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Credible Information Is Heart of 60-Day Rule; OIG: Self-Disclosure Pauses the Clock

By Nina Youngstrom

When a hospital realized it had been billing for annual wellness visits without documentation of opioid and substance use screening,[1] it wasn't a heavy lift to calculate how much to repay Medicare in time to meet the deadline of the 60-day overpayment refund rule. The trail of breadcrumbs was followed to the effective date of the requirement and the hospital's failure to communicate it to physicians and nonphysician practitioners and/or build prompts in electronic medical records to capture documentation. "Sometimes the 60-day rule is easy," the compliance officer said. But often that's not the case, as the hospital is finding with clinical validation of diagnoses that drive MS-DRGs. "Where it is harder is those areas that are grey and not so straightforward." The compliance, health information management and legal departments are digging into diagnosis upcoding that could have caused higher-paying MS-DRGs. It's expected to take six months, and when the picture comes into focus, the 60-day countdown will begin, according to the compliance officer, who prefers not to be identified.

That captures one of the perennial challenges of compliance with the Medicare 60-day rule, which requires providers to return overpayments 60 days after identifying and quantifying them. The 2016 regulation[2] interpreting the 60-day rule, which was created by the Affordable Care Act, requires providers to use reasonable diligence to identify overpayments by doing proactive compliance activities to monitor for overpayments and investigating potential overpayments in a timely manner. CMS defined "timely" as within six months of receiving "credible information" about an overpayment. Providers must look back six years when they find errors themselves or get credible information of overpayments.

"Understanding how to define credible information is the key to understanding this entire rule," said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. Credible information "is the doctrine of whether you have the reasonable belief you might have an overpayment." That and other aspects of the 60-day rule, including when to start the clock, should be set forth in a policy, experts say. They also recommend a defined method for investigating credible information.

The stakes are high. Refunding overpayments under the 60-day rule is a litmus test of an effective compliance program. It's also a feature of the HHS Office of Inspector General's (OIG) provider compliance audits and a tripwire for False Claims Act violations if providers knowingly hang onto Medicare money they're not entitled to.

"We talk about this pretty frequently when we get in situations of 'do we have an overpayment or potentially an overpayment?'" said Patrick Kennedy, executive director of hospital compliance at UNC Health in North Carolina. "We immediately say, 'At what point on the spectrum are we at?' If it's a single account based on a patient complaint, for example, and through that review we have identified we were overpaid, that's pretty easy, and we will refund quickly and hit the 60-day mark easily." But life gets messier if, for example, an audit from UNC's work plan yields a high error rate based on a random sample of 30 claims. "These situations are not as clear cut because there are different aspects of the audit results and any subsequent audits we need to consider," Kennedy said. At this point, the work begins on quantifying the overpayment and perhaps extrapolating it because the total overpayment amount is still an unknown. "We can't refund the overpayment until we know

how much it is. In other words, until we've identified it," he noted.

The 60-day rule has been useful because it helps compliance professionals light a fire under operations people who sometimes drag their feet, Kennedy said. "We're in a better position because of it. We are on the clock here. We have to make a repayment." He doesn't think there are major challenges understanding or complying with the 60-day rule. "Six months to investigate could be a crunch if there is a really big issue, but generally speaking, we have not had a challenge getting it done in six months."

OIG: Self-Disclosure Temporarily Stops the Clock

In CMS's eyes, anything from the government could qualify as credible information of an overpayment, including Medicare cost report adjustments, Targeted Probe and Educate reviews, OIG reports and the Program for Evaluating Payment Patterns Electronic Report (PEPPER).

Findings from internal audits also could be credible information. Presumably that's more than a single improper claim, Ruskin said. If you learn "a nucleus of facts" that gives you a reasonable belief that a pattern of error is emerging, a claims review should follow, he said. Were specific procedures or clinicians involved? Did the billing error only affect certain patients? Did the error correlate to a timeframe when a specific person (e.g., coder, clinician) was employed? "You get to the point where you have a command of the facts and can define your universe and do a random sample review because the universe is properly defined," Ruskin said. Then take your findings and ask more questions, he suggested.

"If you have an overpayment policy that says we only extrapolate if the error rate is 5% or 10% and it's an overly large universe, you may have too much noise and fall below the error rate when it may be a systemic problem and you won't catch it because the net was cast too wide," he explained. That's why he thinks the definition of credible information is at the heart of the 60-day rule.

When providers are unable to nail down a particularly complex matter in time, there's another way to minimize their exposure under the 60-day rule. "The HHS Office of Inspector General's Self-Disclosure Protocol is a good option, because the 60-day reporting obligation is suspended as long as the submission is timely made," said Susan Gillin, chief of the OIG's Administrative and Civil Remedies Branch. "Providers should be mindful that OIG does require that submitters calculate a damages figure within 90 days of submitting a disclosure, however."

Lab Error Repayment Was Laborious

The process of identifying overpayments is painstaking for various reasons. For example, one critical access hospital discovered it had overpayments in connection with its lab, which was billing Medicare for tests performed on lab specimens the same way it billed for tests administered directly on patients who walked through the door, said Traci Waugh, a senior manager at PYA. Sorting this out was time consuming because every lab account was registered the same way, and the hospital had to review years of data manually to separate the specimen from the in-person claims, she said. The hospital easily blew through 60 days quantifying the overpayment. "It was quite an experience trying to do the right thing. It was a long, laborious process," Waugh said. Ultimately, the hospital repaid the money, with the Medicare administrative contractor reprocessing the lab claims.

Sometimes hospitals are focused on the big picture and let small-dollar claims slide by even when they shouldn't, Waugh said. The business office may be in such a hurry to bring the money in that "they don't have time to sit back and say, 'I have been getting the same denial over and over.'"

When to start the clock is still murky, said Margaret Hambleton, president of Hambleton Compliance LLC and

former chief compliance officer at Dignity Health in California. "The frustrating part about the 60-day rule is you are never going to get a one-size-fits-all," she said. "Every time you're refunding money, you're making a determination about whether you have to go further, and it's a completely different analysis based on timing and process and whether it's a one-off or systemic."

60-Day Process, Policy Is Necessary

Compliance with the 60-day rule requires a solid investigation process, which gets a leg up from a recall analysis tool or failure mode and effects analysis tool (a process for identifying failures in a system by breaking down the component parts and analyzing cause and effect), Kennedy said. "These types of tools help bake in what the process should be on the backside when you come out and identify the overpayment and issue," he explained. "Then you can hardwire the process."

Hospitals and other providers also should have a policy on overpayments. Although "it's an art as opposed to a science," the policy can include "guideposts" on what will be considered "systemic" for purposes of extrapolating the overpayment up to six years and define credible information "even if it's not perfect," Ruskin said.

UNC's overpayment policy is part of its billing and reimbursement policy, Kennedy said. "We have 10 standards in the compliance billing and reimbursement policy," and one standard explicitly includes refunding identified overpayments and credit balances in a timely manner, he explained.

Overpayments may fall through the cracks without tracking and coordination among departments, Hambleton said. But who's monitoring overpayment identification and watching the clock? Credible information about a potential error may come in through the health information department, internal audit, patient quality, investigations or the revenue cycle without a word to compliance, she said. As a result, there may be no tracking "to ensure a timely overpayment return and additional evaluation."

Because it can take years to sort out complicated issues, hospitals may not be able to refund overpayments within the six months plus the 60 days, Ruskin said. "It can take forever to do the review even if you are working the file on a routine basis," he noted. "If you are trying to prove you have been acting in good faith, creating a written record of the reasonableness of the time period for completing the steps is very important." Coupled with the overpayment policy, documentation will "vitiate" a prosecutor or whistleblower's attempt to prove you were reckless in not returning the money by the deadline, Ruskin said.

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1 CMS, "Review of Opioid Use during the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV)," *MLN Matters*, SE18004, August 28, 2018, https://go.cms.gov/3xcbjso.
2 Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7,654 (December 2, 2016), https://bit.ly/2UTAGT2.