CMS 14-Day Rule Revisions Ease Precision Medicine Access for Patients, Stakeholders Say

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NEW YORK (GenomeWeb) –The Centers for Medicare & Medicaid Services released a final rule this week for public comment revising its controversial 14-day rule that has long hindered molecular diagnostics labs from directly billing the government payor when tests are ordered within two weeks of an outpatient's discharge from the hospital.

CMS' 14-day rule, or the Date of Service Regulation, has been in place for around a decade to ensure that hospitals get paid for services they provide to patients while they're at the hospital, including lab tests. The rule allows molecular diagnostics labs to bill CMS only for tests that are ordered at least 14 days after patient discharge. If the test is ordered earlier, only the hospital can bill CMS, and the lab would have to seek payment from the hospital.

This has proven administratively challenging for labs. There is also accumulating data suggesting that the policy may be negatively impacting patient care, particularly in the cancer setting where large genomic sequencing panels are increasingly used and timely access to test results can impact the treatments patients receive.

In the Hospital Outpatient Prospective Payment final rule, which the public can comment on until Dec. 31, CMS this week agreed to exempt from this requirement certain advanced laboratory diagnostic tests (ADLTs) and molecular pathology tests that are not included in bundled payments to hospitals. According to CMS, it is carving out an exemption to the 14-day rule for these tests since they "can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment."

"It appears that CMS is concerned that if they make the exception too broad, a large number of tests will qualify and it may create incentives for hospitals to recharacterize their own analytics to have them be de-bundled," said Charles Mathews, VP at consulting firm Boston Healthcare Associates.

The revised policy also comes while there is already much confusion about what CMS considers an ADLT in the reimbursement context. For all practical purposes, ADLTs are advanced diagnostics that analyze multiple markers using a proprietary algorithm — also called multianalyte algorithm assays (MAAAs) — and are performed at a single lab. However, in promulgating the final rule implementing the new Medicare clinical lab test pricing law, the Protecting Access to Medicare Act (PAMA), CMS added additional requirements that a test would have to meet in order to be certified an ADLT.

In that rule, CMS defined ADLTs as tests furnished by a single lab that gauge multiple DNA, RNA, or proteins using an algorithm and provides "new clinical diagnostic information" that can't be obtained by

another test; or a test provided by a single lab that is cleared or approved by the US Food and Drug Administration.

With regard to the 14-day rule, CMS is now saying it is prepared to exempt only the first category of ADLTs, and molecular pathology tests that are not part of bundled payments to hospitals. According to CMS, tests that are ADLTs because they are FDA cleared or approved, can be billed as part of bundled payment to the hospital, as can be genomic sequencing procedures (GSPs), tests with Proprietary Laboratory Analyses (PLA) codes, and protein-based MAAAs that are not considered molecular pathology tests.

As such, CMS will not include these additional test categories as part of the revised date of service policy. "We intend to study this issue, and if warranted, consider proposing changes to the laboratory tests subject to a [date of service] exception in future rule-making," the agency wrote.

But these distinctions are confusing, wrote reimbursement expert Bruce Quinn in his blog, because "Genomic Sequencing Procedures … are certainly human molecular pathology tests," and tests with PLA codes "in some cases will be genetic tests that are closely equivalent to genetic tests in the genetic code series."

In deciding which tests are exempt from the 14-day rule, CMS seems to be concerned about ensuring that that category of test is unlikely to be performed by the hospital during the outpatient stay, and one way to determine that is to consider whether a test is available only at a single lab or if it can be performed at multiple labs. A hospital lab will not be able to perform a proprietary, sole-source ADLT, and when such tests are subject to the 14-day rule, it could result in delays to patient access.

But if CMS is concerned about exempting too many tests, "I believe their concerns regarding ADLTs specifically are overstated because to be an ADLT you need to be an MAAA and sole source, or FDA approved and sole source," Mathews pointed out. "They are saying the FDA-approved, sole-source tests cannot be paid separately, but there are actually not many tests that fall into the latter category."

Further, in deciding to exempt molecular pathology tests but not less well-established coding categories like GSPs, MAAAs, and PLAs, "there is an element of concern about panel testing," he observed, adding that CMS may not yet be fully convinced of the clinical value of any particular PLA-coded test yet.

The American Medical Association's CPT Editorial Panel began accepting applications from labs for these new propriety codes in response to CMS' requirements for implementing PAMA. Over the past months, AMA has rapidly issued around two dozen PLA codes, but it remains to be seen how willing CMS will be to reimburse for them.

"I am not sure any of this is rooted in a strong understanding of the science behind different test methodologies or in well thought-out policy," Mathews said about CMS' decision to carve out the 14-day rule exception for a certain subset of molecular tests. Ultimately, he suspects that CMS' final rule as it stands currently will likely only incentivize physicians and hospitals to continue to rely on single-gene testing and spur reference labs that perform panels to continue to use stacked coding instead of GSPs or securing PLAs.

Still, "something is better than nothing," according to Mathews. "Without the molecular pathology and ADLT exclusion, you will continue to have labs coming up with a lot of inane workarounds." He noted that the final rule should now allow labs to bill separately for companion diagnostics that gauge KRAS and BRAF gene mutations, for example, as well as helps providers of ADLTs and labs doing liquid biopsy testing that are billing with stacked CPT codes. The final rule likely doesn't benefit genomic sequencing procedures and sequencing platform providers like Thermo Fisher Scientific and Illumina, he observed.

Quinn further writes in his blog that CMS perhaps "misspoke" in stating that its revised date of service regulation doesn't apply to genomic sequencing procedures.

Stakeholders acknowledged that although CMS' exceptions for tests that don't have to abide by the 14-day rule aren't as broad as they had hoped, it's still a step forward for easing patient access to tests.

"Although we recognize the need for continued updates for reimbursement policies to keep pace with developments in personalized medicine, PMC applauds CMS for this constructive revision to its 14-day rule, which arbitrarily limited access to innovative tests," said Cynthia Bens, VP of public policy at the Personalized Medicine Coalition. "The revised policy promises to facilitate more clinical adoption of personalized medicine diagnostics, and leaves the door open to further expansion of the policy revision in future rule-making."

The administrative complexities resulting from the 14-day rule made some hospitals resistant to billing for tests provided by outside labs and caused delays in care for cancer patients. According to data collected by the healthcare research and consulting firm Moran Company, between 2013 and 2014 around 3,000 lung cancer patients had EGFR mutation testing was ordered more than 14 days after their hospital discharge. For advanced non-small cell lung cancer patients, timely ordering of molecular testing matters. For example, when EGFR testing identifies a mutation in patients, they go onto targeted therapy, whereas delays in molecular testing could mean they receive chemotherapy first and endure worse outcomes.

In comments to CMS' proposed rule on this issue, Boehringer Ingelheim cited data that 79 percent of lung cancer patients with EGFR mutations and 94 percent of those with ALK rearrangements received the appropriate personalized targeted treatment when test results were available before they received first-line therapy. However, in 33 percent of cases, EGFR or ALK test results took longer than a month. And because many of these tests were ordered after patients already went on first-line therapy, only 41 percent of patients with EGFR mutations and 65 percent with ALK rearrangements ended up getting targeted drugs.

Given these statistics, the lung cancer patients' advocacy group LUNGevity Foundation and Coalition for 21st Century Medicine (C21), which represents makers of advanced diagnostics, had urged CMS to broadly exempt molecular diagnostics from the 14-day rule.

"Molecular pathology tests, MAAAs, and ADLTs are not routinely performed by hospital laboratories," commented C21 to CMS's proposed rule on the topic. "If a hospital does perform the molecular pathology test, such as certain specialized hospital laboratories at academic medical centers, the hospital would remain the billing entity under a [date of service] policy revision, so there is no change to the current practice."

Anna Pugh, director of public policy initiatives at LUNGevity, acknowledged that as innovative diagnostics continue to become broadly utilized, more efforts will be needed to ease patient access to biomarker testing. But Pugh believes CMS is "definitely going in the right direction" in this final rule, and said the revision is a "big win for patients."

"CMS should continue to look at this rule and keep up with the pace of technology and innovation," she said.

The final rule, meanwhile, also comes at a time when there is already consternation over how the agency is defining ADLTs. Industry players are awaiting further clarification from CMS on its criteria for certifying tests into this category. "CMS notes that tests released from the 14-day rule because they are ADLTs must be certified by CMS as ADLTs, a process I believe is not in place yet," Quinn wrote in his blog.

CMS' requirement that ADLTs be independently developed by the laboratory and not licensed "will prove to be tortuous to apply or may be applied inconsistently," he wrote. Moreover, the requirement that the

ADLT provide "unique information" raises questions about how CMS will evaluate competing multianalyte algorithm assays with the same indication.

Ultimately, this special carve out for ADLTs regarding the 14-day rule might be CMS' way of urging labs to certify their MAAAs as such. Under PAMA, ADLTs are priced every year, as opposed to every three years for clinical diagnostic lab tests, which may result in faster pricing declines. "This new rule provides one incentive to go through the extra work to be certified as an ADLT, because it gives access to the 14-day rule exemption," Quinn opined.

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