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CMS Regulations Overhaul Medicare Clinical Laboratory Fee Schedule

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The Centers for Medicare & Medicaid Services ("CMS") has issued the long-awaited (and long-overdue) final rule (the "Final Rule")[1] implementing Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA")[2], which mandated the most significant changes to the Medicare Clinical Laboratory Fee Schedule ("MCLFS") since its creation in 1984.

CMS currently updates MCLFS rates only to reflect inflation and reductions based on multi-factor productivity adjustments, and it determines pricing for tests assigned new HCPCS codes by crosswalking or gapfilling. Beginning in 2018, CMS will establish and update MCLFS rates based on the prices paid by private payors, including Medicare Advantage and managed Medicaid plans.

No other Medicare provider or supplier submits private payor data or receives Medicare payments that are based on market rates.[3] The California Department of Health Care Services recently implemented a similar system for adjusting its fee-for-service Medicaid rates for laboratory testing. For the fiscal year ended June 30, 2015, the result was cuts to reimbursement associated with 370 CPT codes and a savings of over $20 million for the state.[4] It is no secret that CMS also expects to save money as a result of this payment reform initiative. In fact, in the preamble to the Final Rule, CMS estimated that the changes to the MCLFS in 2018 would save the Medicare program $390 million with a ten-year impact of $3.93 billion.[5] Although this new system is far from perfect, many in the laboratory industry consider it preferable to CMS's 2013 proposal to exercise its statutory authority to adjust prices based on "technological changes" and to arbitrary across-the-board rate cuts threatened by Congress.[6]

Background

Generally speaking, PAMA requires an "applicable laboratory" to periodically collect and report its private payor rates to CMS during set time periods – every three years for clinical diagnostic laboratory tests

[1] Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41,036 (June 23, 2016) [hereinafter "Final Rule"].

[2] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216 (2014), 128 Stat. 1040, 1053 (to be codified at 42 U.S.C. § 1395m-1).

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[3] Notably, pharmaceutical manufacturers are subject to reporting average sales price for Medicare Part B drugs and biologicals.

[4] *California Medi-Cal Prepares for Second Year of Rate Adjustments*, LABORATORY ECONOMICS, May 2016, at 1, 3.

[5] Final Rule at 41,092.

[6] *See* Press Release, American Clinical Lab. Ass'n, ACLA Applauds CMS Decision to Delay New Payment System, Evaluating Final PAMA Rule (June 17, 2016), *available at* http://www.acla.com/acla-applauds-cms-decision-to-delay-new-payment-system-evaluating-final-pama-rule/.

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(''CDLTs'') and annually for advanced diagnostic laboratory tests (''ADLTs''). CMS will then set MCLFS rates equal to the weighted median of private payor rates, with phased-in reductions. If an applicable laboratory fails to submit the required data, civil monetary penalties (''CMPs'') may apply.

CMS issued a proposed rule (the ''Proposed Rule'')[7] in October 2015, nearly four months after the June 30, 2015 deadline mandated by Congress. The Proposed Rule sought to impose an initial data collection period of July 1, 2015 through December 31, 2015, submission of reports in the first quarter of 2016, and implementation of new MCLFS rates as of January 1, 2017, as required by PAMA. Key industry groups, including the American Clinical Laboratory Association (''ACLA'')[8] and the American Hospital Association (''AHA''),[9] as well as members of Congress were highly critical of this tight timeline.[10] Nearly nine months after publication of the Proposed Rule, CMS issued the Final Rule, which revised the proposed reporting schedule and made several other key changes based on comments received on the Proposed Rule.

Delay in Implementation and Fee Schedule Changes

Not surprisingly, the Final Rule delayed the effective date of the MCLFS changes by one year, to January 1, 2018, and thus set the first data collection period to run from January 1, 2016 to June 30, 2016, with initial reporting during the first quarter of 2017. Subsequent data collection periods will occur every three years for all CLDTs, and each will run for six months (the first and second quarters of the calendar year).

CMS had originally proposed that future data collections periods would run for a full calendar year, but ultimately decided that it could obtain adequate data and minimize reporting burdens by requiring the collection of only six months of data.

CMS expects that the six-month gap between the end of the data collection period and the beginning of a reporting period will give laboratories sufficient time to collect and organize data. Given that CMS published the Final Rule with only days remaining in the first data collection period, laboratories may find that they are pressed for time when considering implementation.

During this period, each laboratory must determine whether it meets the definition of ''applicable laboratory'' and, if so, whether it is exempt from reporting based on the low expenditure threshold, as further described below. If reporting is required, the laboratory should immediately begin organizing its private payor data according to the instructions received from CMS thus far.

New Definition of 'Applicable Laboratory'

One of the most significant changes between the Proposed Rule and the Final Rule is the definition of ''applicable laboratory'' and CMS's introduction of the concept of a ''reporting entity.'' PAMA defined an ''applicable laboratory'' as a laboratory that receives a majority of its Medicare revenues under the MCLFS or the Medicare Physician Fee Schedule (''MPFS'') and authorized CMS to set a low Medicare expenditure threshold to exclude smaller labs from reporting obligations.[11]

CMS originally proposed to define ''applicable laboratory'' by reference to an entity's taxpayer identification number (''TIN''). Multiple commenters on the Proposed Rule, including the ACLA and the AHA,[12] expressed concern that this definition would exclude hospital laboratories with outreach (i.e., nonpatient) business from reporting. Even though some hospitals may have a large volume of outreach business, a hospital laboratory likely would not qualify as an ''applicable laboratory'' when revenues received under the MCLFS are combined with other Medicare revenues at the TIN level.

As AHA and others noted, excluding hospital outreach laboratories would distort the payment data collected and lead to lower reimbursement rates. AHA thus recommended that CMS should assess Medicare revenues at the National Provider Identifier (''NPI'') level rather than at the TIN level. In addition, AHA suggested that CMS permit laboratories that do not meet the definition of an applicable laboratory to report voluntarily so that their data can be included in the weighted median. For the same reasons, ACLA proposed that CMS define an applicable laboratory by CLIA number.

Based on these and other concerns, CMS decided to revise the definition of ''applicable laboratory'' to mean a laboratory (as defined under CLIA) that bills Medicare Part B under its own NPI and that receives more than 50% of its Medicare revenues during the applicable data collection period under the MCLFS or the MPFS.[13] Such revenues include fee-for-service payments under Parts A and B, Medicare Advantage payments under Part C, prescription drug payments under Medicare

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[7] Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 80 Fed. Reg. 59,385 (Oct. 1, 2015).

[8] Letter from Alan Mertz, President, American Clinical Lab. Ass'n, to Andrew Slavitt, Acting Admin., Ctrs. for Medicare and Medicaid Servs. (November 23, 2015), available at http://www.acla.com/acla-comments-on-pama-proposed-rule/ [hereinafter ''ACLA Comments''].

[9] Letter from Thomas P. Nickels, Exec. Vice President, American Hosp. Ass'n, to Andrew Slavitt, Acting Admin., Ctrs. for Medicare and Medicaid Servs. (November 24, 2015), available at http://www.aha.org/advocacy-issues/letter/2015/151124-cl-labproprule.pdf. [hereinafter ''AHA Comments''].

[10] Letter from Sherrod Brown et al., U.S. Senators, to Andrew Slavitt, Acting Admin., Ctrs. for Medicare and Medicaid Servs. (December 14, 2015), *available at* http://www.acla.com/senator-brown-dear-colleague-on-pama-cy16-clfs-proposed-rule/; Letter from Bill Pascrell, Jr. et al., Cong. Reps., to Andrew Slavitt, Acting Admin., Ctrs. for Medicare and Medicaid Servs. (December 16, 2015), *available at* http://www.acla.com/wp-content/uploads/2015/12/LETTER_Clinical-Lab-Fee-Schedule-Proposed-Rule-Letter-to-CMS-12.16.152.pdf; Letter from Pat Tiberi et al., Chairman, Comm. on Ways and Means, to Andrew Slavitt, Acting Admin., Ctrs. for Medicare and Medicaid Servs. (March 29, 2016), *available at* http://waysandmeans.house.gov/wp-content/uploads/2016/03/PAMA-letter_March-29.pdf.

[11] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216 (2014), 128 Stat. 1040, 1053 (definition to be codified at 42 U.S.C. § 1395m-1(a)(2).

[12] *See* ACLA Comments, *supra* note v & AHA Comments, *supra* note vi.

[13] *See* Final Rule at 41,098 (to be codified at 42 C.F.R. § § 414.502).

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Part D, and any deductibles or coinsurance payments received from Medicare beneficiaries.

While eligibility for reporting will depend upon the entity's NPI, reporting will still occur at the TIN level. That is, each corporate entity with a single TIN that operates a facility meeting the definition of an ''applicable laboratory'' – defined as a ''reporting entity'' in the Final Rule – must submit a report that aggregates the data for its components that qualify as applicable laboratories.[14]

CMS's decision to require reporting at the NPI level likely will result in only a small number of hospital laboratories meeting the requirements to qualify as an ''applicable laboratory'' because most hospitals do not bill for hospital outreach services using a separate NPI number. Hospitals and hospital systems with significant outreach volume should consider whether obtaining a separate NPI for this purpose would be worthwhile.

CMS reduced the low-expenditure threshold for defining an ''applicable laboratory'' to $12,500 over the six-month data collection period. CMS had originally proposed a low-expenditure threshold of $25,000 for the initial six-month collection period and $50,000 for subsequent twelve-month reporting periods. This threshold does not apply to reporting related to ADLTs.

Finally, CMS was not convinced that it should allow voluntary reporting even though some commenters argued that doing so would allow for more accurate market data. CMS believes that PAMA requires it to consider only data submitted by applicable laboratories.[15] Even though CMS decided not to apply the low-expenditure threshold to ADLTs, it still may not receive adequate data for pricing tests that are offered by small specialty laboratories.

Additional Guidance on Information to Report

The Final Rule provides laboratories much-needed guidance on how to categorize private payor rates for reporting purposes. Even so, many questions remain unanswered and will need to be addressed in subregulatory guidance. As laboratories prepare for initial reporting in early 2017, they will need to review the Final Rule and additional guidance carefully, but this process is certain to present challenges.

If past experience under the Physician Payment Sunshine Act is any indication, CMS is likely to issue subregulatory guidance, in the form of FAQs and User Guides, at the last minute – and possibly even during the 2017 reporting period – which will complicate the compliance efforts of all laboratories.

The Final Rule did provide some clarity on certain reporting requirements.

First, applicable laboratories need not report data related to claims denied, not yet paid, or under appeal during the collection period. ''Zero dollar'' payments thus will not skew the weighted median.

Second, CMS clarified that reports should include non-contracted, out-of-network payments.

Third, tests paid for on a capitated basis are not subject to reporting due to the difficulty inherent in determining accurate per-test reimbursement rates.

Fourth, the payment rate must reflect patient cost-sharing obligations (e.g., copayments, deductibles, coinsurance) and must include any price concessions, except for price concessions granted by the laboratory, such as financial hardship waivers.

The mechanics of data submission remain a mystery. CMS has indicated that reporting entities will submit through an online data collection system, either manually or by uploading a.csv file.[16] CMS likely will establish a registration process and will provide template spreadsheets for reporting, as it did with respect to data reported under the Physician Payments Sunshine Act.

Phase-In of Reimbursement Reductions

As noted above, CMS expects to realize substantial savings on Medicare Part B payments as a result of its repricing efforts, but laboratories will have some protection from dramatic payment rate decreases as the new rates are implemented. For tests that are not new ADLTs or new CDLTs, payment rates may decrease by no more than 10% per year in 2018-2020 and by no more than 15% per year in 2021-2023.[17]

Revised Definition for ADLTs

PAMA and the Final Rule also address changes to the MCLFS related to pricing ADLTs. Under PAMA, an ADLT is defined as a CDLT ''offered and furnished'' only by a single laboratory that is ''not sold for use by a laboratory other than the original developing laboratory (or a successor owner)'' and which meets one of the following criteria:

- 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.

- The test is cleared or approved by the Food and Drug Administration.

- The test meets other similar criteria established by the Secretary.[18]

CMS's proposed interpretation of this definition set off alarm bells for many in the laboratory industry.[19] CMS proposed to define a ''single laboratory'' by reference to a single CLIA certificate and further provided that if a successor owner purchased the laboratory that initially developed the ADLT, it could continue to qualify for ADLT status only if it were a single laboratory. Multiple commenters on the Proposed Rule stated that the definition was unduly limiting and reflected a lack of understanding of the structure and operation of many laboratory companies. Finally, in the Proposed Rule, CMS interpreted PAMA's criteria as requiring

[14] *See* Final Rule at 41, 407 (discussing the new ''reporting entity'' concept).

[15] *See* Final Rule at 41,048.

[16] *See* Ctrs. for Medicare and Medicaid Servs., Overview of CMS-1621-F: Medicare Clinical Diagnostic Laboratory Test Payment System Final Rule (July 6, 2016), *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-07-06-Clinical-Labs-Presentation.pdf.

[17] Final Rule at 41,099-100 (to be codified at 42 C.F.R. § 414.507(d)).

[18] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216 (2014), 128 Stat. 1040, 1057 (definition to be codified at 42U.S.C. § § 1395m-1(d)(3)).

[19] *See* ACLA Comments, *supra* note v.

that the test analyze multiple biomarkers of DNA or RNA, without mentioning proteins.

The Final Rule made revisions to the definition of ADLT meant to address the comments received. First, a ''single laboratory'' now includes both the laboratory that furnishes the test (which may also design, offer, and sell it) and any entity that owns or is owned by the laboratory (which also may design, offer, and sell the test).[20] According to CMS, the revised definition is more consistent with laboratory operations and will make ADLTs more accessible to Medicare beneficiaries. This change allows a successor owner to continue to take advantage of ADLT status even if the successor owner already owns multiple laboratories, so long as the transaction includes the entire original single laboratory corporation. However, CMS clarified that where one entity (like an academic institution) creates a test but does not fully develop and commercialize the test, a laboratory that purchases the intellectual property from the creator and then commercializes it would not also obtain the test's ADLT status.

Second, the Final Rule addressed CMS's proposed exclusion of tests solely comprised of protein biomarker analyses from the definition of an ADLT. In response to comments about the importance of protein-based tests to fields like precision medicine, CMS revised the definition of ADLTs to include tests solely comprised of proteins and eliminated the requirement that an ADLT be a molecular pathology analysis.

Finally, in keeping with the other delayed timeframes, CMS revised the definition of a ''new ADLT'' to mean an ADLT for which payment has not been made under the MCLFS prior to January 1, 2018 (rather than 2017).

The Final Rule offered little information on how a laboratory will apply for ADLT status and indicated that CMS would make further information available through sub-regulatory guidance. CMS presumably will use the sub-regulatory guidance process to establish the timeframe for its review of applications as well as the requirements for demonstrating ADLT status.

Payments for ADLTs

For ADLTs that are not new ADLTs, laboratories must collect private payor rate data for the first six months of each calendar year (beginning in 2016) and report annually (beginning in 2017). MCLFS rates will be based on the weighted median of private payor rates beginning in 2018.

For new ADLTs, the payment process is more complicated and can involve recoupment by CMS. The ''new ADLT initial period'' is defined as the three calendar quarters beginning with the first calendar quarter following the later of (a) a Medicare Part B coverage determination for the ADLT or (b) the grant of ADLT status by CMS.

During this initial period, the ADLT payment rate equals its ''actual list charge,'' which is publicly available rate on the first day that a patient covered by private insurance can obtain the test or that its availability is marketed to the public. After this initial period, payment will equal the weighted median of the private payor data reported. If the actual list charge is greater than 130% of the subsequently established weighted median, CMS will recoup the difference in the amounts paid during the initial period.

Penalties for Non-Compliance

PAMA permits the imposition of civil monetary penalties (''CMP'') of up to $10,000 per day for failure to report or misrepresentation or omission in reporting information. In the Final Rule, CMS gave little guidance on how it plans to impose penalties for non-compliance. Though the agency indicated that it does ''not intend to assess CMPs for minor errors'' and that penalties will be based on the facts and circumstances of the violation, it indicated that additional information would follow in guidance. [21] The Physician Payments Sunshine Act also imposes CMPs on those who fail to comply with its reporting requirements, but CMS has not yet publicized any action taken to impose such penalties. CMS presumably has its hands full with data collection and reporting.

Confidentiality of Reported Data

Laboratories have understandably expressed concerns about reporting their private payor rates to CMS because this information is typically considered to be proprietary and confidential. PAMA provides that CMS cannot disclose the payment data in a form that identifies ''a specific payor or laboratory, or prices charged or payments made to any such laboratory,''[22] except that CMS may release this information as necessary to implement PAMA (e.g., disclosure to OIG or the Department of Justice in the context of an enforcement action) or as required by the Comptroller General, the Congressional Budget Office, or the Medicare Payment Advisory Committee. Importantly, CMS indicated in the Final Rule that it does not interpret these confidentiality provisions as applying to a laboratory's application for ADLT status. CMS noted that a laboratory can label its application as proprietary and confidential, but indicated that ''[b]ecause there is no guarantee such information will be withheld,. . .laboratories will have to decide for themselves whether to apply for ADLT status and risk the possibility of public disclosure of information they do not want to be publicly disclosed.''[23]

CMS also noted in the Final Rule that by publishing payment rates for ADLTs, it may indirectly disclose the identity of the laboratories offering these tests and the rates of payment they receive. CMS indicated that it does not believe that this disclosure is barred under PAMA.[24]

Conclusion

Laboratories with Medicare billing privileges should immediately determine whether they must report their private payor rates to CMS in early 2017 and, if so, begin implementing a system for analyzing, aggregating,

[20] *See* Final Rule at 41,509 (discussing this definition).

[21] Final Rule at 41,069.

[22] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216 (2014), 128 Stat. 1040, 1054 (to be codified at 42 U.S.C. § 1395m-1(10)).

[23] Final Rule at 41,062.

[24] Final Rule at 41,071.

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and reporting that data. CMS has promised that additional sub-regulatory guidance is forthcoming. Laboratories with reporting obligations should track this additional source of information carefully.

With less than six months until the reporting period begins, laboratories have limited time to digest this entirely new data collection and reporting system, which will profoundly affect the laboratory industry for years to come.