Puzzling out the positive shift in the final 14-day rule

Anne Paxton

March 2018—When the CMS' new 14-day rule took effect Jan. 1, conditions for laboratories doing outpatient reference testing might have changed for the better. But for labs navigating the new billing regulations, some forecasters are predicting confused seas ahead.

"We've been reaching out to a number of our customers who I know will be affected by this and saying 'What's your take?' and together just putting our heads around what it really means. But there is still quite a bit of confusion out there," says Kurt Matthes, vice president, reengineering and service, at revenue cycle management software provider Telcor.

The 14-day rule has been a standing regulation of the Centers for Medicare and Medicaid Services for some 10 years, he explains. The basic provision was: "If you were seen in a hospital outpatient setting and you had a specimen collected, the hospital would bill Medicare for all the services provided during that outpatient stay. But if there was subsequent testing on that specimen that needed to go to a referral lab, within 14 days of the discharge date, then the hospital had to bill for the technical component of that test."

Until this year, the date of service requirements were that 1) for any specimen stored more than 30 days, hospital or non-hospital, the date of service was the date the specimen was recovered from storage, and 2) for hospital outpatient specimens stored for 14 to 30 days post-discharge, the date of service was the date the test was performed.

Now some tests are exempt from those requirements. The revised rule added exclusions to the Hospital Outpatient Prospective Payment System (OPPS) for tier one and tier two molecular pathology tests and advanced diagnostic laboratory tests (ADLTs). Tier one codes represent the majority of single-analyte molecular tests; tier two codes are for molecular diagnostics performed less often—for example, for a rare disease. A specific set of CPT codes is used for ADLTs, which analyze multiple markers using a proprietary algorithm and are performed by a single lab.

These limited exemptions were chosen, the CMS explains in the final rule, based on the fact that the tests "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." These molecular diagnostics are typically not tests that the hospital performs, Matthes says. "They're a step away from the traditional types of tests that might be performed during that outpatient stay." Now laboratories may bill Medicare for those tests, using the same rules for hospital outpatient specimens stored from one to 13 days as for those stored 14 to 30 days.

The CMS opted against also exempting tests that are ADLTs because they are FDA cleared or FDA approved, genomic sequencing procedures, tests with PLA (proprietary laboratory analyses) codes, and other tests not considered molecular pathology tests. But the agency says it is studying the possibility of further exemptions.

Although the old rule had been in place for many years, confusion was fairly common from the outset, Matthes points out. "Labs had to appropriately understand that an outpatient was involved, what was the discharge date, and what was the time frame between discharge and the date the hospital sent a request." They had to ask: "Do I need to bill Medicare for the whole fee or the technical fee back to the hospital or can I bundle them together and bill them globally?"

Matthes

That wasn't always clear, Matthes says, noting that laboratories always struggle to get timely receipt—or any receipt—of patient billing information from their hospital customers. Many laboratories thus view it as fortunate that the CMS' new 14-day rule did away with the split billing for these tier one and two codes. "Now CMS is stating that if the hospital is going to order some referral testing and it was within 14 days, the lab can bill Medicare globally. You don't have to send the technical component to the hospital to bill."

But the CMS' change in the date-of-service requirements for the exempted tests has stirred concern. The problem now is that the labs have to change the date of service on the claim. "The date of service is not the date of collection by the hospital; it's now the date the lab performs the test," he points out.

Why the CMS put the original rule in place and why it recently decided to revise the rule are not clear to Matthes. He speculates that perhaps Medicare hoped to differentiate the outpatient stay and the financial liability around that stay from the referral testing of the stay. But "it's rather nebulous what the true intent of the new rule is. All they're really doing is shifting the administrative burden from the hospital to the lab, and at the end of the day, I don't think any lab knows what the impact will be." Although controlling utilization continues to be a CMS priority, he thinks the change could lead to some increased utilization because the hospital will have less of a billing burden.

"One customer called their representative for CMS for that part of the country, and the rep didn't have a good understanding to begin with and ended up simply providing a link to the CMS webpage that contains the regulation. So there's been a lack of clarity." However, Matthes does not believe the new 14-day rule will bring sweeping change. "I don't think you will see any big shift in who is providing these tests, because many of them are more specialized in nature; it's not just any lab that's performing those types of procedures."

While there were objections based on the feared impact of the new rule on lung cancer patients for timely care, he doesn't foresee that as a problem. "The perception was that the add-on testing was at times delayed," to keep the charge for the testing separate from the bundled outpatient fee. "But now that you have that administrative hoop-jumping off the table, you don't need to delay, since we're just going to let the lab bill for all of it now instead of having to go through this split-billing scenario of the hospitals versus the lab. To me it almost streamlines things, because there's no reservation on the part of the doctor or the pathologist within the hospital about ordering that referral test on you. They don't have to worry about where the billing happens."

The bigger issue, he suspects, is that "labs still aren't really certain about implementation of regulations, especially by their MACs [Medicare administrative contractors]. And they're reluctant to put processes into place based on interpretations of regulations and potentially have them result in claim denials. They want it clear-cut, so they are really in a 'wait and see' mode, and will submit claims and watch for denials." Adding to the uncertainty: Some of Telcor's customers reaching out to their MACs or private health insurers were told the MAC was not going to implement the new rule because the CMS hadn't specifically said it applies to Medicare Part B.

Despite the CMS having followed standard rulemaking and invited feedback on a draft rule in October and November, labs are still having to puzzle out many details of the final rule, Matthes says. He urges the CMS agency to take heed. "We need a clear-cut statement from CMS and their MACs on the intent of the law and that it is being implemented consistently."

Generally, Medicare's new rule can be considered a step in the right direction, says Kyle Fetter, executive vice president of diagnostic services and general manager at Xifin, which offers laboratory revenue cycle management and LIS solutions. "It's obviously a positive trend for labs because it indicates a willingness of the Medicare program to cover some of these tests directly that would have previously been bundled into other outpatient procedures."

He agrees that the rule was driven by the CMS' worry that many hospitals were holding back on ordering tests in some cases because they knew they would have to absorb the costs. "So they archive the specimen for a certain period of time rather than order the test when it is needed and absorb the cost. And obviously, if the patient had already started getting care, some of the molecular diagnostic or genetic tests might have helped guide better treatment."

Laboratories are required by Medicare to use the sample collection date as the date of service, "but they don't actually bill for the services until they are signed out or final reported," Fetter points out, and there is good reason to do so. "That's when you actually know what you're billing for. If a test result was indeterminate, the sample was insufficient, or the order was cancelled midstream, that would change how and what you can bill for."

Xifin is still seeking clarification on the tests that are included and excluded. "But certainly some codes have already been negotiated. Some of the PLAs have been in the guidelines for a while, so they're already included in the overall bundle."

However, labs that have felt that testing wasn't being ordered at the right time for certain patients because of the billing issue have been lobbying for a long time to get tests covered where the order was placed or the specimen was drawn during the outpatient stay, Fetter says. The CMS' fix of that problem "is probably the positive to take here."

Controlling utilization can be tricky with the number of new molecular tests, he notes. "When you look at bundled payment structures, they're generally meant to enforce efficiency from the hospitals, to say this is what we're paying and you've got to make it work from an efficiency standpoint within that range. But most of those ranges that were established didn't include a lot of the newer molecular tests, which are more expensive, as part of that bundle."

Lung cancer patients have been cited as one group negatively affected by the old rule. "An example would be a patient who doesn't get an *EGFR* [mutation test] ordered in time to determine the correct therapy, because it would have been bundled in with the prospective payment under the old 14-day rule. So they'd pull the specimen to run the test later after they'd already figured out treatment. That was a normal thing because the lab wouldn't get reimbursed for it unless it was performed outside the 14 days," Fetter says. "The new rule, however, fixes that problem because it basically enables the hospital to order the test without having to absorb the cost of it."

Many similar tests, if ordered too late, are not as useful for the patient, he notes. "So from that perspective, perhaps you will see an uptick in utilization for those types of tests. But I think the bigger benefit here is that you will see utilization at the correct time as opposed to later in the patient's care, meaning the patient is more likely to get the correct care."

The stipulation that the rule applies only to tier one molecular tests has to do with tier one CPT codes being linked to specific genes while tier two tests could involve any one of hundreds of genes, Fetter says. "The more important point is whether the codes are somatic in nature and probably need to be ordered right away, or hereditary in nature, which typically means they can wait a bit longer to get a result back because it's not immediately affecting their treatment choices that day."

Fetter

Building the new 14-day rule into Xifin software has been a priority for the company. “As part of our package, all of our customers have to have the most current regulations, so what we had to do was say, ‘Okay, if this particular test is on a patient who is an outpatient, we need to create system logic that identifies and facilitates resolution of the problem so the lab isn’t billing for an incorrect date of service.’” If, for example, there is an outpatient procedure performed and discharge at the end of one day, and the testing was performed after that, “that’s relevant and fairly standard in molecular testing. So from our perspective we have to make sure we correctly identify when there is going to be a requirement for date of service to be based on the report date as opposed to the sample collection date.”

It’s a little more challenging for independent labs, Fetter adds, to make sure they understand exactly when the discharge date was for each outpatient procedure and are able to bill for that effectively. “You don’t want to set yourself up in a scenario where you’re actually billing for procedures routinely and waiting to get a denial from the Medicare program. That can be a compliance issue. Systems need to be able to account for processes like this to keep their labs from getting into trouble.”

Fetter stresses two important messages for laboratories about the new 14-day rule. First, “Obviously keep close track of what tests are being considered under this rule, and there are different resources labs can utilize to figure out which tests are excluded. That’s the big one. Second, you have to have really good tools for making sure you understand, in the case of a Medicare outpatient, when the discharge date is, when the test was completed, and when the collection date is. You want heavy automation compliance around these processes because you don’t want clerical decision-making driving incorrect changes in the date of service.”
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