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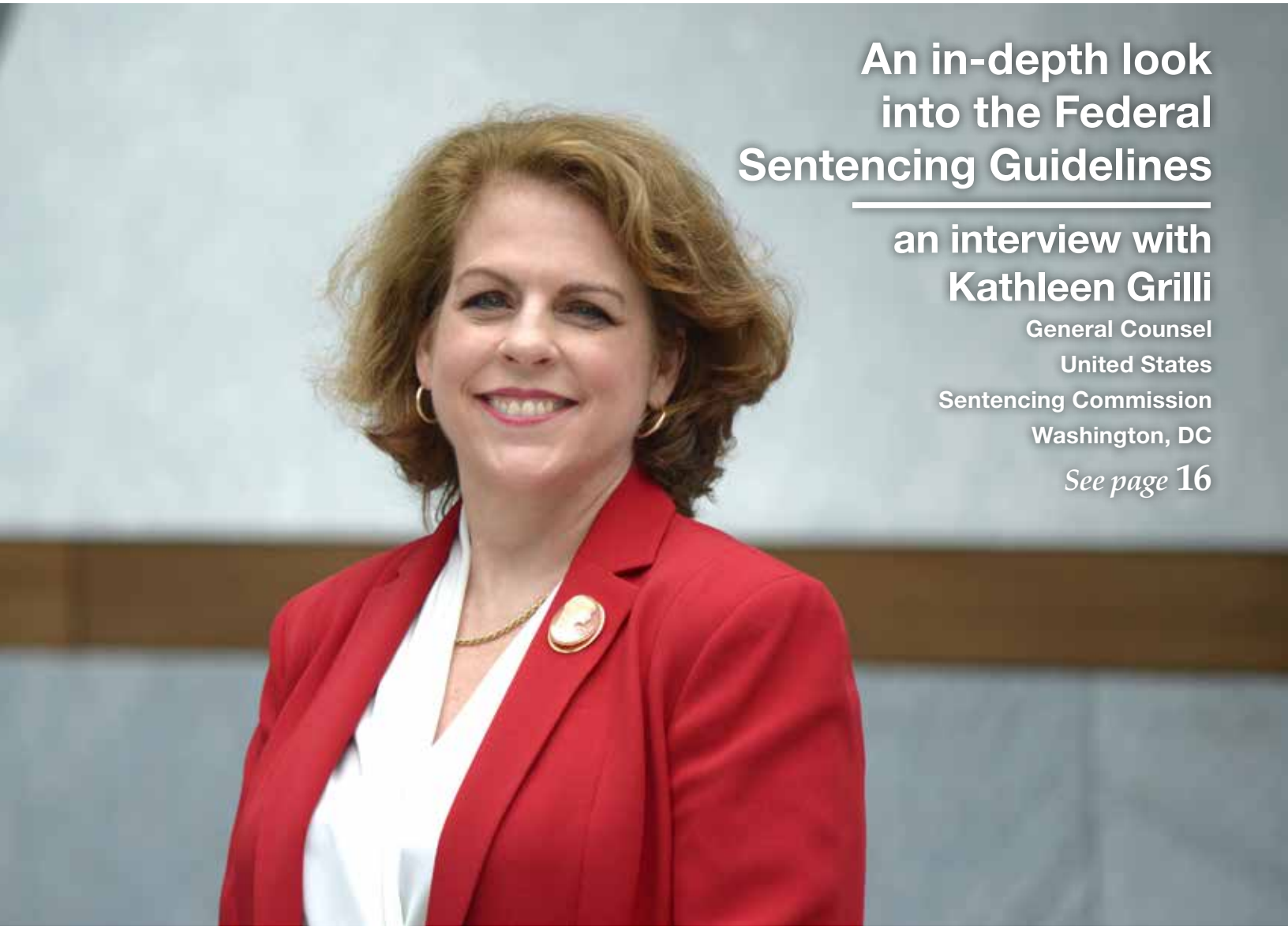

An in-depth look into the Federal Sentencing Guidelines

an interview with Kathleen Grilli

General Counsel
United States Sentencing Commission
Washington, DC

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COLUMNS

DEPARTMENTS

by, Cornelia M. Dorfschmid, PhD, MSIS, PMP, CHC

IRO claims reviews revisited

» Independent Review Organization (IRO) claims review requirements in recent corporate integrity agreements (CIAs) have changed significantly.
» The 5% error rate is no longer used to determine overpayment extrapolation in CIAs.
» Entities under CIA, not IRO, must determine whether to extrapolate.
» The CMS Overpayment Rule is critical in the determination.
» Recent CIAs require IROs to focus more on medical necessity of items and services.

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Healthcare entities that enter into corporate integrity agreements (CIAs) or integrity agreements (IAs) with the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG)[1] typically have various corporate integrity obligations. These obligations often mandate the engagement of an Independent Review Organization (IRO) and in some cases also a compliance expert to the Board. The IROs most often must conduct either claims reviews or arrangements reviews, or both. IROs must be professionally independent and objective and follow the most recent Government Auditing Standards issued by the U.S. Government Accountability Office (GAGAS or Yellow Book standards).[2] Although compliance experts typically are not specifically subject to GAGAS, they still must conduct impartial reviews of the compliance program. In the context of the review, they can provide expert advice and recommendations to the Board. CIAs often mandate that the Board certifies in an annual resolution that they made reasonable inquiry that the organization has implemented an effective compliance program. The compliance expert's compliance program review report supports that inquiry.


Dorfschmid

IRO claims reviews as well as compliance expert reviews may lead to the detection of deficiencies, which in turn can imply overpayments made by federal healthcare programs (e.g., Medicare, Medicaid, Tricare, and VHA). Some of these identified overpayments may even require extrapolation. However, at what point exactly an extrapolation becomes necessary is all but clear cut, and the CIA language has changed significantly in recent CIAs (2015/2016) on this very matter. This warrants careful consideration. A healthcare entity under CIA may want to review internal procedures to address extrapolations in claims auditing and monitoring and assess preparedness for making the right decision.

IRO claims reviews with the 5% error rate—Then

In the past, the instructions for IRO claims reviews in most CIAs stated that the IRO must extrapolate whenever the error rate in the randomly selected discovery sample of paid claims was equal to or exceeded a 5% threshold. The error rate was defined as the percentage of *net* overpayments identified

in the random sample, such as a discovery sample of 30, 50, or 100 paid claims. The IRO had to determine the net overpayments in the sample, which was calculated by subtracting all underpayments identified in the sample from all gross overpayments.

IRO claims reviews typically came and still come in two versions in many CIAs. They were either annual IRO claims reviews for CIAs with five reporting periods, or quarterly IRO claims reviews for CIAs with three reporting periods. In either version, the claims review began with a random sample of paid claims review and the IRO's determination of the error rate in the sample.

- **Annual reviews:**
  In annual claims reviews, the IRO was required to expand the discovery sample to a full sample. A full sample and extrapolation were required only if the error rate was equal to or greater than 5%. The findings of the full sample were to be used by the IRO to estimate the actual overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. The IRO had to extrapolate from the full sample to the population of paid claims to generate the estimate of overall overpayments.

- **Quarterly reviews:**
  In the quarterly IRO claims reviews, the process was simpler. A review of a random sample of 30 paid claims per quarter was the norm. Whenever the error rate in the random sample of 30 paid claims in the quarter was 5% or more, the IRO automatically had to extrapolate the error rate in sample of 30 paid claims. The effect of the sample size on the precision and confidence levels was irrelevant.

What is noteworthy is that, in the past, the 5% error rate threshold set a clear guideline. The IRO determined if the threshold was met—in an independent and objective fashion—and if so, had to extrapolate the overpayment in the population. One may note, however, that the CIAs also clarified that the 5% guideline did not imply that this is an acceptable error rate. Accordingly, the organization was supposed to, as appropriate, further analyze any errors identified in the discovery sample. This instruction left the burden of a decision in the case of a low error rate (less than 5%) with the entity under the CIA; there was no discretion or decision to be made in the case of an error rate >5%. In other words, in those situations where it was clear what to do, it was decided up front. The IRO had to extrapolate and the organization was expected to refund the estimated amount. More recent CIAs lack this clarity and shift the burden of the decision whether or not to extrapolate to the healthcare entity under a CIA. Making the wrong decision and not adequately reporting and refunding overpayments pose great risk: being out of compliance with the CIA and facing a potential false claims situation.

IRO claims reviews without the 5% error rate—Now

There are significant changes in recent CIAs with claims reviews:

- No 5% error rate threshold is mandated to help decide if there should be extrapolation or not.
- The error rate may be defined in terms of overpayment and no longer uses net overpayment. In those cases, it is left to the IRO to determine what the entity has received in excess of the amount due and payable under Medicare, any state Medicaid program, or other federal healthcare program requirements. "Gross or net?" is the question.
- The following or similar language is now common in recently released CIAs and

requires the entity under CIA to decide whether or not to extrapolate:

> *Repayment of Identified Overpayments. [Entity] shall repay within 60 days the Overpayment(s) identified in the Claims Review Sample, as determined by the IRO in accordance with Section…above, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). **If [Entity] determines** that the CMS overpayment rule requires **that an extrapolated Overpayment be repaid**, [Entity] shall repay that amount at the **mean point estimate as calculated by the IRO.*** (emphasis added)[3]

- Annual claims reviews now typically have at least 100 randomly sampled paid claims that need review, rather than discovery samples of 50 paid claims. Larger sample sizes imply more certainty than smaller samples, everything else being equal, and indicate better if there are significant overpayments in the population that may warrant extrapolation.
- In CIAs with a 100-paid claims sample (as well as in CIAs with a quarterly 30-paid claims sample), the entity must repay within 60 days any overpayment identified by the IRO in the claims review sample. In addition, the IRO must identify the potential extrapolated overpayment amount in its claims review report. However, it appears to be up to the provider to determine, based on the claims review results, whether the CMS Overpayment Rule requires repayment of an extrapolated overpayment amount or some other corrective action, such as additional sampling.
- How to interpret sample results and implications clearly is more complicated. Statistical, regulatory, and reimbursement considerations and careful analysis are warranted so that the right and compliant decision is made.

IRO claims reviews and medical necessity

Lastly, it is noteworthy that there is more focus on quality of care and clinical aspects in IRO claims reviews. Medical necessity review seems to become a standard requirement in claims reviews. Many current CIAs require that, as part of the claims review, the IRO should ensure that the paid claims were correctly coded, submitted, and reimbursed. More recent CIAs require the IRO to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claim was correctly coded, submitted, and reimbursed. Documentation that should be relied upon to make these determinations include, but are not limited to, national policies, local policies, program memoranda from the Centers for Medicare & Medicaid Services, Medicare carrier or intermediary manuals or bulletins, medical records, claim forms, and any other supporting documentation. Simply put, this means more expansive and more costly reviews than ever before.

IRO claims reviews and the CMS Overpayment Rule

The entity must determine if the CMS Overpayment Rule requires that an extrapolated overpayment be repaid. That will not always be an easy decision. Clearly, even in the case of small error rates, high dollar value populations, and larger samples to begin with, the stringent expectations of the CMS Overpayment Rule will require careful consideration before an entity decides not to extrapolate and only report and refund the sample overpayments. Statistical expertise may be recruited to analyze the particular sample results and number of errors in

addition to the overpayment amounts. Confidence and precision levels of the estimate always warrant a look when making such a decision. A knowledgeable IRO may render findings and an independent opinion on that. Furthermore, the entity may have learned through the IRO review, or through its own proactive reviews or mock IRO reviews, that issues are persistent. All of that will ultimately impact what to do with the IRO claims review results.

The IRO may calculate the estimated overpayment amount from the sample data and then leave the decision what to do with it to the entity. Clearly, more thought has to be given to this scenario. In some instances, more sampling may be required, and a discussion with the OIG Monitor would be a good idea. As part of a proactive stance, it may be prudent to avoid any ad hoc decisions and develop a CMS Overpayment Rule policy for the compliance program to be prepared for the final decision, once the day comes.

Conclusion

Healthcare entities are advised to engage an IRO that is experienced and understands the differences, intricacies, and variations in CIAs. Both old and new versions of IRO claims reviews in CIAs are currently in place. As there is now an increased attention to medical necessity, in addition to billing, coding, and reimbursement accuracy in reviews, a solid documentation of clinical decision-making is a must. Healthcare organizations may also want to develop procedures and engage statistical, legal, and technical advice on how to handle the extrapolation issue in a compliant manner. Similarly, if a compliance expert to the Board is mandated in the CIA, expertise may be sought on this issue and how the compliance program can tackle this risk area effectively. Lastly, the "old" 5% error rate may still be useful as a criterion in the decision to extrapolate, but it is not likely going to be the only one.

1. HHS OIG website: Corporate Integrity Agreements. Available at http://1.usa.gov/1x8xXT9
2. HHS OIG: OIG Guidance on IRO Independence and Objectivity. Available at http://bit.ly/2vCztxS
3. Federal Register: Medicare Program; Reporting and Returning of Overpayments. 81 FR 7653, February 12, 2016. Available at http://bit.ly/2tvscyt