THE OIG AUDITS DIAGNOSTIC SLEEP STUDIES — HOW PROVIDERS SHOULD RESPOND

Date: 19 July 2019

U.S. Health Care Alert

INTRODUCTION

On June 7, 2019, the Office of Inspector General ("OIG") for the U.S. Department of Health and Human Services ("HHS") released a report summarizing its investigation into whether Medicare made payments to providers for diagnostic sleep studies that did not meet Medicare's billing requirements. [1] The OIG — under its statutory mandate to protect the integrity of HHS programs, as well as the health and welfare of the beneficiaries served by those programs — conducts nationwide audits, investigations, and inspections. [2] These audits have important implications for all types of health care providers, including the need to timely respond to medical records requests, appeal denied claims, and conduct internal investigations, if necessary. The following information and analysis is relevant to all provider types enmeshed in an OIG audit.

There are a myriad of types of OIG provider audits, but all OIG audits are intended to assess HHS programs and operations to help reduce waste, abuse, and mismanagement to promote economy and efficiency throughout HHS. One type of OIG audit examines individual providers to determine if the Centers for Medicare and Medicaid Services ("CMS") overpaid that provider over a certain period of time. These audits purportedly review a statistically valid sample of that provider's claims or beneficiaries, and if a high error rate is uncovered, the OIG will extrapolate the sample error rate to the universe of claims and recommend, among other suggestions, that CMS notify the provider of the audit results and demand refund of the extrapolated overpayment amount. Also, if the error rate is significant, CMS may instruct providers to investigate and refund money from claims implicated by the denial reasons before and after the audited time period.

Another type of OIG audit is nationwide in scope and audits a specific provider type, item, or service. These audits purportedly review a statistically valid sample of beneficiaries' medical records and documentation supplied by different providers across all Medicare jurisdictions. The OIG extrapolates the national error rate to the universe of claims and then reports to CMS the underlying issues uncovered and the financial loss the OIG believes CMS accrued. The OIG's audit report will also make recommendations to CMS, such as operational changes to reduce recurring overutilization, provider and beneficiary education, and recoupment of funds associated with the sampled claims deemed improper. While the statistically valid sample may be used to extrapolate an estimate of CMS's total loss, it is not statistically valid to extrapolate a provider's denied claim(s) to that provider's universe of claims during the audit period. However, the OIG typically recommends that CMS notify the providers with denied claims of the OIG's audit and the potential overpayment and then instruct the provider to investigate and return any overpayments in accordance with the 60-day rule. CMS typically accepts and acts on these OIG recommendations.

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Regardless of OIG audit type, providers must take these audits and assessments seriously and undertake further investigation. However, providers should disagree and challenge the OIG's audit methodology and discrepancies through the administrative appeals process if warranted by the internal investigation.

The OIG audit of facility-based diagnostic sleep studies is no different. In short, the OIG determined the Medicare Administrative Contractors ("MACs") improperly paid providers for these services that did not meet Medicare billing requirements. Further, and perhaps most relevant to providers, the OIG made a number of recommendations to CMS. [3] While the OIG's audit here was limited to facility-based diagnostic sleep studies, or "polysomnography services," the process and guidance herein is applicable to any provider responding to any national OIG audit.

SCOPE OF THE OIG'S REVIEW

The OIG conducted a nationwide audit of approximately $755 million in Medicare payments to providers for 974,901 beneficiaries with 2,056,690 corresponding lines of polysomnography service billed using CPT codes 95810 (related to sleep disorder diagnostic services) and 95811 (related to both full-night PAP titration and split-night services), all between January 1, 2014 and December 31, 2015. [4] From that pool of beneficiaries and claims, the OIG reviewed a stratified, random sample of 200 beneficiaries with 426 corresponding claim lines with payments totaling $148,198. [5] From this random sample, the OIG requested records from the providers who were responsible for those claims.

THE OIG'S FINDINGS

The OIG concluded that of the 200 beneficiaries reviewed, Medicare made improper payments to providers for 83 beneficiaries, with 150 corresponding lines of service — resulting in a combined overpayment amount of $56,668. [6] The types of errors identified by the OIG, as well as the prevalence of the error, corresponding to those 83 beneficiaries [7] is as follows:

Type of Error	Number of Beneficiaries (Out of 200)
Incomplete Medical Record Documentation	57
Documentation Was Missing/Not Provided	18
Attending Technologist Did Not Have Required Credentials or Training Certification	10
Payments for Duplicative Services	1
Incorrectly Coded Line of Service	1

The vast majority of the identified errors related to "incomplete medical record documentation" and "documentation [that] was missing or not provided." [8] With respect to incomplete medical record documentation, the OIG concluded, "For 57 beneficiaries with 106 corresponding lines of service, providers' documentation was

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incomplete because it did not contain the face-to-face clinical evaluation, the attending physician's order, or the technician's report." [9] By comparison, the OIG stated the following regarding documentation either missing or not provided:

> For 18 beneficiaries with 27 corresponding lines of service, providers did not provide any documentation to support the lines of service. For six beneficiaries with eight corresponding lines of service, we contacted the providers multiple times and requested documentation to support the services; however, the providers did not respond to our requests. For the remaining 12 beneficiaries with 19 corresponding lines of service, the providers stated that they did not have the required supporting documentation. [10]

Based on the results of the sample of 200 beneficiaries, the OIG extrapolated the total overpayment amount made by Medicare to providers of polysomnography services between January 1, 2014 and December 31, 2015, to $269,768,285. [11]

THE OIG'S RECOMMENDATIONS TO CMS

The OIG made a number of recommendations to CMS regarding how CMS should proceed in light of the above findings. [12] CMS concurred in each instance. [13] Specifically, the OIG recommended:

- CMS instruct the MACs to recover from providers the portion of the $56,668 already identified by the OIG from the sampled claims that are within the four-year reopening period.
- CMS instruct the MACs to notify the 117 providers associated with 147 claims (83 beneficiaries with 150 corresponding lines of service) with potential overpayments of $56,668 so that those providers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.
- CMS work with the MACs to conduct data analysis allowing for targeted reviews of claims for polysomnography services.
- CMS work with MACs to educate providers on properly billing for polysomnography services, which could have reduced or eliminated an estimated $269,768,285 in overpayments over the two-year audit period.

As discussed in detail below, actions of CMS and the MACs will have major operational and financial consequences for providers of polysomnography services, particularly if such providers fail to take action to protect themselves to the greatest extent possible.

WHAT IS NEXT FOR PROVIDERS OF POLYSOMNOGRAPHY SERVICES, AND HOW SHOULD THEY RESPOND?

Initially, providers should be aware of these types of OIG audits and the requests for records that result. Providers

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should take care to provide the OIG with thorough and complete responses and, when possible, provide beyond what is requested if such information could assist in demonstrating the propriety of the claims. Providers should include, if appropriate, a cover letter listing all Medicare coverage requirements for the item or service audited, with references to the enclosed medical records and documentation.

If the OIG determines that a provider's claim(s) was paid in error, and CMS concurs, providers should expect to receive an initial demand letter from the MAC after the OIG publishes its final audit report. The MAC will demand repayment of the alleged overpayment amount identified by the OIG and instruct the provider to conduct a self-audit as required by the 60-day rule. Because it is unlikely any single provider of polysomnography services would have a significant number of beneficiaries included in the OIG's audit, the total overpayment amount will be relatively small. However, how a provider responds to this demand is of the utmost importance and can have significant consequences.

Per the OIG, the results of its audit constitute "credible information of potential overpayments." [14] As such, the 60-day rule requires providers who receive notification of these potential overpayments to: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a six-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments. [15] This "self-audit," with its six-year lookback period, is a substantial undertaking for any provider. If a self-audit is required, providers will typically utilize outside counsel, a medical review consultant, and a third-party statistician in order to properly structure, complete, and report results of the audit in timely fashion.

CMS indicates providers must complete this investigation to identify any additional overpayments within six months, [16] and by statute, providers have 60 days to report and return overpayments. [17] Thus, providers will generally have a maximum of 240 days to notify CMS of the results of their self-audit and return any identified overpayments. However, if a provider completes the self-audit in less than 180 days, the overpayment must be returned within 60 days of the self-audit completion.

CMS's issuance of a final overpayment notice to the provider for the audited claim(s) does not mean that the OIG's recommendations or CMS's concurrence are correct. If a provider appeals the overpayment identified by the MAC, the provider is excused from immediately commencing the self-audit; specifically, the preamble published in conjunction with the 60-day rule states:

> If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process. [18]

Further, if the provider is able to *fully* overturn the MAC's findings on appeal, there is no obligation to conduct the self-audit. Therefore, it is crucial that any provider with a denied claim(s) included in the OIG's audit sample timely appeal each claim. This will — at the very least — delay the timeframe under which providers must commence a self-audit and return any identified overpayments, [19] and — at most — excuse the provider from any obligation to perform a self-audit or return any moneys to CMS.

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CONCLUSION

The OIG's report will greatly impact those polysomnography service providers that receive overpayment notices for denied claims. CMS, and its contractors, will likely increase their review of polysomnography services billed within the four-year reopening period, in addition to those claims included in the OIG's audit. Providers should be prepared to respond to document requests and demands for repayment of allegedly improper claims. Particularly, providers with claims included in the OIG audit must prepare to respond to, and appeal, overpayment demands from the MACs and, when required, conduct the required self-audit. However, receipt of a final overpayment determination is not evidence that the OIG's audit and recommendations are accurate or correct. Providers should be prepared to challenge and appeal these determinations if warranted.

K&L Gates' health care practice group routinely assists clients in responding to OIG audits and overpayment demand letters, navigating the administrative appeals process and, if necessary, conducting self-audits. However, each provider is different and will have unique concerns and goals in responding to these types of audits or requests. K&L Gates assists clients in developing and implementing a strategic response tailored to each client's particular needs.

NOTES:

[1] *See generally* DEP'T OF HEALTH AND HUM. SERVS., OFF. OF INSPECTOR GEN., Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements, A-04-17-07069 (June 2019), https://oig.hhs.gov/oas/reports/region4/41707069.pdf (hereinafter, "OIG Report").
[2] *See* 5 U.S.C. § APP. 3 §§ 1 *et seq*.
[3] OIG Report, at 5–9.
[4] OIG Report, at 3–4 (These CPT codes were selected based on billing errors identified in prior OIG audits.).
[5] OIG Report, at 4 (For a detailed accounting of the sampling and statistical methodology, *see* Appendix A and D, respectively, of the OIG Report.).
[6] OIG Report, at 5.
[7] The total exceeds 83 beneficiaries because four of the beneficiaries reviewed contained more than one type of error.
[8] OIG Report, at 5 (discussing the LCDs published by the respective MACs).
[9] OIG Report, at 6.
[10] OIG Report, at 6–7.
[11] OIG Report, at 5, 8.
[12] OIG Report, at 8–9.
[13] OIG Report, at Appendix F: CMS Comments.
[14] OIG Report, at 4.
[15] 42 U.S.C. § 1320a-7k(d); 42 C.F.R. § 401.305(a)(2), (f); 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).
[16] 81 Fed. Reg. 7654, 7662 (Feb. 12, 2016) ("[CMS] adopt[ed] the standard of reasonable diligence and

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establish[ed] that this is demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances.").
[17] 42 U.S.C. § 1320a-7k(d)(2)(A).
[18] 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016).
[19] However, the normal processes for recoupment still apply to allegedly improper claims appealed through the administrative appeals process.

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