

## CMS Finalizes Medicare Laboratory Payment Overhaul

+Insights

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The long-awaited final rule sets the Centers for Medicare & Medicaid Services' course to modernize clinical laboratory payments by implementing reforms in the Protecting Access to Medicare Act of 2014



On June 17, 2016, the Centers for Medicare & Medicaid Services (CMS) released a final rule implementing the reforms to clinical diagnostic laboratory payments established by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), legislation enacted on April 1, 2014, that requires CMS to substantially overhaul how and how much Medicare pays for clinical laboratory services. PAMA replaced the historical processes of “crosswalk” and “gapfill” to determine Medicare payment amounts for lab services with a market-based and -driven payment system that will peg Medicare payments to payments made by private payers for lab services.

As in most legislation, Congress provided a broad framework in PAMA but left it to the regulatory agency to fill in specific details. CMS was required by statute to complete this rulemaking, including issuing a *final* rule, by June 30, 2015, and to implement the new payment amounts derived from these changes by January 1, 2017. The laboratory community and other affected stakeholders have been anxiously awaiting the release of this final rule to see how and when CMS will implement the various reporting, rate-setting

and other requirements established by PAMA.

In response to consensus stakeholder advocacy efforts, and consistent with delays in publishing the proposed and final rules for this complex new payment system, CMS is postponing the first payment year under the new system to 2018. Laboratories must collect data on private payer rates paid between January 1 and June 30, 2016, and report those data to CMS between January 1 and March 30, 2017. CMS will use these reported data to set rates for clinical diagnostic laboratory tests beginning with dates of service on or after January 1, 2018.

### Reporting

#### *Applicable Laboratories: Laboratories Subject to the Reporting Requirement*

Under PAMA, “applicable laboratories” must report payment rates to CMS for diagnostic laboratory tests. How CMS would define the term “applicable laboratories” and which laboratories would be required to report payment rate data pursuant to this requirement has been the focus of much speculation, concern and lobbying.

CMS proposed a variety of criteria to define an applicable laboratory, but two criteria in particular best defined the class of laboratories that would be required to report. Under the proposed rule, a laboratory would be required (and permitted) to report private payer rate information only if it (1) derived more than 50 percent of its Medicare revenues, as measured at the Taxpayer Identification Number (TIN) level, from payments made under Medicare's Clinical Laboratory Fee Schedule (CLFS) or Physician Fee Schedule (PFS) during a defined collection period, and (2) realized at least \$50,000 in Medicare revenues for CLFS services in that same period.

Many stakeholders objected to these criteria because of the extent to which they would limit the data CMS receives and uses in rate-setting. The large laboratory community, as well as hospitals, opposed evaluating the majority of revenues criterion at the TIN level, because doing so would bar most hospitals and hospital-based outreach laboratories from reporting. Others, including medical device manufacturers that make diagnostic kits commonly used in physician offices, opposed the \$50,000 threshold for fear that this standard would block most physician office labs from reporting and that CMS therefore might not get data, or adequate or accurate data, for tests commonly or exclusively furnished in physician office labs.

CMS moved to accommodate stakeholder concerns on both complaints, albeit not entirely. In the final rule, an applicable lab is still one that receives 50 percent of its revenues during a data-reporting period under the CLFS or PFS, but CMS decided to

determine the majority of revenues criterion at the National Provider Identifier (NPI) level instead of the TIN level. CMS expects that this change will result in more hospital-based outreach laboratories reporting, while still preventing reporting by most hospitals that have laboratories principally for patient use. CMS will determine the denominator of this ratio by summing all Medicare payments (under Parts A, B, C and D) received by the entity at the NPI level; the numerator will be determined by summing payments made under the CLFS or PFS.

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CMS also lowered the low expenditure threshold to \$12,500 as measured over the six-month reporting period. With this change, CMS effectively halved the reporting period and the low expenditure threshold. Although this move might result in more physician office labs reporting, CMS's impact analysis suggested that no increase is expected. CMS acknowledged concerns that exclusion of most physician office labs would result in tests for which CMS will receive no private payer data, or a sample of private payer data that may not represent rates obtained by the majority of labs. CMS agreed to continue to monitor this issue and consider modifications in the future to address this concern.

In a nod to labs providing Advanced Diagnostic Laboratory Tests (ADLTs) that

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may otherwise be barred from reporting during the launch of new tests because they might not realize more than \$12,500 in Medicare payments in the early stages of marketing a new test, CMS excepted ADLTs from the low expenditure threshold. Therefore laboratories marketing ADLTs that meet the other criteria of an applicable laboratory must always report private payer data for their ADLTs, regardless of how much they receive from Medicare. If these same labs also provide Clinical Diagnostic Laboratory Tests (CDLTs) and do not meet the \$12,500 low expenditure threshold for all tests combined, then they would not be required (or permitted) to report for tests other than ADLTs.

#### *Applicable Information: Data Subject to the Reporting Requirement*

Under the statute, applicable laboratories must report information on rates paid by private payers for their laboratory services (“applicable information”). The statute was fairly prescriptive and broad, seeking to cover the waterfront of private payers, including Medicare Advantage and Medicaid managed care organizations. Acknowledging the prescriptive nature of the statute, CMS rejected calls to exclude managed care plans from the definition of “private payer,” finalizing its policy to define a private payer as a health insurer, group health plan, Medicare Advantage plan or Medicaid Managed Care Organization. Consistent with the statute, CMS will exclude payments made on a capitated basis.

#### *Reporting Process*

Although CMS partially accommodated laboratory concerns by adjusting the applicable laboratory determination to the NPI level, applicable laboratories will still be

expected to roll-up applicable information and report at the TIN level.

Under the final rule, CMS clarified that laboratories must report for tests for which final payment is made during the reporting period. As a result, if a test is furnished but not paid during the reporting period, a lab would not be required to include that test in the data submitted to CMS. Similarly, if a test is furnished before the reporting period but paid during the reporting period, the lab would be required to include data for that test in its submission. CMS also specified that claims undergoing appeal (*i.e.*, those that have not been finally adjudicated and for which *final* payment has not been received) or denied claims (so-called “zero-dollar” payments) are not “final payments” for the purposes of PAMA and should not be reported.

In its final rule, CMS recognized that some labs may provide price concessions directly to patients, such as discounted co-payments, but determined that these types of concessions should not be used to reduce the payment rate.

CMS also finalized a policy whereby data on tests that are billed using unlisted Current Procedural Terminology (CPT) codes or Not Otherwise Classified codes would not be considered applicable information and would not be reported.

While CMS has hinted that it will require laboratories to submit data through a data portal, the agency has not fully described that mechanism yet. CMS told labs that it will announce the process and attendant requirements through forthcoming subregulatory guidance.

## Reporting Frequency

PAMA distinguishes between two types of tests: CDLTs and ADLTs (the latter are a subset of the former). The statute prescribes different data reporting intervals for each type of test. The law requires labs to report payment data for CDLTs every three years, but to report annually for tests that are ADLTs.

CMS finalized an abbreviated six-month data collection period for all tests (rather than the twelve-month collection period the agency proposed), spanning the timeframe from

January 1 to June 30 of each data collection year.

In its final rule, CMS provided labs with a “six-month window” between July 1 and December 31 of each data collection year, during which labs would be able to verify and validate their collected data, as well as determine whether they meet the majority of Medicare revenues and low expenditure thresholds to be considered an applicable laboratory. Data would be reported to CMS beginning January 1 but no later than March 31 of the following year.



Figure 1: PAMA Data Reporting Timeline (Click to Enlarge)

## Rate-Setting

### Rate-Setting for Existing Tests

Beginning in January 2018, Medicare payment for existing diagnostic laboratory tests will be based on the weighted median of the payment rates from private payers reported by laboratories for the test. CMS made no changes to its proposed methodology for calculating the weighted median. CMS will update the payment for CDLTs every three years, and for ADLTs annually.

CMS plans to publish preliminary rates each September with final rates the following November, to become effective the following

January. Recognizing the complexity of the new system and the risk of errors that accompanies this change, CMS committed to releasing a file containing codes, payment rates and summary-level background information stakeholders can use as an aid in reviewing and commenting on payment rates. CMS will not release data revealing the lab or the payer; for that reason, CMS will not release data for uncommon or sole-source tests, such as ADLTs.

PAMA protected laboratories from potentially dramatic reimbursement cuts by limiting payment reductions to 10 percent each year between 2017 and 2019, and to 15 percent each year between 2020 and 2022. CMS

adopted this glide path but delayed its implementation one year to 2018 to be consistent with the overall delay in the program. In the final rule, CMS limited reductions in years 2018 through 2020 to no more than 10 percent, and from 2021 through 2023 to no more than 15 percent. CMS also announced that it will base a year's stop loss on the previous year's payment amount, not on the original payment amount. Therefore, a test paid \$20 in 2017, which would be paid \$15 under the new market-based payment system, will be paid \$18 in 2018 (\$20 minus \$2), \$16.20 in 2019 (\$18 minus \$1.80, rather than minus \$2) and \$15 in 2020.

Because CMS is delaying the new payment system for one year, Medicare will continue to pay for lab services off of the CLFS in 2017. It appears—but is not expressly stated by CMS in the final rule—that Medicare payments for laboratory services in 2017 will be increased by the Consumer Price Index for urban areas, but then decreased by the multi-factor productivity adjustment to the extent permitted by statute.

#### *Payment for New Tests*

Payment amounts for CDLTs that are assigned to a new or substantially revised HCPCS code after the date of enactment (April 1, 2014), and that therefore may not have private payer data to report to CMS, will first be determined using traditional cross-walk processes or, if no existing test is comparable to the new test, by gap-fill processes.

The statute requires that CMS set the payment rate for new ADLTs (*i.e.*, those ADLTs for which payment has not been made under the CLFS prior to January 1, 2018) at the Actual

List Charge (ALC) for the tests. CMS finalized its proposal to peg the ALC at the lowest publicly available price at which the test is first available according to sources such as websites, test registries or price listings for patients without the benefit of negotiated prices. Labs must attest to the ALC of their tests.

Laboratories offering ADLTs are entitled to the ALC-based payment for three calendar quarters (nine months), *i.e.*, the Initial Period. CMS had initially proposed to define the Initial Period as a period beginning on the first day of the first quarter after the test is *first performed*. Stakeholders raised concerns about starting the Initial Period at this juncture because the test likely would not be covered by Medicare at this point and might not obtain Medicare coverage for several months (or even years) after this date. Moreover, ADLT developers pointed out that the laboratory would first need to apply for and receive ADLT status for the test. CMS responded favorably to these concerns by changing the start of the Initial Period to begin after the test is first covered by Medicare and designated as an ADLT, whichever is later. Medicare administrative contractors will determine the Medicare payment amount for the ADLT before the Initial Period, and CMS will use gapfill or crosswalk methodologies to determine payment after the Initial Period, if the laboratory does not have private payer data to report for the test.

Under the legislation, if CMS finds that the ALC for an ADLT is greater than 130 percent of the market-based payment amount ultimately determined for the test, CMS is



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required to recoup the difference between payment amounts for tests furnished during

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the Initial Period. CMS proposed to recoup the full difference between the market-based amount and the ALC. After significant pushback from stakeholders, CMS agreed that its proposal could create a disparity in recoupments, and pulled back from its proposal. Under the final rule, CMS will only recoup the difference between 130 percent of the weighted median payment rate and the test's ALC.

### **Defining Advanced Diagnostic Laboratory Tests**

The legislation defines ADLTs as tests that analyze multiple biomarkers of DNA, RNA or proteins using a unique algorithm and producing a single patient-specific result, or that are cleared or approved by the US Food and Drug Administration (FDA). (A CDLT is a laboratory test that is not an ADLT.) In its proposal, CMS chose to deviate considerably from the statute by excluding protein-based tests from being considered ADLTs unless those tests also include the “molecular pathology” of DNA or RNA. CMS responded favorably to complaints and revised its proposed definition to mirror the statutory definition of an ADLT to include protein-based tests.

CMS further proposed that the algorithm associated with an ADLT must be empirically derived and that the test itself must provide new information that cannot be obtained from an existing test or combination of tests. In spite of stakeholder comments objecting to this “new information” requirement, CMS held firm in its belief that an ADLT must include a unique algorithm that produces a new result. How broadly and aggressively CMS applies this standard is unclear at this point.

The PAMA statute also requires that an ADLT be offered and furnished only by a *single laboratory*. CMS proposed to identify a single laboratory as one with no more than a single CLIA Certificate. CMS relented to commenters who complained that this requirement would block a number of legitimate business arrangements. CMS also moved away from a requirement that the single laboratory entity design, offer, market, perform and sell the test in order to meet the single laboratory criterion. In the final rule, CMS acknowledged that related entities might design, offer, market or sell the test and still be part of a single laboratory as long as a related CLIA-certified laboratory actually performs the test.

CMS noted that where a laboratory purchases or licenses the intellectual property or technology involved with a novel laboratory test, the laboratory would not meet the single laboratory criterion, and therefore such test would not be eligible for ADLT designation.

### **Coding**

In the proposed rule, CMS acknowledged that PAMA contemplated and intended to ensure that ADLTs and FDA-cleared or approved

laboratory tests are identifiable by a unique code. After considering stakeholder input, CMS chose to continue to use CPT codes to describe lab tests where such codes exist and meet CMS's needs, and to use HCPCS G-codes as temporary codes (which may be renewable) where a CPT code does not exist. Although CMS did not address the American Medical Association's proposal to adopt a new Proprietary Laboratory Analysis section of CPT, CMS did indicate that G codes would be adopted only if a code does not exist or meet CMS's needs. At this time, it is unclear whether CMS will find that the Proprietary Laboratory Analysis code section meets CMS's needs. CMS acknowledged the proposal to use McKesson's Z-code identifiers but concluded that these identifiers are not HIPAA-compliant codes at this point in time.

CMS also maintained its view that a separate coding structure is not necessary for unique test identifiers to be used for tracking and monitoring purposes. CMS indicated that it would establish a HCPCS code for tracking and monitoring at the request of a laboratory for an ADLT or an FDA-cleared or approved test.

### Conclusion

The PAMA final rule reflects CMS at its finest. While stakeholders certainly did not get all that they requested, and the new system will continue to present a number of substantial challenges to the affected community, CMS clearly listened to industry concerns about proposals that would frustrate legitimate business operations and responded

with reasonable, thoughtful solutions that smooth a number of major anticipated obstacles.

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Under the new payment system, payment amounts are expected to change dramatically from the calcified rates that have been in place for years (and in some instances, decades). Most observers expect payment amounts for routine laboratory diagnostic tests to fall when the new payment system is brought on line. With hospital outreach labs now required to report, those reductions may be moderated somewhat.

Laboratories of all types are expected to face significant administrative and technological hurdles assembling and reporting the data required under the new system, especially in the early years. Because of the penalties at stake for failure to report or incomplete reporting, laboratories are expected to take these reporting obligations seriously. Likewise, CMS is expected to encounter a few hiccups of its own receiving, arraying and processing the data into payment rates. Until CMS issues forthcoming subregulatory guidance clarifying the reporting process, the extent of those challenges is not known. Stakeholders undoubtedly will seek additional regulatory or legislative changes in the future to address these issues.

For more information, please contact [John Warren](#), [Paul Radensky](#) or [Eric Zimmerman](#).

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