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Thinking Through Voluntary Refunds for Potential Overpayments

Practical Considerations to Understand the Process

With the February 12, 2016 publication of the Centers for Medicare & Medicaid Services' (CMS') "60-Day Rule," providers, suppliers, and compliance officers were faced with additional considerations in determining when and how to perform internal audits to comply with the law.[1] Under the Rule, providers and suppliers have a legal duty to investigate *credible* allegations of potential overpayments. In the event an overpayment is identified, the provider is to refund the potential overpayment within 60 days to avoid violating the False Claims Act.[2] According to the government, the Rule is meant to ensure compliance with applicable standards and protect the Medicare Trust Funds against fraud and improper payments.

Although providers and compliance officers had been performing audits and compliance training to identify and address potential overpayment issues for years, the 60-Day Rule added new dimensions to their efforts. This article provides some key steps and practical suggestions to highlight some critical considerations in thinking through compliance issues with the Rule.

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Obligations under the 60-Day Rule: Duty to Investigate?

Whether something is a "credible" allegation of an overpayment triggering the duty to investigate depends on the specific facts and circumstances raised. For instance, suppose that an anonymous hotline caller states that a certain physician provider is always "upcoding" claims. Upon receiving this information, the compliance team pulls its audit reports for the identified doctor and discovers that there are regular third-party audits focused on evaluation and management (E/M) coding for this physician. Those audits are "clean," with no reported errors.[3]

Now suppose that the Medicare administrative contractor (MAC) has audited several E/M claims for this same physician without issuing denials. In addition, other independent reviewers auditing physician claims reviewed other records for the physician and concluded that no upcoding occurred. In light of these facts, it is reasonable to conclude that the hotline allegation is not credible. The compliance team should document its work before closing out the matter.

Of course, this analysis simplifies many facts, but it illustrates the point that not all allegations are ones that are credible and trigger a need for extensive reviews. To make the hypothetical a little more complicated, suppose that the results of a MAC audit for the physician were just received, showing that of the 25 claims reviewed for accuracy of E/M coding, there are a few claims for which the auditor determined that the claim was upcoded. Does this change the analysis?

Possibly. Because the government has stated that an auditor's adverse determination is a "credible allegation" of an overpayment, the compliance team may have more to do in this situation.[4] What if the coding staff determines that they will appeal the adverse findings and include records that should have been sent initially? Perhaps those missing records will demonstrate that the coding is accurate. Moreover, depending on the number of "errors" identified, arguably, the MAC did not find—and the compliance records do not show—that there is a systemic issue for which additional review is indicated under the Rule. If the compliance team concludes that no further review is required, then documenting those findings should end the work on this issue.

These scenarios, although simplified, illustrate important steps to consider in analyzing potential overpayments. It is appropriate to recognize that although there can be credible hotline allegations or audit findings that are concerning, there are also times when providers can also demonstrate that there are no patterns of improper coding that necessitate additional reviews or extensive audits to demonstrate compliance with the Rule.

Turning to a different hypothetical, what happens if a government auditor conducts another audit of the provider and determines that 10 of the 25 claims fail to meet all the elements in an applicable local coverage determination (LCD)? After an initial review, the compliance team concludes that although the exact element in an LCD may not have been documented, the record demonstrates that appropriate, medically necessary care was provided. In these circumstances, the provider should further analyze the denials and standards used to determine appropriate next steps.

Determining the Appropriate Standard

When faced with denials based on LCDs, regulations, or guidance, as a threshold matter it is critical to verify that the cited basis for denial was actually in effect at the time that the claims were filed.[5] As providers and suppliers well know, changes to these references occur frequently, so identifying the appropriate guidance is critical. If the auditor applied an outdated or irrelevant standard to deny a claim, the record (and subsequent appeals) could demonstrate that there were no errors or overpayments in the claims audited for another time period.

Importantly, not all standards are cut and dried. Therefore, knowing what the applicable reimbursement standards are and determining whether all elements of an LCD are "material" to payment are important next steps in the compliance review.

Materiality under *Escobar*

Understanding the impact of *Universal Health Services, Inc. v. United States ex rel. Escobar* and the evolving case law regarding "materiality" issues in reimbursement are central in the analysis.[6] Briefly stated, in *Escobar*, the Supreme Court concluded

that for a provider to be liable under the False Claims Act, the alleged billing "error" must have been "material" to the government's decision to pay the claim.

For example, if a provider learns that for a certain period of time, the information in its 855 misstates the legal name of the provider submitting claims. Is that error material to payment? Some courts have directly addressed that question, and their conclusions are instructive.[7] What if the provider's team alerted the MAC that the error existed, but the MAC continued paying claims? That fact suggests that the mistake was not "material" and the provider was not overpaid.

If, however, after consulting with counsel, you determine that a potential error in claims submission could be material in the government's decision to reimburse the provider, then an additional review is indicated.

Probe Audits

After determining that there is a credible allegation of an overpayment for claims, providers then must determine whether the error was a one-off or a systemic issue. At this point, a probe audit of the impacted areas could be appropriate.

At this phase of the review, it is important that whoever reviews the probed claims knows the proper standard to apply in her review and can be an appropriate "judge" of whether that standard is satisfied. For instance, if there is a question regarding whether care provided was medically necessary, a provider could determine that an independent, third party should review the probed claims—not the doctor who performed the service.[8] If, on the other hand, there was a question as to whether the correct number of units of a particular drug is appropriately recorded on a claim, it may be that internal staff can review the records pulled in the probe.

In conducting the probe audit, providers should first identify what claims are in the "at-risk" pool for review. For instance, if a compliance officer is concerned that there could be a coding error impacting therapy services, the probe audit could focus first on therapy claims filed within the most recent past three months, identifying all claims with the particular code of concern. For the probe of that period of time, the provider could then pull at random a small number of claims for review.

Importantly, there is no standard number of claims that "must" be pulled in a probe audit; however, it is reasonable to pull anywhere from 30 to 50 claims for initial review. Should there be claims from different locations, with different personnel performing the critical coding functions, you may need to consider sampling each location to appropriately probe the areas that could have an error.

Compliance officers can use the publicly available RAT-STATs program to generate the random numbers that will be drawn for the probe review.[9]

Knowing When to Stop

Suppose that after reviewing a probe audit of 50 total samples, the reviewer concludes that only one of the 50 claims may be erroneous. Assuming that the provider appropriately identified the at-risk claim and applied the correct standard of review, then the probe supports concluding that there is no systemic issue for which additional auditing is indicated. At this point, even when someone is convinced that there "must" be a problem, the probe demonstrates otherwise, and no additional analysis is required. Importantly, if the one identified error resulted in an overpayment, the provider should voluntarily refund that amount to the government. In addition, if appropriate, the compliance officer may want to conduct additional education or training to reinforce compliant coding.

Performing the Statistically Valid Random Sample (SVRS)

If your probe audit results suggest that there are multiple errors in the sampled

claims, additional review is indicated, including considering whether to perform an SVRS. The first step in conducting an SVRS is to identify what period to review. Although the 60-Day Rule states that providers should refund monies dating back six years, depending on the circumstances you might not need to look back so far.

Suppose in the course of analyzing the issue you determine that there was a process change that occurred two years earlier than was the "start" of the problem. If you conduct a probe review of claims filed before that process change and no errors are identified, then it may be reasonable to define the SVRS for a period from two years ago to the current date. For example, we have identified issues that began with the installation of new electronic medical record systems with corresponding changes in the coding process. Of course, there may be circumstances in which there is no means to define a specific time period of concern, and in those cases, an SVRS would likely have to date back six years.

After determining the review period, you should work with appropriate experts to design a valid sampling method and extrapolation. As part of that work, the sampling methods should be designed to be sufficiently precise and representative. Again, the RAT-STATS program is useful in this process. It is also important to review the Web site for the MAC to which any refund would be made to ensure that your sample includes the necessary claims information.

Once the SVRS is completed and an error rate determined, the decision has to be made as to what refund may be owed. If the error rate is high, then an extrapolated refund should be considered. Although there is no defined standard, it can be reasonable to assert that error rates under 5 percent do not indicate a sufficiently systemic issue to require extrapolation.

Importantly, in the event you determine that extrapolation is not indicated, refunding any individual errors identified is appropriate. Moreover, additional training or education to ensure ongoing compliance for the identified issue is another factor to weigh as part of this process.

Making a Voluntary Refund

If you determine that a refund is appropriate, you may be able to correct the claim using the ordinary claims processing system. If that is not an option because of timing, or because you are refunding an extrapolated amount, then we typically have prepared explanations of the circumstances leading to the voluntary refund as well as filling the claims-specific information required by the MA. As part of the explanation, you can also include whatever compliance initiatives or training you initiated in response to a concern. Importantly, you should closely track the claims that you refund in case a subsequent auditor requests those same records for review. If that subsequent audit relates to the issue underlying the voluntary refund, the auditor may not need to conduct the new review.

Also, remember to refund all payers (*e.g.*, Medicaid, TRICARE) as needed, not just Medicare. Moreover, as noted, there are instances in which this process involves more significant issues, thereby requiring additional reporting to the U.S Department of Health and Human Services (HHS) Office of Inspector General (OIG) or other entities.

Does the Time it Takes to Perform an Investigation and Voluntary Refund Matter?

Under the 60-Day Rule, providers are expected to refund overpayments within 60 days of identification. As one might expect, a 60-day timeline is aggressive, so although providers must be diligent in conducting investigations of potential overpayments, making a voluntary refund within six months of identifying an issue is typically reasonable.[10]

Do You Need Independent Reviewers? Attorneys?

When providers identify potential compliance issues, including whether a voluntary refund is appropriate, consultation with independent experts and counsel should be considered. As noted, for some issues, it could be that retaining independent experts for determinations of medical necessity or coding compliance is preferred. In addition, it could be important to engage counsel to analyze standards for review, particularly given the evolving case law under *Escobar.* Conducting the analysis under the attorney-client privilege may be an important consideration as well.

Conclusion

In thinking through an overpayment analysis, the importance of an objective, step-by-step strategy cannot be overstated. Although there is no doubt that providers can make mistakes and determine that voluntary refunds are appropriate, there are clearly times when the guidance or law changes so rapidly—as we have all witnessed during the recent COVID-19 pandemic—that having a plan to tackle the relevant issues that can arise is paramount.

Endnotes

1. 81 Fed. Reg. 7654-01 (Feb. 12, 2016).
2. 81 Fed. Reg. 7659.
3. *Id*.
4. 81 Fed. Reg. 7667.
5. *See Caring Hearts Personal Home Services, Inc. v. Burwell*, 824 F.3d 968 (10th Cir. 2016).
6. 136 U.S. 1989 (2016).
7. *See, e.g., United States ex rel. Patel v. Catholic Health Initiatives*, 312 F. Supp. 3d 584 (S.D. Tex. 2018), *aff'd* No. 18-20395, 2019 WL 6208665 (5th Cir. Nov. 20, 2019) (dismissing complaint on materiality grounds where the dispute was "entirely and only about which business entity is the proper recipient of th[e] reimbursements.")
8. Indeed, because at least some courts have recognized that differences of reasonable opinions between physicians cannot support False Claims Act liability, it may be important to retain an independent reviewer. *See, e.g., United States v. AseraCare, Inc.*, 938 F.3d 1278, 1301 (11th Cir. 2019) ("[T]he mere difference of reasonable opinion between physicians, without more…does not constitute an objective falsehood.")
9. RAT-STATS Statistical Software, OIG, *oig.hhs.gov/compliance/rat-stats/index.asp#:~:text=RAT%2DSTATS%20is%20a%20free,OIG's%20Office%20of%20Audit%20Services* (accessed June 1, 2020).
10. 81 Fed. Reg. 7662.

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