HHS-OIG Year in Review 2023

BASS BERRY SIMS

Introduction

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) is tasked with providing objective oversight to protect the integrity and promote the efficiency of Medicare, Medicaid, and more than 100 other federal healthcare programs, as well as the health and welfare of the people they serve.

OIG is the largest inspector general's office in the federal government and plays a critical role in preventing and detecting healthcare fraud and abuse, and, where necessary, taking appropriate enforcement action. Guidance issued by OIG is essential reading for those in every corner of the healthcare industry.

In 2023, OIG offered the healthcare industry new and updated guidance tools and a late flurry of advisory opinions while continuing to fend off legal challenges to the advisory opinion process and OIG's application of the federal Anti-Kickback Statute (AKS).

In March, OIG announced a new, expanded frequently asked questions (FAQ) process. In April, OIG continued to shine a spotlight on telehealth arrangements by issuing a toolkit for analyzing telehealth claims. In June, OIG issued its long-anticipated information-blocking enforcement rule. And, in November, after a 15-year hiatus, OIG embarked upon a process of updating and modernizing its voluntary compliance program guidance with a new 91-page General Compliance Program Guidance. Industry-specific Compliance Program Guidance documents, likely starting with nursing facilities and Medicare Advantage Organizations, are expected in 2024 and beyond. OIG also published 15 advisory opinions, almost half of which were issued in December, and we observed a slight uptick in self-disclosure protocol (SDP) settlements.

Bass, Berry & Sims is pleased to share its second annual HHS-OIG Year in Review (HHS-OIG YIR), a novel industry resource highlighting key guidance, self-disclosure settlements, a new rule, and other significant issuances from OIG in 2023.

Our goal for the HHS-OIG YIR is not to exhaustively describe every guidance document OIG published in 2023. Rather, our team highlights the items we think are the most significant or helpful to the healthcare industry. When evaluating any particular OIG guidance document, we think it is critical to understand the context in which OIG issued it. For example, Special Fraud Alerts and Compliance Program Guidance inform the public of practices that OIG considers to be of particular importance and reflect its enforcement priorities. On the other hand, OIG does not control the types of arrangements that are submitted through the advisory opinion process, so these opinions do not necessarily reflect the agency's enforcement priorities or the matters it believes present the greatest risks.

In this HHS-OIG YIR, we discuss the following topics:

- The new General Compliance Program Guidance.
- The expanded informal FAQ process.
- The new civil monetary penalties for information blocking.
- OIG's strategic plan for managed care oversight.
- A consumer alert regarding remote patient monitoring.
- The end of the public health emergency (PHE) declaration.
- OIG's new telehealth toolkit.
- Significant advisory opinions.
- Significant SDP settlements.
- Litigation against OIG challenging unfavorable advisory opinions.

We hope that this HHS-OIG YIR will assist you in understanding how OIG frames and analyzes fraud and abuse issues so that you can assess and manage risk as you navigate the increasingly complex and ever dynamic healthcare regulatory environment.

General Compliance Program Guidance

In November, in connection with its effort to modernize the accessibility and usability of its publicly available resources, OIG released its most up-to-date, comprehensive, and practical general compliance guidance in decades. The new General Compliance Program Guidance (GCPG) includes summaries of relevant laws, generally applicable compliance program basics, key resources, and practical tips.

The GCPG is organized in a user-friendly manner and provides thoughtful commentary on the seven elements of an effective compliance program, including the increasing importance of risk assessments and current areas of focus in healthcare compliance (such as patient quality and safety considerations), new entrants in the healthcare industry, and financial incentives promoting compliance.

The GCPG applies to all individuals and entities involved in the healthcare industry. In addition to a detailed discussion on the basic elements of a compliance program, the GCPG provides:

1. General background on OIG's previous and current compliance guidance.
2. A useful summary of applicable laws and regulations over which OIG has agency oversight.
3. Specific tips that serve to remind the industry of OIG's general views on compliance structure and priorities.
4. Suggestions for adapting compliance programs based on entity size.
5. A discussion of specific considerations regarding compliance that suggest the OIG's current focus.
6. A list of OIG resources with embedded links.

Beginning in 2024, OIG plans to issue industry segment-specific CPGs (ICPGs). The GCPG and ICPGs will serve as resources for voluntary, nonbinding guidelines and tips to identify risk areas that OIG believes the healthcare community should consider when developing a compliance program. OIG is seeking feedback and suggestions in connection with the GCPG and forthcoming ICPGs on an ongoing basis at a designated email.

In November, in connection with its effort to modernize the accessibility and usability of its publicly available resources, OIG released its most up-to-date, comprehensive, and practical general compliance guidance in decades.

OIG plans to update the GCPG and ICPGs as needed. In a departure from past practices, OIG explained that it will no longer publish updated or new CPGs in the Federal Register and that, going forward, the GCPG and ICPGs will be published on OIG's website. While this will promote ease of access to the CPGs, it is not clear whether OIG will make archived versions available on its website as it revises or updates these documents.

Adaptations for Small and Large Entities

In what may be a response to a long-standing critique of previous compliance guidance, OIG included a discussion of compliance program adaptations for small and large entities in the GCPG. While the GCPG does not define the terms small and large entities, it cites individual and small-group practices and other entities with a small number of employees as examples of small entities, and healthcare systems in large metropolitan areas, chain retail pharmacies, and manufacturers with locations and operations statewide or nationwide as examples of large entities. It is not clear whether or how entities that fall between these two disparate types in terms of size should consider these adaptations to their compliance programs.

Guidance for Small Entities

In an effort to recognize potential financial and staffing constraints for smaller entities, the GCPG includes suggested modifications to the seven elements of an effective compliance program for small entities. By taking a more flexible and practical approach, these modifications allow smaller entities to stretch and optimize resources to ensure their compliance programs are effective. For example, in lieu of having a compliance officer, the GCPG suggests that small entities designate one person as the "compliance contact" who would be responsible for monitoring compliance efforts and report to the CEO (in the absence of a board), but with the caveat that this individual should not have responsibility for the performance or supervision of legal services and should not be involved in billing, coding, or submission of claims.

Guidance for Large Entities

Probably the most significant takeaway from the GCPG treatment relating to compliance programs for large entities is the emphasis on the need for such organizations to dedicate "significant" resources and expertise to compliance. In practical terms, this means a large organization will likely need a well-resourced and skilled compliance department and compliance committee, as well as a board that is actively engaged and focused on compliance. Among the suggestions and tips included in this section of the GCPG are the following:

- Boards should have input on the appointment, evaluation and compensation of the compliance officer.
- If the board combines compliance with its audit committee, it should consider setting up a separate compliance committee with its own charter and comprised of individuals with appropriate knowledge and expertise (e.g., compliance, regulatory, and clinical expertise).
- For organizations with separate facilities and/or locations, having a dedicated compliance resource (e.g., a facility compliance officer/liaison) at the facility level.

Other Compliance Considerations

The GCPG addresses several additional compliance considerations that apply to organizations of all varieties, including quality of care and patient safety, new entrants into the healthcare industry, financial incentives, and the tracking of financial arrangements.

Quality is defined broadly to include both quality in manufacturing and supplying drugs, devices, and other items, as well as quality of care in the provision of items and services, particularly for entities that provide direct patient care. The GCPG suggests that an organization's compliance committee should include individuals who are responsible for quality assurance and patient safety.

New entrants in healthcare—including technology companies, new investors, and organizations providing non-traditional services in healthcare settings—as well as existing healthcare organizations that are expanding into different lines of healthcare business are particularly susceptible to compliance risks. The GCPG emphasizes the need for these new entrants to avail themselves of the GCPG, OIG's existing materials, and forthcoming ICPGs to ensure their compliance programs are appropriately structured, up-to-date, and operating as effectively as possible.

The GCPG also addresses issues inherent to ownership and payment methodologies. OIG is clearly alert to the risks associated with private equity and other forms of private investment that could potentially impact the quality of healthcare. The GCPG emphasizes that private investors who provide management services to, or maintain a significant amount of operational oversight or control over, a healthcare entity need to become familiar with all of the laws that apply to their operations and carefully scrutinize their operations and incentive structures.

Finally, the GCPG addresses the need to track all financial arrangements, specifically those with referral sources and referral recipients. OIG recognizes

that while it is common for organizations to have an established system for vetting and structuring these arrangements, it is also common for the same organizations to fail to monitor ongoing compliance with the terms of the arrangements. The GCPG recommends that organizations develop effective and robust arrangements tracking systems and regularly audit to prevent violations and mitigate liability.

OIG's Expanded Informal FAQ Process

In March, OIG announced a new, expanded FAQ process. Although OIG has long maintained FAQs on topics such as advisory opinions and exclusion authorities, it has addressed only a limited range of issues. Under the new FAQ process, which is an outgrowth of OIG's Modernization Initiative and its experience issuing FAQs during the COVID-19 PHE, stakeholders may now submit questions related to subjects traditionally reserved for the formal advisory opinion process, including the AKS and the civil monetary penalty provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP).

New FAQ Categories

The FAQ process is designed to improve the timeliness and utility of its guidance and offers a new avenue for insight regarding how OIG analyzes particular arrangements outside of the advisory opinion process. The new categories of FAQs include:

- General applicability of the AKS and Beneficiary Inducements CMP.
- OIG's administrative enforcement authorities in connection with the AKS and Beneficiary Inducements CMP.
- Application of the AKS and the Beneficiary Inducements CMP to certain types of arrangements.
- Compliance considerations.
- OIG's Health Care Fraud Self-Disclosure Protocol.

FAQ Submission Process

OIG's expansion of the FAQ process offers a new pathway for OIG to provide guidance to the industry more rapidly and allows stakeholders to present OIG with innovative questions outside of the formal advisory opinion process.

Stakeholders interested in using the FAQ process should submit their questions to OIGComplianceSuggestions@oig.hhs.gov. The submission should include sufficient background information and facts to allow OIG to understand the inquiry. For example, if stakeholders submit an inquiry regarding a specific type of arrangement, OIG seeks information critical to understanding the arrangement, such as the key parties and the arrangement's general terms. OIG is not obligated to respond to a particular question. Rather, OIG will issue informal, non-binding FAQ responses to selected inquiries, subject to a number of caveats discussed below, when it believes such feedback would be "appropriate and beneficial."

Limitations on the FAQ Process

OIG will choose which questions it answers and may modify the question to deliver "a more useful or meaningful response" and "to ensure generality in any response." Additional limitations include:

- **Non-Binding.** The informal guidance issued in FAQ responses does not bind OIG, HHS, Department of Justice (DOJ), or any other agency.
- **No Immunity.** In contrast to the advisory opinion process, FAQ responses do not confer prospective immunity from OIG administrative sanctions on any party.
- **Publication.** While OIG will not provide identifying information about the party that submitted a question through the FAQ process, it cautions that the information submitted may be disclosed in response to a Freedom of Information Act request.

Newly Issued FAQs

Since the announcement of the new FAQ process, OIG has published several new FAQs, including guidance on compliance considerations and fraud and abuse authorities, such as:

- Assessing risk under the AKS.
- The interplay between the AKS and the Beneficiary Inducements CMP.
- Gift cards.
- Electronic health record (EHR) vendor arrangements;
- Physician investment in ambulatory surgery centers (ASCs).
- Remuneration between entities with common ownership.

Takeaways

OIG's expansion of the FAQ process offers a new pathway for OIG to provide guidance to the industry more rapidly and allows stakeholders to present OIG with innovative questions outside of the formal advisory opinion process. Stakeholders may find this new FAQ process helpful, particularly as healthcare models rapidly shift to value-based care.

With that said, how the FAQ process will be used remains to be seen. The limitations are significant, and it is unclear how OIG will exercise its discretion to respond to inquiries made under the FAQ process. Moreover, OIG is clear that the FAQs are not binding on any agency, including OIG, leaving some doubt as to the value of FAQs in the enforcement or whistleblower context. Finally, unlike in the advisory opinion context, where requestors can withdraw a request if OIG is planning to issue unfavorable guidance, FAQ submissions cannot be withdrawn.

Additional information from our client alert can be found here: OIG Offers Stakeholders a New Avenue for Informal Fraud and Abuse Guidance.

New CMP Authority for Information Blocking

In July, OIG published a final rule that adds information blocking CMP authority to the existing regulatory framework for CMPs and explains OIG's approach to enforcement. As OIG explained:

> Information blocking poses a threat to patient safety and undermines efforts by providers, payers, and others to make the health system more efficient and effective. Information blocking may also constitute an element of a fraud scheme, such as by forcing unnecessary tests or conditioning information exchange on referrals.

Information blocking includes practices that certain specified entities "know[], or should know, [are] likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information,"[1] unless the practice is required by law or covered by an exception. In addition to CMPs, a violation of the information blocking rules could constitute a False Claims Act (FCA) violation.

This final rule does not impose new information blocking requirements. The Office of the National Coordinator for Health Information Technology (ONC) published a final rule promulgating the information blocking rules in 2020. Additional information about ONC's final rule from our client alert can be found here: What Healthcare Providers Need to Know About the Information Blocking Rules.

Entities Subject to Penalties

Only the following entities are subject to information blocking penalties:

1. Health information technology (IT) developers of certified health IT.
2. Entities offering certified health IT.
3. Health information exchanges.
4. Health information networks.

The information blocking CMPs do not apply to healthcare providers unless they also fall within one of the categories above.

1 42 U.S.C. § 300jj-52(a)(1)(B); 45 C.F.R. §171.103(a)(2).

Subject to a six-year limitations period, OIG may impose CMPs of up to $1 million per violation against these entities if OIG determines, following an investigation, that the entity committed information blocking. In assessing the amount of the CMP, OIG will take into account factors such as:

- The nature and extent of the information blocking.
- Harm (physical or financial) resulting from the information blocking.
- The number of patients affected.
- The number of providers affected.
- The duration of the information blocking incident.
- Other mitigating and aggravating factors under the CMP laws.

Enforcement Priorities

OIG anticipates it will receive more information blocking complaints than it can investigate, such that it will have to allocate resources to target information blocking allegations that have a negative impact on patients, providers, and healthcare programs. Accordingly, OIG will select cases based on the following priorities:

1. **Actual or potential patient harm.** Rather than focusing on individual harm, OIG will broadly consider harm to a patient population, community, or the public in general.
2. **Impact on provider's ability to care for the patient.**
3. **Duration of the conduct.**
4. **Financial losses to federal healthcare programs (FHCPs) or other government or private entities.**
5. **Actual knowledge of the conduct.** Though actual knowledge is not required to commit information blocking, due to the egregious nature of conduct committed with actual knowledge, OIG indicated it would likely prioritize such conduct.

None of these priorities are dispositive, and OIG expects that it also will investigate allegations of conduct that do not fall within these priorities. OIG will reassess priorities as it gains more experience in investigating information blocking.

Investigations and Enforcement

OIG will use a variety of mechanisms to investigate information blocking complaints, including conducting interviews and requesting documentation from the entity under investigation. OIG will consult with ONC, the Office for Civil Rights (OCR) (e.g., for HIPAA issues), the Federal Trade Commission (FTC) (e.g., for anti-competitive conduct), and other agencies as appropriate throughout the course of the investigation, including during any appeals. If OIG determines an entity committed information blocking, it will send a demand letter to the entity, which will allow the entity to appeal OIG's imposition of CMPs to an administrative law judge (ALJ). OIG will coordinate with other HHS agencies to avoid duplicative penalties.

OIG began enforcing information blocking penalties on September 1 but will not impose penalties on information blocking conduct occurring before this date.

OIG may impose CMPs of up to $1 million per violation against certain entities if OIG determines, following an investigation, that the entity committed information blocking.

Self-Disclosures

OIG will create a self-disclosure protocol specifically for information blocking, which will allow entities to self-report conduct and potentially resolve CMP liability for a lower penalty amount. OIG encourages self-reporting, noting that taking appropriate and timely corrective action in response to a violation is a mitigating factor for the imposition of CMPs and often reduces costs and disruptions associated with government-directed investigations.

Provider Disincentives

OIG's final rule does not establish healthcare provider disincentives; rather, HHS is developing a separate rule to establish those disincentives. Additional information on the provider disincentives from our client alert can be found here: HHS Proposes Rule to Establish Disincentives for Healthcare Providers That Engage in Information Blocking

OIG's Strategic Plan Prioritizes Managed Care Oversight

More than half of Medicare beneficiaries and more than three-quarters of Medicaid beneficiaries are now insured by managed care plans. In response to this rampant growth in enrollment, in August, OIG released its Strategic Plan: Oversight of Managed Care for Medicare and Medicaid, (Strategic Plan) outlining a framework for aligning its audits, evaluations, investigations, and enforcement in the managed care space. The Strategic Plan has three goals:

1. Promote access to care for people enrolled in managed care.
2. Provide comprehensive financial oversight.
3. Promote data accuracy and encourage data-driven solutions.

To achieve these goals, OIG created a "managed care life cycle" comprised of four stages, identified the risks associated with each stage, and proposed a framework for managed care entities to use to assess risks and apply OIG's guidance to address identified risks.

The four stages of the managed care life cycle are as follows:

1. Plan establishment and contracting.
2. Enrollment.
3. Payment.
4. Services to people.

OIG intends to engage more closely with managed care plans, Centers for Medicare & Medicaid Services (CMS), states, providers, vendors, and other stakeholders in each of these areas to ensure managed care programs fully achieve their dual purpose of providing more efficient, high-quality care. The Strategic Plan highlights several potential focus areas for OIG's oversight efforts, such as managed care contracting; managed care program marketing initiatives and eligibility determinations; risk adjustment processes and payment accuracy; adequacy of access to quality healthcare services; and, more broadly, the presence of overlapping fraud schemes across FHCPs.

The Strategic Plan, as well as an examination of recent fraud enforcement involving Medicare and Medicaid managed care, demonstrates OIG's growing commitment to address fraud, waste and abuse in managed care programs.

The Strategic Plan, as well as an examination of recent fraud enforcement involving Medicare and Medicaid managed care, demonstrates OIG's growing commitment to address fraud, waste and abuse in managed care programs. With the government dedicating more than $700 billion annually to managed care programs, there is little question that managed care oversight will remain a top priority for OIG in the years ahead.

Consumer Alert: OIG Alerts the Public About Remote Patient Monitoring Fraud Schemes

In November, OIG issued a "Consumer Alert" warning the public about fraud schemes in which scammers contact Medicare beneficiaries to set up monthly billing for remote patient monitoring (RPM), regardless of medical necessity. According to OIG, unscrupulous companies are contacting Medicare enrollees through phone solicitations and internet and television advertising; stealing beneficiaries' Medicare numbers and personal information; and, ultimately, signing up beneficiaries for medically unnecessary or sham monthly monitoring services. Enrollees are then billed monthly for monitoring that never occurs. While OIG acknowledges legitimate medical uses of RPM, particularly for patients suffering from chronic medical conditions, the Consumer Alert evidences OIG's enhanced focus on telehealth services and schemes.

OIG Issues Notice Reminding Healthcare Industry of End to COVID-19 PHE Flexibilities

In March, OIG issued a notice reminding the healthcare community that the flexibilities OIG implemented to assist providers during the COVID-19 PHE would end on May 11, upon expiration of the COVID-19 PHE declaration. The notice describes the flexibilities OIG initiated to alleviate burdens on the healthcare

industry following HHS's January 31, 2020, declaration of the COVID-19 PHE, including a Telehealth Policy Statement, a Policy Statement Regarding Application of Certain Administrative Enforcement Authorities (collectively, the Policy Statements), and a series of answers to Frequently Asked Questions (PHE FAQs).

In recognition of the unique patient care challenges the PHE presented, both Policy Statements relieved parties who satisfied the conditions set forth in the Policy Statement of liability for actions that might otherwise result in the imposition of administrative sanctions. The Telehealth Policy Statement permitted healthcare practitioners to remove or waive cost-sharing obligations for FHCP beneficiaries receiving telehealth services during the PHE. Similarly, the Policy Statement Regarding Application of Certain Administrative Enforcement Authorities expressed OIG's intention to exercise its enforcement discretion not to impose certain administrative sanctions for COVID-19-related remuneration covered by CMS's Blanket Waivers. Finally, through the PHE FAQs, OIG offered informal, non-binding guidance that explained how OIG viewed certain arrangements that were directly connected to the PHE and implicated OIG's administrative enforcement authorities, including the AKS and Beneficiary Inducements CMP.

The announcement makes clear that each of these flexibilities ceased on May 11 and cautions that, post-PHE, OIG may take a different position with respect to such arrangements.

OIG's Toolkit for Analyzing Telehealth Claims to Assess Program Integrity Risks

In response to the growth of telehealth services spurred by the COVID-19 pandemic, OIG released the Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks (Toolkit) in April. The Toolkit is intended to help both public and private entities analyze their telehealth claims data to assess program integrity risks and identify necessary safeguards. The Toolkit walks through five steps an entity can take to analyze claims for telehealth services and describes seven measures that may indicate fraud, waste, or abuse in such claims. The five steps are:

1. **Review program policies.** Before beginning the analysis, familiarize yourself with the relevant payment and coverage policies, including which services can be provided using telehealth.
2. **Collect claims data.** When collecting claims data, keep in mind that the process for identifying telehealth claims may vary according to the program's coverage and billing policies.
3. **Conduct quality assurance checks.** Before using the measures, conduct quality assurance checks on the data and check the data for erroneous values.
4. **Analyze data to identify program integrity risks.** Conduct the data analysis to identify program integrity risks using the measures in the Toolkit as a starting point.
5. **Interpret the results of the analysis.** Use the results of the analysis to identify program integrity risks and implement any necessary additional safeguards. Conduct any necessary follow-up with respect to the individuals identified by these measures.

The Toolkit then describes seven measures that may indicate fraud, waste, or abuse. Although these measures may indicate fraudulent billing practices, they are by no means conclusive in nature. For each program integrity measure, OIG describes what the measure is and the type of program integrity risk the measure identifies, how to calculate the measure, and how to identify providers who pose a risk to the program. The seven program integrity measures are:

1. Billing telehealth services at the highest, most expensive level for a high proportion of services.
2. Billing a high average number of hours of telehealth services per visit.
3. Billing telehealth services for a high number of days in a year.
4. Billing telehealth services for a high number of patients.
5. Billing multiple plans or programs for the same telehealth service for a high proportion of services.
6. Billing for a telehealth service and then ordering medical equipment for a high percentage of patients.
7. Billing for both a telehealth service and a facility fee for most visits.

While the COVID-19 pandemic may have officially ended, the fraud and abuse risks posed by its widespread and increased use will continue, and providers alike will need to evaluate and implement safeguards to detect and address any fraudulent practices posed by its use of telehealth services.

Significant Advisory Opinions

OIG issued 15 advisory opinions in 2023, a slight decline from the 22 opinions issued in 2022. Nearly half of the advisory opinions were issued in December 2023, with four issued in the last week of December and posted on OIG's website in the first week of 2024.

In a welcome move, OIG began including a parenthetical alongside the advisory opinion number indicating whether the opinion is favorable or unfavorable. OIG also began including a "favorable" or "unfavorable" flag in the synopses posted on its website.

When reviewing advisory opinions, it is important to remember that the bar to receiving a favorable opinion is high: to receive a favorable advisory opinion, OIG must conclude that an arrangement that implicates the AKS contains enough safeguards and is sufficiently low risk that the parties' intent is largely irrelevant. Consequently, one should not assume that an arrangement that receives an unfavorable advisory opinion violates the AKS. An unfavorable advisory opinion simply means that OIG was not comfortable enough with the arrangement to provide prospective immunity under the AKS.

Below, we highlight several noteworthy advisory opinions issued in 2023.

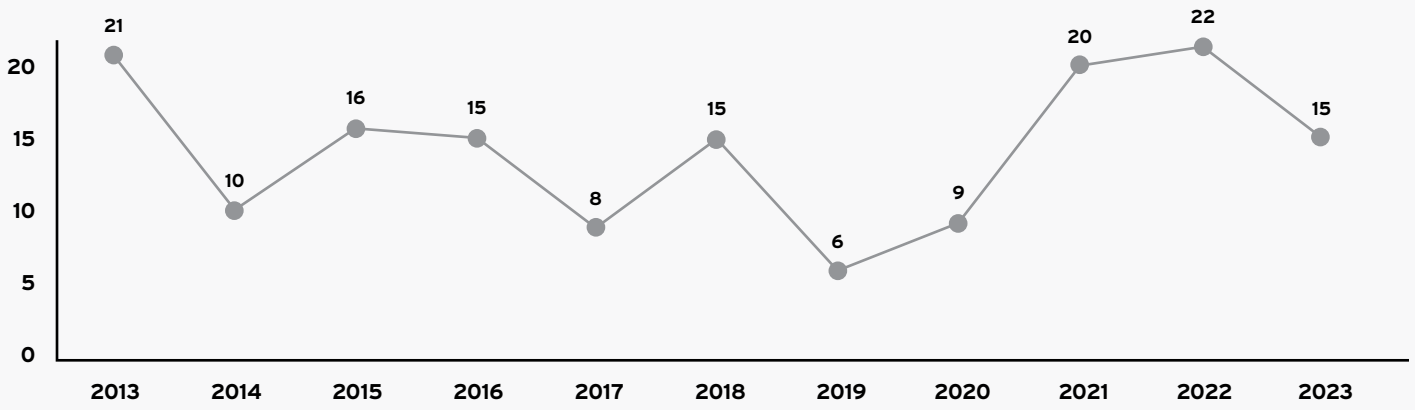
Advisory Opinion 23-01: Approving a drug manufacturer's travel and lodging assistance program for pediatric patients with a rare disorder.

On February 17, OIG issued Advisory Opinion 23-01, approving a drug manufacturer's arrangement to provide transportation, lodging, and meals to financially needy pediatric patients and their caregivers in connection with its regenerative tissue-based therapy drug.

The drug is a one-time, potentially curative FDA-approved treatment for pediatric patients with a rare immunodeficiency disorder that can be administered at only one treatment center. Patients receiving the drug are considered at high risk of infection and, therefore, are unable to safely travel long distances by car or commercial flight. Under the arrangement, the requestor offers financial assistance to patients who meet specific criteria, including distance from the treatment center and gross annual household income limits. The financial assistance would include round-trip medical flights for the patient and two

OIG Advisory Opinions

Number of Advisory Opinions Issued (FY 2013-2023)



caregivers, ground ambulance travel, modest lodging and out-of-pocket expenses.

OIG concluded the arrangement implicates the AKS because it induces patients to purchase the requestor's drug, as well as federally reimbursable items and services from the treatment center, and also because the assistance provides the treatment center and the treating surgeon with the opportunity to earn fees.

OIG determined the arrangement would not satisfy any AKS safe harbor but nonetheless presented a low risk of fraud and abuse under the AKS for a number of reasons, including:

1. The arrangement facilitates safe access to treatment for immunocompromised and financially needy patients.
2. The drug is a one-time, potentially curative treatment and is distinguishable from problematic seeding programs.
3. The arrangement is unlikely to interfere with clinical decision-making or result in overutilization.
4. The arrangement is unlikely to increase costs to FHCPs, and may offset the supportive care costs of this population in the first three years of life and beyond.
5. The fees the treatment center would receive for implanting the drug presented a sufficiently low risk under the AKS for a combination of these factors.

OIG also determined that, although the manufacturer is not a "provider, practitioner, or supplier" under the Beneficiary Inducements CMP, the arrangement nonetheless could influence beneficiaries to obtain the drug and receive other reimbursable items and services from the treatment center. Still, OIG concluded that the arrangement did not constitute grounds for sanctions because the drug's limited availability was the factor likely to influence a patient to select the treatment center, not the remuneration the requestor would provide under the arrangement.

Favorable travel and lodging opinions continue to be a trend for OIG, but we note that they are highly fact-specific to the nature of the drug or the disease.

Advisory Opinion 23-02: Approving a "quick start" free drug program for a population comprised primarily of FHCP beneficiaries.

On February 23, OIG issued Advisory Opinion 23-02, approving a pharmaceutical company's proposal to provide up to a 28-day free supply of an enzyme replacement therapy to treat patients with an extremely rare inherited genetic disorder who face insurance delays. Under the proposed arrangement, the requestor—the pharmaceutical manufacturer who manufacturers the only therapy approved in the United States to treat patients with an otherwise-fatal inherited genetic disorder—proposed to offer a free 14-day supply of the drug to individuals who were prescribed, but who have not yet been treated with, the drug, and who have experienced a minimum 48-hour coverage delay for insurance approval. Patients may access an additional 14-day supply of the drug if coverage was initially denied and timely appealed. The drug is not curative and the only therapeutic alternative is a bone marrow transplant. The requestor works exclusively with one specialty pharmacy to dispense the drug. As of July 2021, 49 patients in the United States were receiving the drug, 38 of whom were FHCP beneficiaries.

OIG concluded that the proposed arrangement would present a minimal risk of fraud and abuse under the AKS for a combination of reasons. Specifically, the condition's rarity meant overutilization was unlikely, prescribers would not receive any special benefit under the program, and the program did not increase costs to the FHCPs. OIG also cited the fact that the program would not inappropriately induce the use of a specialty pharmacy (because only one specialty pharmacy provides the drug) and the requestor's certification that it would not advertise the program as safeguards. Finally, OIG distinguished the program from problematic "seeding" programs because the free drug would be offered only in the event of an insurance coverage delay.

OIG also concluded that the program would not implicate the Beneficiary Inducements CMP with respect to the requestor, because pharmaceutical manufacturers are not providers, practitioners, or suppliers and that the program would be unlikely to influence a beneficiary to purchase the drug from the specialty pharmacy because the specialty pharmacy is the only pharmacy that dispenses the drug.

As we see a significant increase in innovative medications for rare diseases, it is important to remember that OIG's favorable "quick start" opinions involve

nuanced analyses that are narrowly tailored to the disease, the drug, and the patient population at issue.

Additional information from our client alert can be found here: OIG Approves Free Drug Program for Ultra-Rare Condition in Advisory Opinion 23-02.

Advisory Opinion 23-03: A favorable gift card opinion reminds stakeholders of separate analyses under AKS and Beneficiary Inducements CMP.

On March 24, OIG issued Advisory Opinion 23-03, approving a proposal by a manufacturer of at-home cancer screening tests and its wholly-owned laboratory to provide gift cards to certain patients as an incentive to return their screening samples for testing.

The requestors are the manufacturer of the only FDA-approved non-invasive at-home colorectal cancer screening test and its wholly owned laboratory, which performs and processes the testing. Under the proposed arrangement, the requestors would send a reminder letter promising a prepaid gift card of up to $75 to patients who had not returned their samples in a timely manner after at least two outreach attempts if those patients returned the test kit by a specific date. The gift card would not be redeemable for cash and would not be reloadable after use.

The requestors proposed numerous safeguards to prevent fraud and abuse, including the following:

1. Mailing the gift cards only to those patients who return the kits by the deadline specified in the reminder letter.
2. Advising patients that they may not use the gift cards on items or services provided by the requestors.
3. Limiting patients to one gift card every 36 months, which is consistent with Medicare's coverage period for the screening test.
4. Prohibiting advertising or marketing the gift cards to patients or healthcare providers who may order the test.

OIG first concluded that the proposed arrangement would not generate prohibited remuneration under the Beneficiary Inducements CMP because it would satisfy the requirements of the exception to the definition of remuneration for incentives given to beneficiaries to promote the delivery of preventive care.

OIG then went on to analyze the proposed arrangement under the AKS, noting that its conclusion that the gift card does not constitute remuneration under the Beneficiary Inducements CMP does not require it to conclude that the proposed arrangement is low risk under the AKS. Still, citing the numerous safeguards listed above, OIG concluded that the proposed arrangement posed a minimal risk of fraud and abuse because it is unlikely to result in overutilization or inappropriately increase costs to FHCPs and encourages patient compliance with a test recommended by the U.S. Preventive Services Task Force (USPSTF), the American Cancer Society, and CMS.

This opinion is noteworthy because OIG highlighted the different analyses under the AKS and the Beneficiary Inducements CMP and cautioned that if any of the facts supporting the proposed arrangement were different, the agency would likely reach a different conclusion with respect to the risk presented by this type of arrangement under the AKS regardless of whether the arrangement satisfied an exception to the Beneficiary Inducements CMP.

Additional information from our client alert can be found here: OIG Approves Gift Cards to Promote Patient Compliance with a Preventive Screening Measure.

Advisory Opinion 23-04: Providing a rare glimpse into how OIG analyzes closely related but slightly varied arrangements.

On July 6, OIG issued Advisory Opinion 23-04, approving the per-booking fees healthcare providers pay the requestor-technology company for each new patient who books an appointment through the requestor's online platform (per-booking fees) and the per-click and per-impression fees the requestor charges for advertising on the platform.

The advisory opinion—which was requested by the same party that requested Advisory Opinion 19-04, itself approving a similar arrangement—addresses aspects of the requestor's online platform that were not covered by the earlier opinion, along with proposed changes to the platform's

Comparing Advisory Opinion 23-04 and Advisory Opinion 19-04 offers the rare opportunity to see OIG's analysis of closely related but slightly varied arrangements.

algorithm and search results. OIG concluded that the arrangement, both before and after the proposed changes, implicates the AKS and the Beneficiary Inducements CMP because the per-booking, per-click and per-impression fees all result in the requestor being paid to arrange for or recommend services paid for by FHCPs, and because beneficiaries' free use of the platform may induce them to purchase federally reimbursable services or, more generally, influence their provider selection.

Nonetheless, OIG stated it would not impose sanctions under either law due to the following reasons:

1. The fees are fair market value and do not vary with the business the requestor generates for providers.
2. The requestor's algorithm does not favor providers based on the fees they pay.
3. The requestor planned to implement transparency safeguards for providers hitting a monthly spend-cap.
4. The requestor is not a healthcare provider.
5. The requestor's advertising and platform are general and passive in nature and do not specifically target FHCP beneficiaries or promote certain items and services.
6. The remuneration provided to FHCP beneficiaries is limited to the functionality of the requestor's platform.

Advisory Opinion 23-04 illustrates the breadth of the AKS and Beneficiary Inducement CMP—even technology companies that do not furnish items or services payable by FHCPs must be aware of the risks created when they are paid to facilitate connections between patients and providers or advertise for providers, and when they offer free services to beneficiaries. In addition, comparing Advisory Opinion 23-04 and Advisory Opinion 19-04 offers the rare opportunity to see OIG's analysis of closely related but slightly varied arrangements. While OIG heavily scrutinizes marketing, the opinion demonstrates that, in certain limited circumstances, per-booking, per-click and similar fees can pose low risk.

Additional information from our client alert can be found here: OIG Approves Online Platform's Per-Booking Fees for Medical Appointments and Per-Click Fees for Advertisements.

Advisory Opinion 23-05: A proposed contractual joint venture in the intraoperative neuromonitoring space with an unsurprising result.

On August 15, OIG issued Advisory Opinion 23-05, finding that an entity's proposal to facilitate referring surgeons' ownership of turnkey intraoperative neurophysiological monitoring (IONM) companies could violate the AKS.

IONM is used to monitor a patient's neural pathways during surgery and prevent damage to neurological structures. It involves both a technical and a professional component. The requestor typically contracts directly with ASCs and hospitals to perform the technical component of the IONM services and arranges for neurologists who are employed or engaged as independent contractors by a physician practice that has a management services agreement with the requestor to perform the professional component.

The requestor sought to assist referring surgeons in the formation of a new entity to provide IONM services. Through a series of personal service agreements and leases with the requestor and its managed practice, the new entity would delegate its day-to-day operations to the requestor and the requestor would provide or arrange for the technical and professional components of the IONM services. The new surgeon-owned entity would generate profits by contracting directly with and billing ASCs and hospitals for the technical component while billing payors for the remote professional component. The new entity would receive certain discounts on the services provided by or arranged for by the requestor and thus stand to increase its profit margins. Although the requestor certified that it would attempt to carve out FHCP business, it could not guarantee the efficacy of the carve-out.

OIG concluded the proposed arrangement would implicate the AKS and pose a significant risk of fraud and abuse, highlighting the inherent risks in arrangements where surgeon-owners expand into a new service line, contract significant operations out to a would-be competitor, and share in the profits generated by their referrals. OIG determined that at least some of the remuneration would not qualify for protection under any safe harbor, pointing to the surgeon-owned entity's opportunity to generate substantial profits through the difference between its payments to the requestor for the

requestor's administrative and professional services and the revenue the surgeon-owned entity would generate from directly billing ASCs, hospitals, and payors for IONM services. OIG also highlighted the minimal business risks the physician owners would encounter because of their ability to direct business to the new venture.

This request appears to have been designed to draw an unfavorable response from OIG and bears many hallmarks of OIG's past guidance regarding suspect contractual joint ventures. That it involves the IONM industry merely demonstrates that OIG's concerns remain alive and well in the remote monitoring age.

Additional information from our client alert can be found here: Expect the Expected: OIG Remains Suspicious of Suspect Contractual Joint Ventures in Advisory Opinion Involving IONM Industry.

Advisory Opinion 23-06: A laboratory "carve-out" arrangement with an unusual certification.

On September 25, OIG issued Advisory Opinion 23-06, declining to approve an anatomic pathology laboratory's proposal to purchase technical component (TC) services for commercially insured patients from out-of-network pathology laboratories.

The requestor operates laboratories that perform both the TC and the professional component (PC) of anatomical pathology services. Under the proposed arrangement, the requestor would enter into written agreements with laboratories that also are capable of performing both TC and PC services, but that cannot directly bill commercial payors with which they are not in-network. The requestor, which is in-network with the commercial payors, would pay the laboratories a fair market value fee for the TC services, perform the PC services itself, and then submit a global claim to the commercial payors for both the TC and PC services.

The outcome in Advisory Opinion 23-06 is noteworthy because it hinged on the requestor's certifications, including the highly unusual certification that the arrangement was commercially unreasonable and likely would involve referrals of federal healthcare program business.

The requestor certified the following:

1. Its agreements with the laboratories would not meet the commercial reasonableness requirement of the personal services and management contracts safe harbor.
2. It could perform the TC services at a lower cost in the absence of the proposed arrangement.
3. The proposed arrangement "likely would result" in referrals of FHCP business even though the arrangement was not conditioned on such referrals.

Despite the fair market value fee and FHCP business carve-out, OIG concluded that the arrangement could function as a mechanism to pay remuneration to potential referral sources of federally reimbursable laboratory services, in violation of the AKS.

Although OIG applied familiar principles in reaching its conclusion, the outcome is noteworthy because it hinged on the requestor's certifications, including the highly unusual certification that the arrangement was commercially unreasonable and likely would involve referrals of federal healthcare program business.

Additional information from our client alert can be found here: Labs Take Note: New OIG Opinion Highlights that FMV Per Test Payments Can Still Violate the AKS.

Advisory Opinion 23-07: Approving the payment of bonuses based on ASC profits to employed physicians.

On October 10, OIG issued Advisory Opinion 23-07, approving a physician practice's proposal to pay its physician-employees a bonus based on facility fee profits from procedures performed at the practice's two ASCs, both of which were part of the same legal entity as the physician practice.

The requestor, a multi-specialty physician practice with approximately 11 physician-employees, proposed to pay each physician-employee a bonus equal to 30% of the net profits from the ASC facility fees attributable to the

physician's procedures. The requestor did not ask OIG to opine on distributions of the remaining 70% of the ASCs' net profits. Also noteworthy is the fact that the requestor certified that it would not furnish "designated health services" (as defined by the federal physician self-referral law, or Stark Law, as it is commonly known)—circumstances that are unusual for a multi-specialty practice that operates two ASCs.

OIG concluded that the proposed arrangement would not generate prohibited remuneration under the AKS. Specifically, because the requestor certified that the physicians were bona fide employees of the requestor and because the bonuses would constitute payment for employment in the furnishing of federally reimbursable items or services, OIG concluded the bonus payments would be protected by the employment safe harbor.

OIG cautioned that "[p]ayment structures that tie compensation to profits generated from services furnished to patients referred by the compensated party are generally suspect" under the AKS. But the employment safe harbor can protect such payments if (1) the compensation is from an employer to a bona fide employee and (2) the employment is for the furnishing of items or services payable by FHCPs.

As always, this opinion is limited to the requestor and to the particular facts and circumstances described by the requestor, which, as noted above, are somewhat unusual. Where a physician group owns and operates an ASC, it often does so through a separate legal entity. OIG's analysis leaves open the question of whether similar bonus payments would violate the AKS in cases where the ASC is a wholly-owned subsidiary rather than a division of the employer.

Additional information from our client alert can be found here: OIG Approves Paying Employed Physicians Profits from ASCs Operated by Employer.

Advisory Opinion 23-08: A proposal to provide free items that yields a predictable result.

On October 20, OIG issued Advisory Opinion 23-08, declining to approve a proposal by a manufacturer and distributor of hearing solutions to provide a free compatible hearing aid to certain patients who would receive the requestor's cochlear implant.

The requester sells cochlear implant devices, which do not rely on the use of a hearing aid to function properly, to hospitals and ASCs. The requestor proposed to offer eligible patients a bimodal hearing bundle consisting of the cochlear implant and sound processor along with a free, compatible hearing aid. The requestor certified that it would condition receipt of the free hearing aid upon purchase of the cochlear implant device. The requestor acknowledged that the patients and providers at the hospitals and ASCs would have knowledge of the arrangement, including the provision of free hearing aids, and that its cochlear implant is not more clinically appropriate than similar implants from other manufacturers and does not rely on the hearing aids to function properly.

Notwithstanding the seemingly altruistic nature of the proposed arrangement, OIG's refusal to approve Advisory Opinion 23-08 offers a good reminder that OIG evaluates arrangements holistically.

The requestor proposed several safeguards to mitigate risks of fraud and abuse, including requiring hospitals and ASCs to certify they would not bill FHCPs for the hearing aids, advising patients and providers they could not claim insurance reimbursement for the hearing aid, only charging customary fees for related ancillary services, and proposing to establish financial need criteria for the program.

OIG concluded the proposed arrangement would implicate the AKS and expressed its longstanding concerns regarding the provision of free items and services to FHCP beneficiaries. OIG then declined to approve the proposed arrangement, citing its concerns that the offer of a free hearing aid would encourage eligible patients to choose the requestor's cochlear implant bundle over a competitor's device or a more clinically appropriate item.

OIG concluded the proposed arrangement also would implicate the Beneficiary Inducements CMP because the free hearing aid could influence beneficiaries to select the requestor's cochlear implant. OIG noted that because the hearing aid was not required for the cochlear implant to work properly but was nonetheless conditioned on the purchase of the implant, neither the promotes access to care exception nor the financial need-based exception applied.

Notwithstanding the proposed arrangement's apparent benefits, OIG's refusal to approve it offers a good reminder that OIG evaluates arrangements holistically. Here, OIG looked beyond the beneficial aspects of the arrangement and focused

on harms such as steering, unfair competition, improper utilization, and quality and cost concerns.

Additional information from our client alert can be found here: Déjà vu? OIG Reiterates Concerns about Providing Free Items or Services to Federal Healthcare Program Beneficiaries.

Advisory Opinion 23-11: A cost-sharing subsidy that facilitates diversity in a clinical trial.

On December 21, OIG issued Advisory Opinion 23-11, approving a medical device manufacturer's proposal to subsidize certain Medicare cost-sharing obligations in a clinical trial for which the device manufacturer serves as the sponsor. The medical device-based therapy is designed to modulate the strength of cardiac muscle contraction in patients experiencing heart failure and is currently FDA-approved for use in patients who satisfy certain criteria. The clinical trial the requestor is sponsoring is designed to determine the therapy's safety and efficacy in a different category of patients. The FDA awarded the device-based therapy "Category B Investigational Drug Exemption" status, which allows the device to be used in a clinical trial for the investigational indication, and CMS approved the study, thus making the items and services furnished in the study eligible for Medicare reimbursement.

Under the proposed arrangement, the requestor would pay Medicare beneficiaries' cost-sharing obligations for items and services furnished in connection with the study directly to the study sites, up to a maximum of $2,000 per person. The requestor would not advertise the subsidies to prospective study participants. The requestor stated that the subsidies would reduce financial barriers to enrollment and prevent attrition from the study due to financial reasons, facilitate socioeconomic diversity of the study population, and preserve blinding of participants.

OIG concluded that the proposed arrangement would implicate the AKS because the subsidies could induce Medicare beneficiaries to participate in the study, as well as the Beneficiary Inducements CMP because the subsidies could influence Medicare beneficiaries to receive items and services from a particular provider, practitioner, or supplier. OIG also concluded that the subsidies would constitute remuneration to the sites participating in the study under the AKS.

OIG nevertheless approved the arrangement, highlighting three reasons for this conclusion. First, OIG concluded that the proposed arrangement "appear[ed] to be a reasonable means of promoting enrollment" in the study, particularly with respect to socioeconomically diverse participants, and could reduce the likelihood that participants would fail to complete the 18-month study course. Second, the proposed arrangement posed a low risk of overutilization or inappropriate utilization because CMS evaluated and approved the study, and study participants must satisfy objective enrollment criteria. Third, the proposed arrangement is distinguishable from problematic seeding arrangements because the device-based therapy is intended to be a one-time treatment.

Arrangements involving cost-sharing subsidies remain a hot topic for stakeholders seeking to provide medically necessary items and services to patients and to regulators charged with protecting public resources. Subsidies in the clinical trial setting are a special subset of OIG's analytical framework, as this opinion demonstrates. OIG offers insight into the safeguards that reduce risk, but no two arrangements are the same, and stakeholders must closely evaluate subsidy programs.

Advisory Opinion 23-12: Approving a redemption offer based on objective criteria.

On December 28, OIG issued Advisory Opinion No. 23-12, approving a physician-owned hospital's offer to redeem over a two-year period the ownership interests of physicians who turn 67 and agree to retire within six months.

The requesting party is a limited liability partnership that operates a hospital and wholly owns a subsidiary that operates a second hospital. The partnership agreement permits a one-time payment for redemption upon a physician's retirement from the practice of medicine but does not require retirement at a particular age. Concerned that it could face a liquidity crunch if numerous physician-partners retire in close succession, the partnership elected to extend a one-time offer to physician-owners who turn 67 to redeem their units over the course of two years and indicated that it expects to continue doing so each year.

To accept the redemption offer, physician-owners must agree to retire from the practice of medicine within six months of receiving the first payment and must certify in writing that they will not refer patients to the hospitals or the other partners in the partnership as of the earlier of their retirement date or the date they no longer satisfy the partnership agreement's eligibility requirements. The partnership would redeem the units of physician-owners who accept the offer in three equal installments over the two-year period at a fair market value price as of each redemption date. Because the units' value

could increase over the two-year period, it is possible that physician-owners who accept the voluntary redemption offer would receive more money than those whose units are redeemed all at once.

OIG determined that the redemption offer implicates the AKS because it involves offering (and, if the offer is accepted, paying) remuneration to the physician-owners, each of whom is in a position to refer FHCP business to the hospitals. Although the arrangement would not meet a safe harbor, OIG concluded that it posed sufficiently low risk under the AKS because:

1. Eligibility for the redemption offer is unrelated to the volume or value of referrals or other business generated by the physician-owners (rather, it is based on an objective criteria—turning 67 years old during the calendar year).
2. The remuneration is unlikely to result in unfair competition by altering referral patterns.

Taking into account referrals or other business generated in redemptions or offerings—when determining whose interests are repurchased, to whom interests are offered, or the apportionment of investment opportunities—can result in violations of the AKS and the federal physician self-referral law (Stark Law), as recent enforcement actions suggest. On the other hand, basing redemptions and offerings on objective criteria unrelated to the volume or value of referrals or other business generated and then applying those criteria consistently to all physicians reduces the risk of non-compliance, as this advisory opinion illustrates.

Additional information from our client alert can be found here: OIG Approves Hospital's Redemption Offer to Retiring Physician-Owners.

Advisory Opinion 23-15: Approving the offer of gift cards in return for marketing, but only when the marketed services are not federally reimbursable.

On December 28, OIG issued Advisory Opinion 23-15, approving a physician practice consultant's proposal to offer gift cards to its customers when they recommend the requestor's services to other physician practices.

The requestor provides various consulting services to physician practice clients, including data analytics, workflow optimization, EHR consulting, and services relating to the Merit-Based Incentive Payment System (MIPS) program. Under the MIPS program, eligible providers must report annually on certain performance measures across different categories and can earn payment adjustments from the CMS based on their performance in those categories. The requestor's consulting fees do not take into account whether a customer earns any MIPS-related payment adjustment, though the requestor acknowledged that its consulting services could generate higher Part B reimbursements for its physician customers.

Under the proposed arrangement, the requestor would offer up to $75 in gift cards to existing physician practice customers who recommend the requestor's consulting services to prospective customers. Notably, the requestor certified to OIG that the services it performs, including its MIPS consulting services, are not payable, in whole or in part, directly or indirectly, by any FHCP. The requestor also certified that it does not recommend to any customer the purchasing, leasing or ordering of any item or service for which payment may be made by an FHCP.

Relying on the requestor's certifications, OIG concluded that the proposed arrangement would not implicate the AKS because the gift cards would not be in return for the physician practice customers' recommendation of federally reimbursable items or services and because the requestor does not recommend to any customer the ordering of any federally reimbursable item or service.

Although OIG's conclusion in Advisory Opinion 23-15 is straightforward, arrangements for marketing services that do not satisfy a safe harbor ordinarily are suspect under the AKS. Consequently, OIG may have reached a different conclusion in Advisory Opinion 23-15 if the requestor's consulting services were reimbursed by an FHCP or used in the furnishing of federally reimbursable items or services.

Additional information from our client alert can be found here: OIG Approves the Use of Gift Cards to Reward Customers' Marketing Efforts.

Significant SDP Settlements

OIG regularly publishes summaries of settlements resulting from its Health Care Fraud Self-Disclosure Protocol (SDP). The summaries are short on detail but provide concrete examples of potential violations of the fraud and abuse laws and other compliance issues. In 2023, OIG posted 79 enforcement actions

resolved through the SDP, a slight uptick from the 70 settlements in 2022. The most common alleged violations involved excluded persons (24), kickbacks (18), unlicensed persons (10), upcoding or similar billing issues (8), and incident-to or split/shared billing (4).

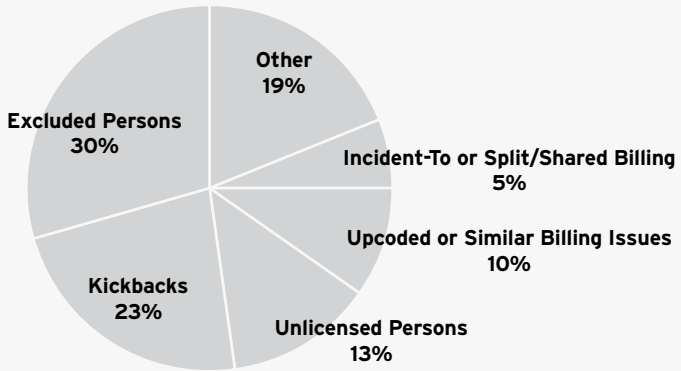
The increase in enforcement actions resulted in more than $47 million in settlement payments. Twelve settlements accounted for over $33 million and averaged $2.7 million. The remaining 67 settlements totaled almost $14 million and ranged from $20,000 to just under $1 million.

Numerous settlements involved providing free or below fair market value services to referral sources, including:

- A health system in Florida agreed to pay $2.4 million for allegedly providing a physician group free or below fair market value space, equipment, and personnel.
- A health system in California agreed to pay $515,000 for allegedly providing free management services to a surgery center.

OIG Enforcement Actions

Advisory Opinions Resolved through SDP in 2023, Most Common Alleged Violations



- A health system in Florida agreed to pay $241,000 for allegedly providing space for less than fair market value to a physician practice.
- A health system in Alabama agreed to pay $100,000 for allegedly providing oncologists free office space.
- A health system in Florida agreed to pay $100,000 for allegedly providing personnel to a physician practice for less than fair market value.
- A health system in Michigan agreed to pay $100,000 for allegedly providing the services of advanced practice providers at no cost to physicians who referred surgery patients to the health system. Compare these circumstances to those addressed in Advisory Opinion 22-20, which we covered in our client alert, which can be found here: OIG Approves Hospital Provision of Nurse Practitioner Services in Advisory Opinion.
- A clinical laboratory in Massachusetts agreed to pay $641,000 for allegedly providing three physician practices with phlebotomists who performed duties that were outside of the scope of their phlebotomy duties, circumstances covered in a 1989 Special Fraud Alert.
- A radiology practice in New York agreed to pay $66,000 for providing referring practices free scheduling activities that were previously performed by the referring physicians' personnel.
- A clinical laboratory in New York agreed to pay $50,000 for allegedly providing primary care practice services for which the laboratory charged less than fair market value.

Two other kickback-related settlements stemmed from ASCs allegedly paying unlawful remuneration based on the volume or value of physicians' referrals to the ASCs:

- An ASC in Michigan agreed to pay nearly $1.2 million for allegedly offering a group additional ownership shares in the ASC based on the volume or value of the group's future referrals.
- An ASC in Utah agreed to pay $448,938 for allegedly distributing profits to physicians based on the volume or value of their referrals.

Compare these two settlements with the circumstances in Advisory Opinion 23-07, which we cover on page 13.

Other notable settlements allegedly involved upcoding, violating certain billing rules, providing medically unnecessary services, or furnishing services through unlicensed persons, including:

- A physical therapy practice in Michigan agreed to pay $12 million for allegedly submitting claims related to billing certain Medicare Advantage plans for time-based CPT codes for physical therapy services when its therapists did not treat the patients for the required time and for routinely performing and billing for medically unnecessary patient reevaluations.
- A health system in Illinois agreed to pay $4 million for submitting claims for audiology services billed under a certain CPT code that were allegedly false because its audiologists did not read, interpret, or sign automated test results.
- A medical college in Wisconsin agreed to pay $2.2 million for allegedly submitting false anesthesia claims because physicians failed to properly perform and document the seven steps of medical direction as required.
- A physician practice in California agreed to pay $1.8 million for allegedly submitting claims for services provided by non-physician providers who were not properly credentialed with FHCPs, for services that did not comply with the incident-to billing rules, and for services that did not comply with the split/shared billing rules.
- A hospital and its affiliated physician practice in Virginia agreed to pay $528,000 for an employed podiatrist's alleged submission of upcoded claims and the hospital's corresponding claims for provider-based facility claims.
- A pharmacy in Louisiana agreed to pay $361,000 for allegedly paying unlawful commissions to an entity in exchange for marketing services.
- A health system in Florida agreed to pay $136,000 for allegedly submitting claims for services provided by unlicensed nurses. OIG calculated the damages as the full salary and benefits paid to the nurses during the period they worked without a valid license and did not reduce the damages by the employer's FHCP payor mix, as it does with excluded persons. This methodology is consistent with an FAQ on unlicensed individuals who do not directly bill FHCPs that OIG published in 2023.

Direct Challenges to OIG Continue to Fail, for Now

In last year's HHS-OIG YIR, we covered two lawsuits against HHS and OIG challenging OIG's application of the AKS in two unfavorable advisory opinions based on alleged First Amendment and Administrative Procedure Act (APA) violations. In the first suit, Pfizer challenged OIG's interpretation of the AKS in an unfavorable advisory opinion (Advisory Opinion 20-05) regarding a proposed patient assistance program. As we previously covered in our 2022 HHS-OIG YIR, OIG prevailed in the Southern District of New York and again in the Second Circuit. The case concluded in early 2023 when the Supreme Court denied Pfizer's petition for certiorari.

The court concluded that OIG's interpretation of the AKS in Advisory Opinion 22-19 adheres to the statute's plain text, comports with its context, and does not offend its history.

In a similar suit, the Pharmaceutical Coalition for Patient Access (PCPA) sued OIG in the Eastern District of Virginia on a number of grounds after OIG issued PCPA an unfavorable advisory opinion regarding a "coalition" model patient assistance program. Like Pfizer, PCPA directly challenged OIG's application of the AKS, asserting that the phrase "to induce" within the AKS requires both a *quid pro quo* exchange and an element of corruption. On January 17, 2024, the district court rejected PCPA's reading of the AKS and its challenge to OIG's unfavorable advisory opinion, granting OIG's motion to dismiss for lack of subject matter jurisdiction and its motion for summary judgment. The court concluded that OIG's interpretation of the AKS in Advisory Opinion 22-19 "adheres faithfully [to] the statute's plain text, comports with its context, and does not offend its history."

If PCPA appeals the decision in the Fourth Circuit, the potential circuit split could set the stage for the Supreme Court to review these fundamental AKS issues.

About Bass, Berry & Sims

Marked by an integrated approach and unmatched healthcare regulatory knowledge, the Healthcare Industry Group at Bass, Berry & Sims is a team of more than 260 experienced healthcare attorneys who leverage their diverse strengths to meet the unique demands of our clients. Over the years, Bass, Berry & Sims has contributed to the evolution of Nashville as the nation's capital of healthcare delivery and entrepreneurialism. From this experience, we know that issues impacting healthcare organizations require a multidisciplinary team informed by historical perspective. Because of this depth, the firm was ranked as the fourth largest healthcare law firm in the U.S. by Modern Healthcare (2023) and fourth largest by American Health Law Association (2023).

Given the complexity of fraud and abuse laws and the level of scrutiny faced by the healthcare industry, it is critical to have experienced fraud and abuse counsel in your corner. Whether our clients are facing a government enforcement action or investigation, conducting an internal/compliance investigation, evaluating an existing arrangement or structuring a new arrangement, our Regulatory Group has the understanding and experience to assist clients in navigating these complex issues. Our talented team of lawyers brings decades of government and industry experience together to devise practical solutions to your most complex fraud and abuse issues.

Click here to view our 11th annual Healthcare Fraud & Abuse Review highlighting significant civil and criminal enforcement issues.

To learn more about our team, industry experience and value-add, visit our website.

AMERICAN HEALTH LAW ASSOCIATION

Ranked 4th Largest Healthcare Law Firm in the U.S. (2023)

Modern Healthcare

Ranked 4th Largest Healthcare Law Firm in the U.S. (2023)

Chambers TOP RANKED USA 2023

Nationally Ranked Healthcare Firm for Eight Consecutive Years (2023)

KRISTIN M. BOHL

Member | 202.827.2987 | kristin.bohl@bassberry.com

Kristin Bohl blends her experience as a healthcare attorney in private practice and government service with first-hand knowledge of care delivery as a registered nurse. Kristin advises hospitals, health systems, and other provider organizations on compliance and regulatory issues and fraud and abuse matters, with a focus on the wide range of Medicare payment models. Before she entered private practice, Kristin was the Technical Advisor in the Division of Technical Payment Policy at CMS. She was part of a team that developed the CMS Voluntary Self-Referral Disclosure Protocol and provided technical assistance in the creation of Stark Law waivers for Accountable Care Organization (ACO) models and other payment initiatives of the Center for Medicare and Medicaid Innovation within CMS.

JUSTIN K. BROWN

Member | 615.742.7725 | justin.brown@bassberry.com

Justin Brown focuses on healthcare fraud and abuse matters, particularly those involving the federal physician self-referral law (Stark Law), the federal Anti-Kickback Statute, and state analogs. He represents hospitals and health systems, ambulatory surgery centers, post-acute care providers, and physician practices, along with their strategic and financial sponsors, regularly serving as healthcare regulatory counsel for transactions, enforcement actions, and internal investigations, and advising on day-to-day operations. Before entering private practice, Justin was a trial attorney in the Massachusetts public defender's office.

DEE HARLESTON

Associate | 202.827.7099 | dee.harleston@bassberry.com

Dee Harleston provides healthcare regulatory counsel on mergers, acquisitions, compliance, and operational matters. He also represents healthcare-focused private equity clients and their portfolio companies in buy-side and sell-side mergers and acquisitions. In addition, Dee advises clients related to compliance with federal healthcare laws such as HIPAA, AKS, Stark Law, and CMP and in matters of medical licensure.

STEWART W. KAMEEN

Member | 202.827.2962 | stewart.kameen@bassberry.com

Stewart Kameen draws on his experience as a former Senior Counsel in the Industry Guidance Branch at HHS-OIG, where he handled OIG advisory opinion requests, drafted several proposed and final regulations associated with the Regulatory Sprint to Coordinated Care, and consulted with DOJ relating to various enforcement matters. Stewart advises healthcare clients on all aspects of federal and state healthcare laws and regulations, with a particular emphasis on fraud and abuse regulatory counseling, corporate compliance, internal investigations and government enforcement actions, *qui tam* litigation, and transactional matters.

TRAVIS G. LLOYD

Member | 615.742.6208 | travis.lloyd@bassberry.com

Travis Lloyd focuses on complex healthcare regulatory matters. He represents a broad range of healthcare industry clients, including hospitals and health systems, ambulatory surgery centers, post-acute providers, behavioral health providers, and physician practices, as well as their strategic partners. A substantial portion of Travis's practice involves advising clients on fraud and abuse issues, including those that relate to AKS and the Stark Law. His experience includes guiding healthcare providers through thorny compliance issues, obtaining advisory opinions, managing internal compliance reviews and investigations, and making voluntary disclosures to government entities.

WILLIAM T. MATHIAS

Member | 202.827.2982 | bill.mathias@bassberry.com

Bill Mathias is a healthcare regulatory attorney with a focus on fraud and abuse and Stark Law issues. He works with healthcare organizations to structure complex business arrangements, including joint ventures and strategic transactions, to manage risk while meeting their business objectives. Bill is a recognized leader on the federal AKS, the Stark Physician Self-Referral Law, EKRA, and the federal Civil Monetary Penalty (CMP) regulations. He regularly assists with government investigations and defending FCA lawsuits and other enforcement actions.

JENNIFER E. MICHAEL

Member | 202.827.2960 | jennifer.michael@bassberry.com

Jennifer Michael draws on her experience as the former Chief of the Industry Guidance Branch at HHS, Office of Counsel to the Inspector General (OCIG) to help healthcare providers and life science companies avoid potential fraud and abuse landmines and defend them in fraud and abuse investigations. Jennifer helps her clients structure their arrangements to comply with the federal AKS, the federal CMP law, and other state and federal fraud and abuse laws and navigate government investigations under the federal FCA. She also leads internal investigations for healthcare companies to identify and quantify potential overpayments from federal healthcare programs; advises on fraud risks of existing and proposed arrangements in connection with pending and proposed transactions; and designs, implements, and evaluates compliance programs.

CHRISTINE M. MORSE

Member | 202.827.2986 | christine.morse@bassberry.com

Christine Morse advises a wide range of healthcare companies on fraud and abuse claims, reimbursement issues and regulatory compliance. She has extensive experience advising provider organizations on key federal healthcare laws, such as the Stark Law, the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). Christine is experienced in conducting compliance effectiveness reviews for numerous types of organizations and providers and frequently advises clients on Office of Inspector General (OIG) and Department of Justice (DOJ) guidance on compliance programs. She has also counseled healthcare companies in numerous investigations led by federal and state law enforcement, and implemented legal strategies for clients on all aspects of government probes.

HEATHER M. PEARSON

Associate | 202.827.7093 | heather.pearson@bassberry.com

Heather Pearson provides healthcare regulatory and transactional counsel as it relates to compliance, operational matters, and mergers and acquisitions. Heather draws on her experience as a public health analyst at RTI International, focusing on program evaluation and health system financing for CMS, and her judicial clerkships in the Minnesota Court of Appeals and the U.S. District Court for the Northern District of Indiana. During law school, she summered at the Center for Health Law & Policy Innovation at Harvard Law School and in the Office of the Chief Counsel at the FDA.

BRIANNA R. POWELL

Associate | 615.742.7883 | brianna.powell@bassberry.com

Brianna Powell provides healthcare regulatory counsel to a wide range of clients, including physician groups, hospices, hospital systems, long-term care providers, and private equity firms. Brianna advises clients on an array of complex regulatory issues, including developing and implementing compliance programs based on the elements considered necessary for a comprehensive compliance program by the Federal Sentencing Guidelines and Office of Inspector General's (OIG) Compliance Program Guidance. She also advises on compliance with state and federal healthcare statutes and regulations such as the Stark Law, Anti-Kickback Statute, Civil Monetary Penalties Law, and False Claims Act.

PAGE MINTON SMITH

Associate | 615.742.7706 | page.smith@bassberry.com

Page Smith helps clients navigate the evolving healthcare regulatory landscape impacting daily operations, compliance and reimbursement matters. She focuses her practice on federal and state administrative appeals and proceedings, including Provider Reimbursement Review Board appeals, payor claims audit appeals, certificate of need proceedings and other regulatory and administrative matters before various agencies, such as state boards of medical examiners. Page also provides guidance in government enforcement and compliance matters, analyzing compliance program documents, conducting internal investigations and advising on the reporting and repayment of overpayments and a provider's response to governmental inquiries.