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With 5% Error Rate Gone As the Extrapolation Trigger, OIG Emphasizes Medicare 60-Day Rule

A 5% error rate—the point at which many providers believe they should extrapolate an overpayment instead of repaying it dollar-for-dollar—has moved to a more subjective judgment under the Medicare 60-day overpayment refund rule. The HHS Office of Inspector General sees the shift away from the 5% standard in corporate integrity agreements (CIAs) as a way to give health care organizations more flexibility and align with the 60-day rule, but it's causing anxiety because 5% has been widely used in internal audits and is considered the only precise statement of when to apply extrapolation, experts say. With the 60-day rule applying pressure on health care organizations, there is concern about the lack of clarity in when to pull the extrapolation trigger.

Five percent has been kind of sacrosanct in the compliance world for many years. "I think everyone has been pointing to the 5% error rate as a guide in their internal overpayment calculations, at least for the first line of scrutiny, but now that it's gone, there isn't much to suggest what the government's expectations are," says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. This has bubbled to the surface because attorneys have noticed that "the 5% threshold has gone away" from CIAs, notes Kelly Sauders, a partner with Deloitte & Touche in New York City.

The 5% guideline in CIAs changed almost two years ago, says Nicole Caucci, deputy branch chief of OIG's Administrative and Civil Remedies Branch in the Office of Counsel. "We transitioned from claims-review language we previously had, which was an initial discovery sample of 50 claims. If the error rate was 5% or greater, that would trigger a full sample and systems review. You had to pay back an extrapolated overpayment." OIG got rid of that structure and now requires a sample of 100 paid claims, with the independent review organization (IRO) doing the initial sample, she says.

But here's where things are really different: whether there is additional sampling or extrapolation is up to the provider. "The 60-day overpayment regulation was one of the drivers in restructuring our approach," Caucci tells *RMC*.

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"The requirement is that the provider reviews and analyzes the results of the 100 paid-claims sample in the context of the overpayment rule. It gives providers more flexibility to make their own determination what the next steps [will be]." There's no error rate threshold (i.e., 5%). And now, she notes, "CIA overpayments are treated the same way as any other overpayments."

Apparently OIG felt too much importance has been attached to the 5% standard. "We wanted to move everyone away from being wedded to 5%," Caucci notes. "We tried to say over and over there is no magic to 5%."

'Reasonable Diligence' Takes Center Stage

The newer CIA approach connects to the requirements in the Medicare 60-day rule, which requires providers to refund overpayments within 60 days of identifying them. According to the Feb. 12, 2016, CMS regulation interpreting the rule, a "person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment" *(RMC 2/15/16, p. 1)*.

In the absence of the 5% bright line and because of the regulation, diligence takes on a whole new meaning, whether or not providers are under CIAs. Caucci notes that the "reasonable diligence" language means providers have to decide how to proceed after identifying an overpayment. "We think the reasonable diligence standard in this regulation is the same standard that applies to the IROs," she says, which are hired by providers to review compliance with the terms of the CIA. "They should be consistent with the overpayment regulation framework."

The new language is apparent in recent CIAs. For example, OIG on March 28 posted a CIA with AmeriCare Ambulance Service, Inc. and AmeriCare ALS, Inc., which was imposed in connection with its $5.5 million false claims settlement with the U.S. Attorney's Office for the Middle District of Florida for allegedly billing Medicare for medically unnecessary ambulance transportation services.

The claims review portion of the CIA doesn't mention 5%. It states that "the IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample)…For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim." The CIA then goes on to say that AmeriCare has to return the overpayments identified in the claims review sample by the IRO in 60 days, consistent with the Medicare 60-day rule. "If AmeriCare determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, AmeriCare shall repay that amount at the mean point estimate as calculated by the IRO," the CIA asserts.

'Process Is Kind of Rudderless'

The evaporation of the 5% bright line for statistical sampling and extrapolation complicates life for providers, experts say. "Providers struggle to comply with the 60-day rule" in the absence of the CIA guidance, or specific guidance from CMS, Waltz says. "The OIG's reliance on 5% provided some guidance, or at least a starting point, in the assessment of how the government would look at the severity of the issue. Now the process is kind of rudderless. How do you approach a calculation that could involve an extrapolation? The preamble [to the regulation on the 60-day overpayment rule] talks about providers being proactive in identifying overpayments, but what does it mean to be proactive?"

The preamble states that "providers and suppliers have a clear duty to undertake proactive activities to

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determine if they have received an overpayment or risk potential liability for retaining such overpayment."

In light of that preamble, Waltz says, "Do you always need to look deeper and do an extrapolation when you have an overpayment, even with a very small error percentage? How do you meet the expectation from CMS to be proactive when you look at overpayments?"

Without the 5% bright line, health care organizations probably have to think through the implications of their audit findings on a case-by-case basis more than they have before, she says. "If you have routine internal audits and come up with a 3% error rate, it will take a lot more inquiry to determine if you have to extrapolate the findings or can just refund the 3% and move on." There will be more of a facts-and-circumstances analysis rather than the straightforward strategy of considering extrapolation when the error rate was 5%, Waltz says.

Sauders agrees that OIG's removing the 5% standard makes it more challenging for organizations to assess an issue and potential repayment. "The 60-day rule doesn't give you any threshold for error rates," she notes. But health care organizations can still look to the 5% standard, which remains in the CIAs that haven't expired. "You should always use your judgment," Sauders says. "When you have a very low or small error rate, that's a good fact that could point to individual errors versus a systemic issue."

Another place to look for guidance is the *Medicare Program Integrity Manual*, she says (see Chap. 8—Administrative Actions and Statistical Sampling for Overpayment Estimates). It says Medicare contractors cannot extrapolate to recoup overpayments unless there's a "sustained or high level of payment error or documentation that educational intervention has failed to correct the payment error."

And there's a trade-off in the CIAs. She says "more meaningful analysis is required. OIG seems to want to better understand the source of [the errors]." For example, the recent CIA with 21st Century Oncology requires the IRO to do a root cause analysis of errors. It states that "The Paid Claims shall be reviewed based on the supporting documentation available…and the applicable coverage, billing, coding, and medical necessity requirements, regulations, and/or guidance to determine whether the items and services provided were medically necessary and appropriately documented, and whether the claims were correctly coded, submitted, and reimbursed."

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