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Compliance Today - February 2024

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Using OIG's cross-component audit and enforcement data to strengthen your compliance program

by Matthew J. Westbrook and David M. Blank

The U.S. Department of Health and Human Services (HHS) Office of Inspector General's (OIG) core responsibility is to promote efficiency and economy in myriad programs by eliminating fraud, waste, and abuse. While HHS deploys multiple tools to oversee $2.4 trillion in federal expenditures spread across more than 100 programs, OIG's creation and promotion of industry compliance standards remains one of its most mission-critical functions.[1]

For years, compliance professionals have come to rely on OIG's advisory opinions, special fraud alerts, advisory bulletins, and industry-specific guidance to develop and evaluate compliance programs. In recent years, OIG has modernized its compliance outreach for the digital age by producing podcasts, videos, brochures, web-based training sessions, tool kits, roadmaps, and even fact pattern-based FAQs to better connect with the healthcare industry. These additional resources have assisted participants in federal healthcare programs (FHCPs) to stay current on emerging issues and strengthen their existing compliance programs.

OIG's modernization efforts have extended beyond developing these additional compliance resources. OIG's strategic Work Plans have also detailed its approach to strengthening program integrity through increased cross-component collaboration, focusing on data-driven enforcement. Achieving such enforcement has been premised on the sharing of information, resources, and talent between and among OIG's key components:

- **Office of Audit Services (OAS)**: Audits HHS programs to identify program risks, vulnerabilities, and mismanagement and also leverages HHS data to identify and target emerging high-risk areas to ensure the best use of resources.
- **Office of Evaluation and Inspections (OEI)**: Conducts evaluations to inform and advise interested stakeholders on significant program-related issues and to make practical recommendations to improve operations.
- **Office of Investigations (OI)**: Conducts criminal, civil, and administrative investigations of alleged fraud, waste, and abuse related to HHS programs and operations.
- **Office of Counsel to the Inspector General (OCIG)**: Provides legal advice to OIG and is responsible for representing OIG in False Claims Act (FCA) cases, monitoring integrity agreements, publishing compliance guidance, and imposing penalties, assessments, and exclusions under the Civil Monetary Penalties Law

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(CMPL)[2] and Exclusion Statute.[3]

While most compliance professionals incorporate aspects of OIG's traditional compliance guidance into daily work, more are beginning to utilize OIG's audit and enforcement data to better identify and understand emerging compliance risk areas. Evaluating such audit and enforcement data in real time is important for developing and improving proactive compliance monitoring tools and allocating compliance resources more efficiently and effectively. If the audit and enforcement data relate to any business line of an organization, the compliance response should mirror the OIG's audit, investigative, and enforcement efforts.

The compliance benefits of this approach are not theoretical. Since 2018, OIG has entered at least 67 CMPL settlements totaling nearly $17 million in CMPL recoveries in matters originating as an OAS audit. These results stress the importance of understanding OIG's internal collaborations to identify emerging industry-specific risks and develop proactive compliance measures. This article focuses on three specific, current enforcement action areas resulting from a partnership between OCIG and OAS as an example of such internal collaboration.

OIG's internal collaboration

OIG publishes its Work Plan monthly to inform the public of specific topics or substantive issues subject to an upcoming audit by OAS or evaluation by OEI.[4] Projects in the Work Plan typically reflect emerging risk areas, statutory obligations, or congressional requests. Each Work Plan item includes a summary overview of the proposed work to be performed by the OIG component.

In the case of OAS, specifically, once an audit topic is selected, OAS establishes a methodology to validate the review's objective. A typical audit involving Medicare or Medicaid claims includes:

1. Reviewing the applicable laws, regulations, and guidance
2. Ascertaining and obtaining the relevant claims universe
3. Developing sampling models
4. Contacting relevant FHCP participants to obtain supporting information and documentation regarding the sample claims
5. Reaching out to third parties or government stakeholders
6. Reviewing preliminary claims and quantifying potential error rates
7. Discussing the preliminary results with the Centers for Medicare & Medicaid Services (CMS)

Once completed, OAS issues a report containing its findings, extrapolates the potential overpayment exposure, and recommends programmatic improvements to CMS. OAS will also often recommend that the Medicare contractors attempt to (1) recover the identified overpayments, (2) notify the relevant FHCP participants so that they may determine if refunds are appropriate under CMS's 60-day overpayment rule,[5] and (3) identify and refer any FHCP participant believed to have engaged in suspect or aberrant billing for additional investigation. OAS may also direct referrals to OI or OCIG for potential investigation and enforcement action.

The following examples provide illustrations of the typical lifecycle of OAS audits and how the OAS–OCIG collaboration has been operationalized, highlighting the potential benefit to compliance professionals to develop proactive compliance activities that mirror OIG's efforts.

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Medicare payments for ambulance transport services

In July 2017, OIG's Work Plan included information on the commencement of an OAS audit examining Medicare payments for ambulance services under Part B for transfers qualifying as a Part A skilled nursing benefit.[6] The audit was intended to address prior concerns of "high error rates and significant overpayments for services subject to skilled nursing facility [("SNF")] consolidated billing." The audit was more specifically intended to determine (1) whether ambulance services paid by Medicare Part B were subject to the Part A SNF consolidated billing requirements, and (2) if existing CMS edits were effective to detect and prevent improper payments. OAS reviewed two years of Part B ambulance payments for beneficiaries under Part A SNF stays totaling over $25 million in paid claims. In February 2019, OAS issued a report, concluding that 78% of the Part B payments in its review were potentially incorrect.[7] OAS extrapolated its findings to estimate that Medicare had potentially made approximately $19.9 million in overpayments. OAS also referred to OCIG for potential CMPL enforcement a list of ambulance companies related to the identified overpayment.

Through September 2023, the referrals have resulted in approximately 25 CMPL settlements with ambulance companies alleged to have falsely and fraudulently obtained Medicare Part B reimbursement for ambulance transports to and from SNFs that were already covered by the consolidated billing payments under Part A. The ambulance companies and at least one owner agreed to pay nearly $10 million to resolve these allegations, including penalties, assessments, and/or multipliers. In addition to the monetary recoveries, OIG excluded two ambulance companies[8] and one owner.[9] A third ambulance was subsequently excluded for default because the company failed to meet its payment obligations under the settlement agreement.[10]

The underlying work resulting in the OAS report catalyzed OCIG's CMPL resolutions. The covered conduct descriptions and the relevant time frames relating to these CMPL resolutions are consistent with OAS's review window and published report. A review of the relevant settlement documents (e.g., the settlement agreements, internal activity reporting summary reports, and press releases) confirmed that the enforcement resulted from OAS and OCIG collaboration. Medicare's double payment for ambulance transports under Parts A and B is an excellent illustration of how the OAS–OCIG collaboration is operationalized; it further highlights the significance of developing proactive compliance activities that mirror OIG efforts as a risk mitigation tool.

As a starting point for such mirroring activities, compliance professionals should refer to OAS reports themselves, where they can glean insightful takeaways about Medicare compliance, including: (1) ambulance companies should obtain confirmation from SNFs about the SNF status of the beneficiaries to be transported before the companies bill Part B for the transportation, and (2) SNFs should inform ambulance companies about the nature and purpose of the beneficiaries' transportation before the company transports the beneficiary to and from the SNF. On this latter point, such information would allow ambulance companies to ascertain whether they should bill the SNF for such transportation or Part B—and in either case, to avoid double billing.

Part B reimbursement for urine drug testing

Medicare Part B payments for urine drug testing are another area subject to increased OAS–OCIG collaboration. OAS's initial audit examined laboratory and physician billing for specimen validity tests (SVT) billed in conjunction with urine drug tests (UDT).[11] A UDT identifies the presence or absence of drugs in a person's system. By contrast, an SVT confirms whether the sample is from a human and has been subject to tampering or identifies an abnormal medical condition. Under CMS guidelines, SVTs are not separately reimbursable when performed on the same day as the UDT. The OAS audit examined a claims universe including nearly 4,500 providers and more than $66 million in reimbursements, finding that all claims for SVTs failed to meet CMS's program requirements for medical necessity.[12]

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OIG noted additional auditing projects focusing on drug test reimbursement in the October 2019 Work Plan.[13] The ongoing audit intends to address OIG's continued concerns with improper Part B reimbursement for UDT and the high error rates involving multiclass definitive drug testing codes. OAS's current audit objective is to determine whether UDT reimbursement for beneficiaries with substance use disorders was paid under applicable program requirements.

The OAS audit work in the UDT space coincides with a noted increase in related OCIG-initiated enforcement actions. Specifically, between 2019 and 2022, OIG entered at least 35 settlements involving FHCP participants who submitted medically unnecessary SVT claims. The settling parties included laboratories, physician medical practices, clinics, and related individuals; the settlements totaled more than $4.8 million in recoveries. Reviewing the relevant settlement documents again confirmed that the enforcement initiative resulted from a specific OAS and OCIG collaboration. Given the ongoing OAS focus on the propriety of definitive UDT billings, we anticipate the announcement of additional CMPL enforcement actions in this space. In anticipation of and to be proactive with respect to the potential for future enforcement actions relating to SVT and UDT billing, providers performing UDT should not be separately billing SVT and should not cause laboratories to separately bill for the same; providers and laboratories should consult with their electronic health record vendors about utilizing and implementing an edit relating to separately billing for SVT and UDT; and providers and laboratories should stay current with applicable local coverage determinations (LCDs), which may specify and explain whether and how SVT is a noncovered service with respect to UDT, as highlighted in the OAS report.

Part B reimbursement for spinal facet joint interventions

A final identified collaboration area involves Medicare Part B reimbursements for spine-related treatments, including facet joint injections and denervation sessions to alleviate neck or back pain caused by arthritis or injury. OIG first raised concerns about facet joint procedures in 2006 because of an elevated risk for overutilization based, in part, on a significant financial return for providing such treatments.[14]

Since October 2020, OAS has published four audits focused on facet joint intervention reimbursement. In the first report, OAS found that Medicare contractors made approximately $750,000 in improper payments relating to the procedure.[15] In February 2021, the second report was published, finding that one Medicare contractor improperly paid more than 50% of facet joint injection claims.[16] OAS published the third report in December 2021, finding that Medicare made more $9.5 in improper facet joint intervention payments.[17] On March 22, 2023, the fourth audit report was published, finding that Medicare made another $30 million in improper payments.[18]

As with prior collaborations, OCIG initiated CMPL investigations shortly after the release of the OAS reports. In 2022, OIG entered seven CMPL settlements with healthcare providers and their medical practices to resolve allegations of false and fraudulent billing for facet joint interventions. The seven settlements totaled more than $2 million in recoveries, and the related settlement documents confirmed that the resolutions resulted from OCIG's collaboration with OAS.

The OIG Work Plan shows a continued focus on the propriety of Part B payments for spine-related pain management procedures. OAS is currently auditing physician reimbursement for facet joint injections, facet joint denervation sessions, lumbar epidural injections, and trigger point injection claims.[19] OAS plans to release the audit report sometime in 2024. Thus, the industry should expect continued CMPL enforcement for spine-related pain management claims driven by OAS's past and current audit work. To be proactive in this area, healthcare providers should review and stay current with applicable LCDs (as highlighted in OAS reports); they should also implement internal controls to ensure that the maximum number of sessions allowable under such LCD is not

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exceeded, especially if there is a time frame component to the maximum allowable value. More information about the potential relevance of LCDs is detailed in OAS's audit reports.

Incorporating OAS's audit reports and OCIG's settlements into actionable compliance

The coordinated enforcement initiatives targeting ambulance companies, SVT, UDT, and spinal facet joint interventions demonstrate a clear connection between identifying an industry-specific risk and enforcement. The success of these cross-component collaborations will undoubtedly lead to additional coordinated enforcement actions predicated on audit findings. However, unlike a traditional FCA enforcement action—which often remains under seal (not publicly available) until settlement—the topic of the next OAS–OCIG collaboration is announced in advance through OIG's Work Plan.

A proactive compliance program should analyze OIG's Work Plan to (1) align resources with OIG focus areas, (2) conduct risk assessments incorporating audit priorities to identify areas of vulnerability and mitigate compliance risks, (3) develop training materials to educate staff and raise awareness about specific compliance risks, (4) increase preparedness through mock audits, (5) strengthen related billing and coding procedures, and (6) serve as a reference authority for deciding when to report and self-disclose any identified noncompliance. The value in identifying potential compliance risk areas before they become subject to an enforcement action is immeasurable.

Final thoughts

Given the recency of OCIG's resolutions relating to this specific conduct, we anticipate additional resolutions relating to any potentially applicable OAS audit reports in the near future. FHCP participants should take notice of the potential for OCIG-initiated CMPL and/or exclusion action if it has already been the subject of any OAS audit. The same can also be said about any FHCP participant subject to any proposed audit set forth by OIG in its current Work Plan.

Compliance professionals should also consider monitoring OCIG's affirmative enforcement efforts as part of an organization's compliance program. At a minimum, these cases provide real-world examples of questionable conduct that can be used as educational materials for compliance training. In other situations, monitoring these enforcement actions can identify the start of a targeted enforcement initiative, allow for reallocating compliance resources, serve as a basis to change organizational behavior, or mitigate liability through the self-disclosure process, where appropriate.

Takeaways

- The U.S. Department of Health and Human Services Office of Inspector General (OIG) is increasingly collaborating across its components to identify and address emerging compliance risks based on data-driven initiatives.
- OIG's Work Plan is a valuable tool for compliance professionals by providing insights into OIG's priorities, helping with risk assessment and mitigation, and guiding the development of effective compliance programs.
- Compliance professionals can reduce the risk of regulatory violations by incorporating audit and enforcement data to develop proactive compliance monitoring tools.
- OIG audit and enforcement priorities should be analyzed to align resources, assess risks, develop training, increase preparedness, strengthen billing and coding, and decide when to report noncompliance.

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- Federal healthcare program participants should implement auditing and monitoring tools to proactively address compliance challenges and reduce the risk of regulatory violations.

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