts, rebates, coupons and other price concessions described in section 1847A(c)(3) of the Social Security Act regarding the average sales price of drugs or biologicals.
[5] Certain information reported by an applicable laboratory under these requirements is confidential and may not be disclosed by CMS in a form that reveals the identity of a specific payor or laboratory, or prices, charges or payments made to any laboratory, with a few exceptions, including disclosure to the Comptroller General, Director of the Congressional Budget Office and the Medicare Payment Advisory Commission (MedPAC).
[6] These exceptions include: (1) laboratories that are not at a fixed location; (2) not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing; and (3) laboratories that are within a hospital that are located at contiguous buildings on the same campus and under common direction.
[7] A "successor owner" is a laboratory that has assumed ownership of the original developing laboratory and meets all other aspects of the ADLT definition. CMS proposes to rely on its change of ownership regulation at 42 C.F.R. § 489.18(a) to define what constitutes assuming ownership in this context. CMS expects a laboratory that obtains CMS approval of ADLT status for a test to maintain documentation on changes of ownership with transfer of rights to market, perform, and sell the ADLT to support correct claims submission and payment.
[8] PAMA permits CMS to issue additional criteria, although CMS declines to do so at this time.
[9] The NLA is a percentage of the median of all the state and local fee schedules. The NLA is 74 percent of the median of all local Medicare payment amounts for tests for which the NLA was established before January 1, 2001. The NLA is 100 percent of the median of the local fee schedule amount for tests for which the NLA was first established on or after January 1, 2001.
[10] For the short period of time between the date that the test is first performed and the date that the test is paid at the actual list charge amount, CMS proposes that local Medicare contractors would work with the applicable laboratory to develop an appropriate payment rate.
[11] The crosswalking methodology is used when a new test is comparable in terms of test methods and resources to an existing test, multiple existing test codes, or a portion of an existing test code on the CLFS. CMS typically assigns the new test code the local fee schedule amount and the NLA of the existing test, and pays for the new test code at the lesser of the local fee schedule amount or the NLA. Gapfilling is used when no comparable test exists on the CLFS. Under gapfilling, local Medicare contractors establish local amounts for the new test code using the following sources of information, if available: (1) charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payors; (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) other appropriate criteria.