HHS-OIG

YEAR IN REVIEW

Examining key guidance OIG issued in 2025 for the healthcare industry.

BASS BERRY SIMS

Go confidently.

Introduction

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) is the largest inspector general's office in the federal government and is tasked with providing oversight to more than 100 federal health and welfare programs, including Medicare and Medicaid. OIG plays a critical role in preventing and detecting healthcare fraud and abuse. OIG guidance is essential reading for everyone in the healthcare industry.

The second Trump administration brought significant changes to OIG, including the departure of several key personnel. On January 24, 2025, HHS Inspector General Christi Grimm was dismissed along with the inspectors general (IGs) from 16 other departments. Over the next several months, OIG saw the departure of a number of other key staff with decades of experience, including the Chief Counsel to the Inspector General, the Chief Medical Officer, the Deputy Inspector General for Audit Services, the Assistant Inspector General for Legal Affairs, and others. The new Inspector General – Thomas "March" Bell – was nominated in March but was not confirmed by the Senate until December 18, 2025, and was sworn in on December 22, 2025. As we move into 2026, we will be watching to see how Inspector General Bell seeks to influence OIG's priorities.

While it is difficult to fully appreciate the effects of these personnel changes on the overall operations of OIG, we saw relatively few major announcements in 2025. OIG did not issue any Special Fraud Alerts, Special Advisory Bulletins or new Frequently Asked Questions (FAQs) in 2025. There was, however, an Enforcement Alert on Information Blocking that was jointly issued on September 4, 2025, by OIG and the Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology. Despite an initial forecast that OIG would issue two new Industry Segment-Specific Compliance Program Guidance (ICPG) documents, none were issued in 2025. OIG issued 12 advisory opinions in 2025, which continued a downward trend over the past several years. For their parts, OIG's Office of Audit Services and Office of Evaluation and Inspection continued to issue reports on their work.

Despite the drop in formal guidance, OIG continued to be actively involved in enforcement actions throughout the country. We saw this through the Civil Monetary Penalty (CMP) and Affirmative Exclusion actions posted on OIG's website, as well as through mentions of OIG cooperation in nearly every Department of Justice (DOJ) press release about healthcare fraud enforcement actions. OIG continued to focus on core priorities such as medically unnecessary services, improper billing and Emergency Medical Treatment and Labor Act (EMTALA) violations. OIG also continued its efforts to investigate misuse of pandemic-era relief funds. In conjunction with False Claims Act (FCA) settlements, OIG entered into 15 Corporate Integrity Agreements (CIAs) in 2025, down slightly from prior years. OIG also identified three entities that refused to enter into CIAs and were placed on OIG's Heightened Scrutiny list.

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Bass, Berry & Sims is pleased to share this fourth annual HHS-OIG Year In Review (HHS-OIG YIR). Our goal is not to offer an exhaustive examination of every guidance document published by OIG in 2025. Instead, we use our team's decades of collective experience analyzing fraud and abuse issues both inside and outside OIG to focus on the items we think are most significant and/or most useful to the healthcare industry.

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

- Joint FCA Working Group Announcement
- Update on CIAs and OIG Heightened Scrutiny List
- Advisory Opinions
- Significant Provider Self-Disclosure Protocol (SDP) Settlements
- Medicare Advantage Industry Segment-Specific Compliance Program Guidance

We hope that this year's HHS-OIG YIR helps you to better understand how OIG frames and analyzes fraud and abuse issues so you can identify and manage risks in today's complex healthcare regulatory environment.

A new DOJ-HHS False Claims Act Working Group signals intensified cross-agency enforcement.

Joint FCA Working Group Announcement

In July, DOJ and HHS announced the establishment of the DOJ-HHS False Claims Act Working Group. The Working Group is intended to strengthen the agencies' ongoing collaboration to combat healthcare fraud and advance priority enforcement areas through False Claims Act enforcement actions. The Working Group's priority enforcement areas include:

1. Medicare Advantage
2. Drug, device, or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting
3. Barriers to patient access to care, including violations of network adequacy requirements
4. Kickbacks related to drugs, medical devices, durable medical equipment, and other products
5. Materially defective medical devices that impact patient safety
6. Manipulation of electronic health records (EHR) systems to drive inappropriate utilization of Medicare-covered products and services

The Working Group will maximize cross-agency collaboration to expedite investigations in these areas and identify new leads, including by leveraging HHS data mining resources and assessing HHS and HHS-OIG report findings. The Working Group will also discuss factors HHS should consider when determining whether to implement payment suspensions, as well as factors DOJ should consider when determining whether to move to dismiss *qui tam* cases.

Membership in the Working Group includes leadership from the HHS Office of General Counsel, the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity, HHS-OIG, and DOJ's Civil Division. The group will be jointly led by the HHS General Counsel, the Chief Counsel to HHS-OIG, and the Deputy Assistant Attorney General of the Commercial Litigation Branch.

Stakeholders that operate in these priority areas should be prepared for an increase in investigations and enforcement activity, including actions initiated through whistleblower suits.

Update on CIAs and OIG Heightened Scrutiny List

In 2025, OIG continued to enter into CIAs in conjunction with certain FCA settlements. New CIA activity reached a multi-year low in 2025, with OIG entering into just 15 agreements—down from 24 in 2024, 19 in 2023, and 28 in 2022. The benefit of a CIA in conjunction with an FCA settlement is that OIG will grant a waiver of its permissive exclusion authority. The downside of a CIA is that the organization is subject to mandatory compliance requirements and annual reporting to OIG for, in most cases, five years (although some integrity agreements have three-year terms). In addition, many CIAs require organizations to hire Independent Review Organizations (IROs) to conduct annual reviews of the types of issues that led to the FCA settlement.

While OIG asserts that CIAs "aim to strengthen an entity's compliance program and promote compliance so that future issues can be prevented or identified, reported, and corrected," OIG also acknowledges that it does not seek a CIA in every case.

In some circumstances, OIG seeks a CIA but the settling organization refuses to agree to one. In response to these situations, OIG developed the "heightened scrutiny" list, which names parties that purportedly warrant heightened scrutiny as a result of this refusal. The ramifications of being placed on this list remain largely unclear. In a 2016 document in which OIG discussed criteria for implementing section 1128(b)(7) exclusion authority, OIG describes "heightened scrutiny" as involving "unilateral monitoring." OIG provided examples of what such monitoring may involve, noting that, in addition to making referrals to CMS contractors for claims reviews, "OIG has audited, evaluated, and investigated persons after fraud settlements where integrity provisions are not in place to protect the Federal health care programs."

In 2025, OIG identified three organizations as having refused CIAs and thus being subject to heightened scrutiny. In 2024, OIG placed two organizations on the list, and in 2023, two parties consisting of individuals and organizations were placed on the list. Although OIG did not originally identify how long an organization would be subject to heightened scrutiny when

The ramifications of being placed on the heightened scrutiny list remain largely unclear.

it established the list, it recently identified the duration of heightened scrutiny as lasting 10 years.

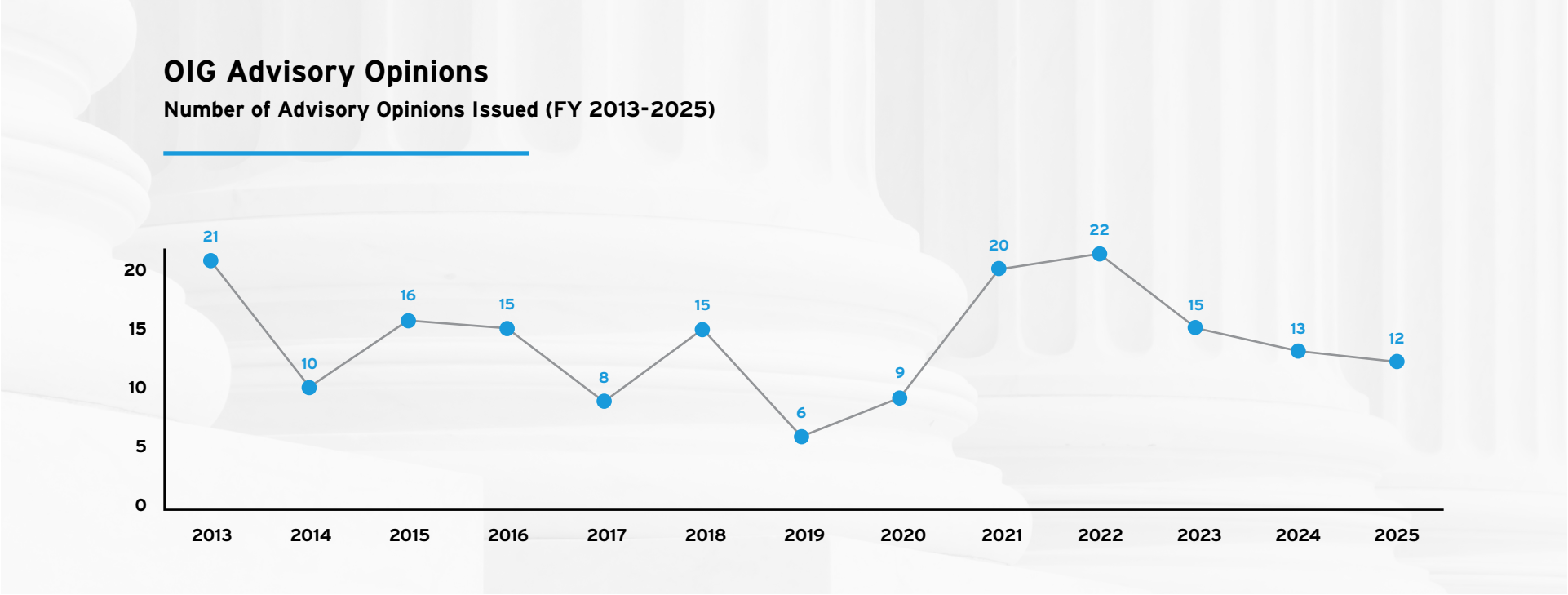
While the number of organizations on the heightened scrutiny list continues to be very small, in the last few years, we have seen large corporations, health systems, and academic medical centers choose to be placed on the heightened scrutiny list rather than agree to a CIA. Time will tell whether more organizations will make this choice, given that the real-world consequences of being placed on the heightened scrutiny list remain unclear.

Advisory Opinions

OIG issued 12 advisory opinions in 2025, continuing a steady decline from 22 in 2022 to 15 in 2023 and 13 in 2024. Most of the opinions were issued in the second half of the year, and most of the opinions were favorable. Consistent with previous years, device and pharmaceutical manufacturer arrangements featured prominently.

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 implicating the Anti-Kickback Statute (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. Rather, an unfavorable advisory opinion simply means that OIG was not comfortable enough with the arrangement to provide prospective immunity under the AKS. Meanwhile, as always, advisory opinions (both favorable and unfavorable) apply only to the parties at issue in the opinion; as such, while they may be useful in assessing how OIG might analyze a similar arrangement, they are not binding on the broader industry.

In this section, we summarize and discuss the advisory opinions issued in 2025.



Advisory Opinion 25-01: Approving Free Access to Pharmaceutical Product

On January 10, OIG issued Advisory Opinion 25-01, approving a pharmaceutical manufacturer's practice of providing free infusion drugs to patients whose insurance does not adequately cover the drug and who meet financial and other eligibility criteria.

The requestor manufactures a product intended to treat a particular disease in patients who have the disease and also have mild cognitive impairment or mild dementia related to the disease. Patients must receive infusions either in the treating physician's office, an outpatient location affiliated with the treating physician, or an independent infusion center with no affiliation with the treating physician.

The requestor provides the product at no cost to qualifying patients. In addition to other criteria, patients must either be uninsured, have insurance that does not cover the product or have Medicare coverage but attest that they are unable to afford the out-of-pocket costs associated with the product. Patients also must have a household income equal to or below 500% of the federal poverty level. Federal health care program (FHCP) enrollees who qualify receive free product for the entirety of the calendar year.

Patients must certify that they: (1) will not submit a request for payment for the free product to any payor, including an FHCP; and (2) understand that neither the free product nor any costs associated with the free product will count toward their applicable out-of-pocket costs. Treating physicians must certify they will not submit a request for payment for the free product from any payor or patient, though they may bill payors and patients for administration of the product in limited situations. Finally, although healthcare professionals may learn about the program from approved printed materials, the requestor does not promote the program directly to consumers and has implemented various safeguards related to the shipping and use of the free product.

OIG noted the arrangement implicates the AKS with respect to both patients, who receive free product, and administering providers, who have an opportunity to earn an administration fee. Nonetheless, OIG determined that the arrangement poses a sufficiently low risk of fraud and abuse for several reasons.

OIG concluded the arrangement is unlikely to inappropriately increase costs to FHCPs because the product itself is not billed to payors, and the administration fee is billable to FHCPs only in limited situations. And although OIG noted the arrangement could function as a "seeding" program, the fact that patients can easily switch products and the requestor intends to offer the program indefinitely serve as safeguards. OIG also highlighted that the arrangement is unlikely to interfere with clinical decision-making, as prescribers generally do not have a financial incentive to order the product when it is provided for free because they will not receive any reimbursement for the product. Finally, OIG concluded the arrangement does not steer patients to any particular provider, practitioner, or insurance plan because eligibility determinations are made without regard to the patients' providers, practitioners, or insurance plans, and patients are free to change physicians or infusion providers at any time without impacting their eligibility for free product.

OIG concluded that the arrangement does not implicate the Beneficiary Inducements CMP because: (1) assistance is available without regard to the patient's treating physician or infusion provider; and (2) the manufacturer (and its vendor) do not fit OIG's definition of a provider, practitioner, or supplier.

OIG typically opines unfavorably on arrangements that may operate as "seeding" programs; however, the unique facts and circumstances present in this arrangement worked to reduce OIG's concerns. Entities considering similar programs may wish to consider requesting an advisory opinion from OIG to confirm that the arrangement presents low risk.

Advisory Opinion 25-02: Approving a Health Center's Proposal to Promote and Schedule Primary Care Services During the Provision of Other Free Services

On April 4, OIG issued Advisory Opinion 25-02, approving a community health center's (CHC's) proposal to identify and inform patients of their need for primary care services and schedule such services, during the course of the center's provision of other non-medical, social and educational services. OIG typically is skeptical of arrangements in which providers promote or schedule reimbursable healthcare services when providing something of value to individuals; however, the unique circumstances and mandates applicable to CHCs under the Public Health Service Act (PHSA) allowed OIG to opine favorably in this case.

The requestor, designated a CHC pursuant to the PHSA, provides medical services as well as certain non-medical, social, and educational services designed to improve access to healthcare and improve outcomes in its service area, including childcare, meals, employment and education counseling and

legal services. The PHSA requires CHCs to conduct certain activities focused on recruiting and retaining patients and permits them to provide supplemental health services that promote and facilitate optimal use of primary health services. The Health Resources and Services Administration (HRSA) formally approved the requestor's additional services as within the requestor's scope of project.

Under the proposed arrangement, the requestor would ask the individuals to whom it is providing the additional non-medical and social services whether they have seen a primary care provider in the last year and, if they have not, provide them with a list of community providers. The list, which would include the requestor, would be organized alphabetically and in a manner that does not promote the requestor. The requestor would include "any willing provider" in the community that wishes to be included on the list. If an individual elects to receive services from the requestor, the requestor would schedule the appointment. If the individual selects another provider, the requestor would make an electronic referral.

A community health center's outreach model was approved due to strong safeguards and its mission to expand access.

OIG determined that the proposed arrangement would implicate the AKS because the HRSA-approved non-medical, social, and educational services the requestor provides could induce the individuals receiving those services to select the requestor for healthcare services. OIG concluded the proposal presented a sufficiently low risk of fraud and abuse even though the additional services might be combined with an offer to schedule an appointment for those individuals to receive primary care services from the requestor, for a number of reasons.

First, the proposal contains safeguards against patient steering, including using objective criteria to identify individuals in need of primary care services; providing a list containing any willing provider's information with no emphasis on the requestor; and continuing to provide the additional services to individuals who select a provider other than the requestor. Second, OIG highlighted that the proposal may increase access to healthcare services, which aligns with the requestor's designation as a CHC under the PHSA, and that the requestor would be providing HRSA-approved social and other services in conjunction with the proposed arrangement. For similar reasons, OIG exercised its enforcement discretion in concluding it would not impose sanctions under the Beneficiary Inducements CMP.

This opinion highlights the natural tension between the broad reach of the AKS and beneficial services approved by HRSA. Still, OIG was able to resolve that tension because the requestor's programs and services are designed to increase access and improve care in underserved communities and because the requestor would implement appropriate safeguards against steering and anti-competitive behavior.

Advisory Opinion 25-03: Approving a Proposal that Expands Patient Access to Covered Telehealth Services

On June 6, OIG issued Advisory Opinion 25-03, approving a proposal by a management services organization (MSO) and its friendly PC to enter into agreements with telehealth providers and the telehealth providers' MSOs to lease employees and provide certain administrative services. The requestor's proposal is designed to increase patient access to in-network telehealth care, particularly in rural and underserved areas, and may provide a framework for industry stakeholders interested in expanding patient access to covered telehealth services.

The MSO requestor of this opinion provides non-clinical management services to the friendly PC requestor, which maintains contracts with payors. The requestors would enter into agreements with certain third-party telehealth providers and their MSOs to lease employees and provide certain administrative services. Specifically:

1. The friendly PC requestor would lease healthcare professionals from the third-party telehealth providers. The friendly PC requestor would credential the leased healthcare professionals and enroll them under the friendly PC requestor's payor contracts so the healthcare professionals could provide covered telehealth services to the third-party telehealth providers' patients who are insured by a plan with which the friendly PC requestor has a payor agreement.
2. The friendly PC requestor would pay the third-party telehealth providers a fair market value hourly rate based on each healthcare professional's licensure type. The requestors certified that the friendly PC requestor would pay the hourly rates regardless of whether it receives reimbursement for the telehealth services from a payor.

3. The third-party telehealth providers' MSOs would provide certain administrative services – including accounting, marketing, administrative support and information technology services – to the MSO requestor. The MSO requestor would pay the third-party MSOs a fair market value administrative fee that does not take into account the volume or value of referrals or business otherwise generated between the parties.

The requestors certified that the proposed arrangement would satisfy all of the personal services and management contracts safe harbor's requirements, and OIG concluded that the hourly and administrative services fees would, therefore, be protected by that safe harbor. Not surprisingly, OIG relied on the requestors' certification as to safe harbor compliance, as well as the fact that the friendly PC requestor would pay the third-party providers regardless of whether it ultimately received payor reimbursement.

Although favorable advisory opinions are binding only on the requesting parties and are limited to the particular facts and circumstances available during OIG's review, they can be helpful in identifying potential safeguards to mitigate fraud and abuse risks in similar arrangements. Stakeholders should exercise caution when evaluating similar arrangements that involve different payment methodologies, as such arrangements may fall outside of safe harbor protections or violate state laws.

Additional analysis about Advisory Opinion 25-03 can be found here: OIG Approves Proposal that Expands Patient Access to Covered Telehealth Services

Advisory Opinion 25-04: Declining to Approve a Medical Device Company's Proposal to Subsidize Exclusion Screening Costs

On June 17, OIG issued Advisory Opinion 25-04, declining to approve a proposal by a medical device company to pay the costs its customers otherwise would incur for a third-party company to screen and monitor the requestor for exclusion from FHCPs and other compliance checks. Although it is common for vendors to conduct—and pay for—their own exclusion screening, the per-customer methodology the company used to charge for screening services likely caused OIG to conclude that the payments could be remunerative to the requestor's customers.

Under the proposed arrangement, some of the requestor's hospital, health system and ambulatory surgical center customers would request or require, as a condition of doing business, that the requestor pay a third-party company to screen and monitor the requestor for exclusion from FHCPs and to ensure compliance with certain other legal requirements. The company would charge the requestor an annual subscription fee for each customer receiving screening and monitoring reports on the requestor—a fee the customers otherwise would incur. The requestor would pay the per-customer fees, which it estimated would cost approximately $450,000 annually, directly to the screening company.

Although it is common for vendors to conduct—and pay for—their own exclusion screening, the per-customer methodology the company used to charge for screening services likely caused OIG to conclude that the payments could be remunerative to the requestor's customers.

OIG explained that the proposed arrangement would implicate the AKS because the requestor's payment of the screening and monitoring fees for which the requestor's customers otherwise would be responsible could induce the customers to purchase federally reimbursable items or services from the requestor. OIG then concluded that the proposed arrangement would not qualify for safe harbor protection and was not sufficiently low risk under a facts and circumstances analysis for OIG to issue a favorable advisory opinion.

In reaching its conclusion, OIG cited anti-competitive and steering risks, finding that the requestor's payments to the company on behalf of its customers could inappropriately steer customers to the requestor over competitors that are not able or willing to pay the fees. OIG acknowledged that, while parties can allocate financial responsibilities in a variety of ways, the proposed arrangement's specific facts could allow the company to serve as a "gatekeeper of referrals" by allowing customers to condition their business on the requestor's payment of the screening costs.

When issuing advisory opinions, OIG must opine on the facts presented. This opinion presents a fact pattern that appears to have been designed to draw an unfavorable outcome. While the requestor's customers bear the primary risk of their vendors' non-compliance with exclusion screening and other laws, vendors often take on the responsibility to conduct their own screening because they represent and warrant that neither they nor their workforce members are excluded, and, more generally, that they comply with all applicable

laws, including laws relating to exclusion. As a result, vendors often engage independent compliance screening services at their own cost.

Perhaps what makes the proposed arrangement unusual is the "gatekeeper" function a particular screening company could play if customers ask vendors to use—and pay for—that company's services as a condition of doing business. Even so, the cost of the screening services does not necessarily have to fall on the customers (and often falls on the vendor). Nonetheless, because the vendor in this case seemingly would subsidize a direct cost for its customers, OIG was unable to conclude that the arrangement poses a low risk of fraud and abuse sufficient to issue a favorable advisory opinion.

Additional examination of Advisory Opinion 25-04 can be found here: OIG Declines to Approve Medical Device Company's Proposal to Subsidize Screening Costs

Advisory Opinion 25-05: Approving a Manufacturer's Warranty for Cost of Injuries Caused by Medical Device

On June 25, OIG issued Advisory Opinion 25-05, approving a medical device manufacturer's proposal to reimburse its customers for the actual costs they incur associated with needle stick injuries caused by the failure of a device it manufactures. OIG analyzed the proposal under the safe harbor for warranties and concluded it would not generate prohibited remuneration under the AKS.

The requestor manufactures and distributes a device that pharmacies, hospitals, clinics, and laboratories purchase for use by their clinicians when administering immunizations and other drugs to patients via injection. The device has a safety mechanism that covers the needle at all times except when penetrating the skin during an injection. This safety mechanism is meant to protect administering clinicians from accidental needle contact. The requestor's device costs more than typical needles.

The proposed arrangement at issue in this opinion is precisely the type of warranty the safe harbor is designed to protect.

The requestor noted that employers typically cover the costs associated with needle stick injuries – including retraining staff, staff absence and replacement, counseling for injured workers, and certain legal costs – if and when they occur. The requestor proposed to reimburse its customers up to $2,500 for the actual costs they incur for needle stick injuries that occur due to failure of its device. The proposal would apply only to purchasers who agree to the terms of the device's warranty and would not apply to injuries that result from user error.

OIG confirmed that the arrangement would implicate the AKS because the requestor would offer something of value to the purchasers (i.e., a payment not to exceed $2,500 for actual costs incurred associated with a needle stick injury caused by a device failure), which could induce purchasers to buy the device. However, OIG confirmed that the proposal would satisfy all of the warranties safe harbor's requirements, including the safe harbor's definition of a warranty.

First, OIG noted the safe harbor requirements relating to the reporting of price concessions would not apply to the arrangement because the warranty does not involve a price concession—only reimbursement for costs incurred during a covered injury.

Next, based on the requestor's certifications, OIG concluded that the requestor would satisfy the remaining requirements applicable to manufacturers. Specifically, the requestor would not pay remuneration for any medical, surgical, or hospital expenses incurred by a beneficiary. Additionally, the requestor would offer a warranty on only one item (and no services) and would not condition the warranty on the buyer's exclusive use of, or minimum purchase of, any of the requestor's products.

The proposed arrangement at issue in this opinion, which would compensate purchasers for the foreseeable costs they incur resulting from the failure of an enhanced safety feature for which they pay a premium, is precisely the type of warranty the safe harbor is designed to protect. Medical device manufacturers that wish to offer a warranty for costs related to a device failure under the protection of the safe harbor for warranties may look to this favorable opinion for guidance.

Advisory Opinion 25-06: Approving Travel, Lodging and Other Expenses to Patients Receiving Manufacturer's Gene Therapy Product

On June 27, OIG issued Advisory Opinion 25-06, approving a pharmaceutical manufacturer's arrangement to provide assistance – including travel, lodging and associated expenses – to qualifying patients receiving its gene therapy product and their caregivers. This opinion is similar to other favorable opinions

OIG has issued to manufacturers on the topic of financial assistance offered in connection with one-time, potentially curative treatments.

The requestor's therapy is approved for the treatment of children with three types of an early-onset disease that is estimated to impact fewer than 40 children annually in the U.S. Without treatment, the children will not survive. The current standard of care focuses on supportive care, symptomatic relief, and end-of-life care. The requestor's product is a one-time gene therapy treatment that may restore certain functions to stop or slow the progression of the disease. There are no other Food and Drug Administration (FDA)-approved treatments for the disease.

Patients must undergo one or more consultations with a physician at an approved hospital treatment center, which are limited in number based on objective criteria, to determine if they are eligible for treatment with the requestor's product. Because the product is created for each patient using the patient's unique blood stem cells, patients who are eligible for treatment with the product must undergo stem cell collection over the course of a week at the treatment center, as well as conditioning prior to treatment, followed by infusion of the product. Consequently, patients may be required to remain in the treatment center for four to eight weeks.

The requestor offers assistance to patients whose families' incomes are below 600% of the federal poverty level, fall within certain distance limitations, and satisfy certain other criteria. The requestor covers ground and air transportation costs, modest lodging, and daily support for meals and incidentals for qualifying patients and their caregivers, subject to certain requirements and limitations. Importantly, the requestor does not promote the assistance program to physicians or caregivers as a reason to prescribe the product.

OIG noted that the assistance program implicates the AKS, both because it may induce patients to purchase the product and also because, by enabling patients to travel and stay near a treatment center, it allows the centers and treating physicians the opportunity to earn fees related to administering the product. As with many other travel and lodging advisory opinions, OIG concluded that the various safeguards and other factors combine to present a low risk of fraud and abuse. In particular, OIG highlighted that the program removes a barrier to care for children and their caregivers, who may be required to travel long distances to receive treatment, and that the duration of the patient's stay is determined by the patients' treating physicians. Moreover, the arrangement avoids potentially problematic "seeding" concerns because it is a one-time treatment that is unlikely to lead to additional referrals and includes other requirements that lower the risk of fraud and abuse.

OIG concluded that the arrangement also implicates the Beneficiary Inducements CMP because it likely would influence a beneficiary to select a particular treatment center, but concluded that the arrangement satisfies the "promotes access to care" exception. In reaching that conclusion, OIG relied on many of the same safeguards it cited in the AKS analysis.

As with similar travel and lodging programs, this advisory opinion is limited to the unique facts and circumstances of the assistance program, the disease and treatment, and the manufacturer at issue.

Advisory Opinion 25-07: Approving Manufacturer Support for Laboratory Testing

On June 27, OIG issued Advisory Opinion 25-07, approving a pharmaceutical manufacturer's program to fund the costs associated with a companion laboratory test for eligible patients before the patients' providers prescribe the manufacturer's drug. The arrangement described in this favorable opinion involves a number of unique factors that distinguish it from other arrangements involving companion laboratory tests. Stakeholders who may be considering similar arrangements should therefore exercise caution when applying OIG's analysis to their own arrangements.

The requestor's drug is an enzyme inhibitor that is FDA-approved to treat patients with tumors that have a specific type of deficient cellular function that makes the tumors particularly sensitive to the type of enzyme inhibitor present in the requestor's drug. According to the requestor, about half of the patients diagnosed with certain specific conditions that may be treatable by the drug have this deficiency. The requestor's drug is approved only for deficiency-positive patients. A competitor's drug is approved for the treatment of both deficiency-positive and deficiency-negative patients.

An FDA-approved companion diagnostic test is available to determine patients' deficiency status. Ordering providers must obtain a tumor tissue sample from the patient and ship it to a laboratory. The results indicate whether the deficiency exists, and thus whether the requestor's drug or its competitor's

drug is appropriate for the patient. The requestor certified that the laboratory test offers no independent value to providers or patients.

The requestor has an arrangement with a laboratory to offer the test for free to certain patients, including patients with the underlying conditions treated by the drug who have a previously collected tumor tissue sample that may be used for testing. Under the arrangement, providers may not seek reimbursement for the test or other services provided in connection with the test. The requestor pays the laboratory a fixed fee for each test it performs. The laboratory may not bill any patient, payor, or other third party for the test. The laboratory provides limited, aggregated, de-identified data to the requestor that the requestor is prohibited from using to re-identify patients or ordering providers. The requestor raises awareness about the deficiency and genomic testing through certain passive, non-promotional methods, such as leave-behind pamphlets and their electronic equivalents. The requestor contractually restricts the laboratory from communicating about the arrangement.

OIG concluded that the arrangement implicates the AKS because it provides remuneration to eligible patients in the form of a free test for which they otherwise may incur out-of-pocket expenses, and to providers by allowing them to offer a free service that may create the opportunity to bill for other services, such as follow-up visits. OIG highlighted its longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including pharmaceutical manufacturers, to providers and patients, that could lead to the ordering and provision of reimbursable items and services. Nonetheless, OIG found that the arrangement presents sufficiently low risk of fraud and abuse for a combination of reasons.

OIG determined the arrangement is unlikely to result in overutilization or inappropriate utilization, to skew clinical decision-making, or to result in unfair competition. OIG noted that providers already may be considering prescribing the requestor's drug or a competing drug and that the test determines whether the requestor's drug may be effective and therefore should be prescribed. The requestor does not provide any incentive to providers to prescribe its drug or any other products it manufactures. Moreover, the test is just as likely to show that the requestor's drug is not indicated for a particular patient and, even when a result indicates the requestor's drug is appropriate, the competitor's drug also is appropriate. OIG also cited the restrictions around marketing and sales communications, as well as the restrictions on laboratory data that prevent the requestor from identifying patients and providers involved in the testing arrangement, as additional safeguards.

Finally, although OIG concluded the arrangement implicates the Beneficiary Inducements CMP because the test could influence a beneficiary to seek follow-up care from the provider who ordered the test, it found the arrangement satisfies the requirements of the "promotes access to care" exception.

As always, the facts and circumstances described in Advisory Opinion 25-07 are unique to the parties and the arrangement under review. Given OIG's reminder about its longstanding concerns related to providing free items or services that lead to the ordering of additional items and services, parties that may be considering offering subsidies for laboratory tests should do so with caution.

Advisory Opinion 25-08: Declining to Approve a Medical Device Company's Proposal to Pay Third-Party Vendor Portal Fees

On July 1, OIG issued Advisory Opinion 25-08, declining to approve a medical device company's proposal to pay a third-party vendor to access its electronic billing portal that some of the requestor's hospital customers use for certain billing operations. In issuing the unfavorable opinion, OIG said the proposed arrangement "presents anti-competitive risks and risks of inappropriate steering" and characterized the arrangement as being "for the purpose of accessing referrals" from hospital customers that use the vendor's services.

The requestor in this opinion supplies "bill-only" products to hospitals that are not part of the hospitals' regularly purchased inventory but rather are purchased in real time, such as when a surgeon selects the right size or component of a device to use during a surgery. Under the proposed arrangement, as a condition of doing business with certain hospitals, the requestor would access a vendor's electronic billing portal to process payment for such "bill-only" items rather than use its own billing process. The vendor would charge the requestor $395 per year for each representative who uses the portal, which the requestor certified could be as many as 3,000 representatives (amounting to about $1.2 million in annual fees). The requestor certified that, because the

OIG's conclusion in Advisory Opinion 25-08 aligns closely with its reasoning in Advisory Opinion 25-04.

billing portal was redundant to its own internal billing processes and provided no additional, appreciable benefits to the requestor, it could not certify that the fees were commercially reasonable. The requestor told OIG that it would pay the vendor's fees for one reason: to access the "bill-only" portal to sell medical devices to hospital customers that request or require, as a condition of doing business, that the requestor use the portal.

OIG concluded that the proposed arrangement would implicate the AKS because the requestor would pay the vendor fees to use the portal, through which the vendor would arrange for hospital customers' purchases of the requestor's "bill-only" items used in procedures, some of which may be reimbursable by FHCPs. OIG also concluded that the requestor's use of the portal and corresponding payments to the vendor, which would enable the hospitals to use the vendor to purchase "bill-only" items from the requestor, may result in cost savings (i.e., financial benefit) to the hospitals, and thus the requestor's payments to the vendor may constitute remuneration to the hospitals to induce the purchase of medical devices that may be reimbursable by a FHCP.

OIG found that no safe harbor applied to the proposed arrangement, specifically noting that it would not meet the personal services safe harbor because the requestor could not certify that the aggregate services for which it would contract would be commercially reasonable. At its base, the proposed arrangement would be for the requestor to pay substantial fees to access the portal "as part of an effort to retain and potentially expand business" from hospitals that use the vendor.

OIG's conclusion in Advisory Opinion 25-08 aligns closely with its reasoning in Advisory Opinion 25-04, which was issued just weeks earlier. Both opinions involve proposed arrangements stemming from medical device companies' customers requesting or requiring, as a condition of doing business, that the company use a specific third-party vendor's services. In 25-04, the manufacturer was asked to pay a third-party company to conduct exclusion screening; in 25-08, the manufacturer was asked to pay a vendor for access to an electronic billing portal. In both cases, OIG expressed concern about the potential for a third party to serve as a "gatekeeper of referrals," with healthcare providers conditioning their business on whether the medical device company agrees to pay vendor fees.

Both opinions also highlight the anti-competitive risks and inappropriate steering concerns that arise when manufacturers relieve healthcare providers of financial obligations the providers otherwise would incur. The per-customer fee structure was central to OIG's concerns in both opinions—in 25-04, the screening company would charge a fee for each customer receiving reports, and in 25-08, the portal vendor would charge a fee per sales representative accessing the portal. These opinions reinforce OIG's longstanding position that manufacturers' payments for services that benefit or subsidize costs for referral sources may constitute prohibited remuneration under the AKS, even when third parties deliver the services.

Advisory Opinion 25-09: Approving a Safe Harbored Arrangement Involving Physician Ownership in a Device Manufacturer

On August 7, OIG issued Advisory Opinion 25-09, approving an arrangement involving profit distributions paid to physician-owners of a device manufacturer. The requestor, which manufactures and sells medical devices relating to emergency stroke treatment, is owned, in part, by physicians who may order or purchase the devices or recommend that a hospital order and purchase the devices. The manufacturer's factual certifications essentially parroted the small entity investment safe harbor's requirements and therefore left little doubt as to what the outcome would be. Specifically, the requestor certified, among other facts, that no more than 40% of the value of the investment interests were held by investors in a position to make or influence referrals to, or furnish items or services to, the requestor, including the physician owners.

OIG noted the arrangement implicates the AKS because the physician-owners are in a position to order or purchase the requestor's products and may receive profit distributions on their ownership interests. Before reaching its conclusion, OIG noted its longstanding concerns about physician-owned entities that derive revenue from selling, or arranging for the sale of, medical devices ordered by their physician owners for use in procedures the physician owners perform at hospitals and reiterated some of the "questionable features" of such relationships that it highlighted in the 2013 Special Fraud Alert regarding physician-owned entities. OIG nonetheless went on to conclude that the small entity investment safe harbor protects the requestor's arrangement in this instance because the requestor certified that it satisfied all of the safe harbor's applicable requirements.

When issuing advisory opinions, OIG relies on the requestors' certifications, including the certification that the information provided constitutes a complete and accurate description of the arrangement's relevant facts and circumstances. When a requestor certifies that its arrangement satisfies all of a safe harbor's requirements, it is therefore unsurprising that OIG would

conclude the arrangement is safe harbored. Perhaps because its hand was essentially forced in this instance, OIG was careful to remind stakeholders that the opinion is limited to the arrangement's specific facts and that similar business arrangements involving physician-owned entities that do not meet all conditions of the small entity investment safe harbor could raise fraud and abuse risks under the AKS. OIG pointed out that the risks of fraud and abuse would increase if, due to the physician owners' financial relationship with the company, the physicians order or purchase (or recommend that a hospital or other provider order or purchase) their devices over competitor devices, or the physicians use their devices over other treatments that may be more clinically appropriate.

The small entity investment safe harbor's requirements are often difficult to satisfy because the 40% limitation on investment interests applies not only to investors in a position to make or influence referrals but also to investors who furnish items or services to the investment entity. The extension of the limitation to investors who furnish items or services means that ownership interests held by entities such as MSOs would count toward the 40% if those organizations provide management services to the investment entity. Entities with physician investors should heed OIG's warning and consider this opinion alongside prior Special Fraud Alert guidance on the subject of physician-owned entities.

Advisory Opinion 25-10: Approving Financial Support for Patients Receiving Certain Therapy Services

On September 8, OIG issued Advisory Opinion 25-10, approving an arrangement under which a company that provides "family-powered therapy" to children with a particular disorder helped establish and provides ongoing financial support to a foundation that makes grants to families receiving such "family-powered therapy." Although the opinion's individual facts and circumstances are unique, the outcome is consistent with OIG's prior guidance, including its 2014 Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Program, in which OIG describes the safeguards that are necessary to ensure the independence of patient assistance programs and other charitable support organizations.

The specialized "family-powered therapy" at issue in the opinion, which is used for pediatric patients with a particular disorder, is typically covered by health insurance, including FHCPs, and requires caregivers to commit at least 15 hours a week to the therapy. The time commitment, which is often during work hours, along with cost-sharing amounts under insurance, can create significant financial burdens, particularly for low-income families, that limit access to the therapy. To help address these financial burdens, company employees formed a nonprofit, tax-exempt charitable organization to provide grants to qualified families. Company resources were used to help establish the foundation, and the company provides financial support to the foundation.

OIG determined that the company's involvement in establishing the foundation and its ongoing financial contributions implicated the AKS and that the foundation's grants to families implicated the AKS and the Beneficiary Inducement CMP. Nevertheless, OIG concluded that the arrangement posed a sufficiently low risk of fraud and abuse risk, citing three key reasons:

1. Donations from the company to the foundation are unrestricted, and the foundation operates with "absolute, independent, and autonomous discretion." In addition, the company does not receive any data on how its donations are used.
2. The foundation is a nonprofit, tax-exempt charitable organization that awards grants to families in an objective manner that is not associated with any support provided by the company.
3. Families' eligibility for support from the foundation is not dependent on the use of a particular therapy provider, and families are free to change their therapy provider at any time.

OIG remains mindful of the importance of ensuring that financially needy beneficiaries receive medically necessary treatment. OIG's analysis in this opinion is consistent with its longstanding approach to reviewing independent charity patient assistance programs, which focuses on whether the arrangement is likely to result in overutilization, inappropriate steering, inappropriately increased costs to FHCPs, or unfair competition.

Advisory Opinion 25-11: Approving Manufacturer's Bundled Discount and Market Share Rebate Structures

On December 15, OIG issued Advisory Opinion 25-11, approving various discount structures – including bundled discounts and rebates contingent on achieving market share requirements – that a biopharmaceutical manufacturer offers its customers on three vaccines. This opinion is noteworthy because it offers helpful insight into OIG's current perspective on discounts and rebates that are contingent on achieving specified market share thresholds for products reimbursed under different FHCP methodologies.

Arrangements that do not satisfy the discount safe harbor's requirements may pose a low risk of fraud and abuse under the AKS as long as they are not paired with agreements for marketing or switching services and include certain other safeguards.

The requestor offers various discounts on vaccines to its customers, including bundled upfront discounts and bundled rebates, both of which are contingent on satisfying certain market share or volume purchase requirements. Two of the vaccines eligible for the bundled discounts and rebates are reimbursable under Medicare Part B, and the third is reimbursable under Medicare Part D. Each vaccine in a bundle is subject to a discount, and both the market share or volume requirement and the upfront discount or rebate for each vaccine are set in advance, although the requestor's agreements with some of its customers allow the requestor to increase the discount or lower the market share requirement on a go-forward basis after providing advance notice to the customer to account for evolving market dynamics. The requestor adheres to the discount safe harbor's reporting requirements, including disclosing discount amounts on customer invoices and informing customers that they may be obligated to report the discounts to payors.

Each of the vaccines has at least one competing vaccine with a list price comparable to the requestor's vaccines. The requestor's customers are neither required nor permitted to provide any services – including any marketing activities or switching patients from one product to another – in connection with the arrangement, and the requestor implemented various other safeguards, including internal training programs, compliance monitoring of field personnel, and policies prohibiting personnel from "marketing the spread."

Like virtually all discount arrangements, the requestor's arrangement implicates the AKS because the discounts are intended to induce customers to purchase its vaccines. While OIG concluded that the bundled discounts and rebates do not satisfy the discount safe harbor's definition of "discount," it concluded that the risk of fraud and abuse posed by the arrangement is sufficiently low under the AKS to garner a favorable opinion.

OIG reasoned that the bundled upfront discounts are sufficiently low risk under the AKS because:

1. The discounts are readily attributable to each separately billable item, and each Medicare reimbursement system benefits equally from the discount.
2. The requestor discounts each vaccine in the bundle (as opposed to offering a discount on one product to induce the full purchase price of a different product).
3. Each vaccine has at least one competing vaccine with a list price that is similar to the requestor's vaccines, which lowers the risk that the discounts disguise pricing of any vaccine in the bundle to raise prices or maintain a higher list price.

OIG noted that certain of the bundled rebate arrangements do not meet this safe harbor's definition of "rebate" because their terms are not fixed at the time of the initial purchase; OIG nevertheless concluded the bundled rebates are sufficiently low risk under the AKS because the customers are aware before the time of their initial purchases that the requestor may adjust the terms and because such adjustments might increase patient choice.

Although this opinion is limited to the requestor and the particular facts and circumstances at issue, it offers comfort that market share rebates – which have been the target of various government enforcement actions – can be structured compliantly. Even arrangements that do not satisfy the discount safe harbor's requirements may pose a low risk of fraud and abuse under the AKS as long as they are not paired with agreements for marketing or switching services and include certain other safeguards. Entities that are considering offering or accepting market share or bundled price concessions may wish to consider implementing safeguards similar to those included in the requestor's arrangement.

Additional information about Advisory Opinion 25-11 can be found here: OIG Analyzes Market Share Rebates and Bundled Discounts Under the Discount Safe Harbor

Advisory Opinion 25-12: Declining to Approve Sign-On Bonuses to Family Caregiver Employees

On December 30, OIG issued Advisory Opinion 25-12, in which it declined to approve a home care agency's proposal to advertise and pay sign-on bonuses to prospective attendant employees who, in most cases, would be family members acting as the decision-makers for Medicaid beneficiaries. While sign-on bonuses are common recruiting tools and employee compensation is often protected under the AKS employee exception and safe harbor, OIG found that the structure at issue in this opinion functions as an inducement to secure beneficiary referrals and falls outside the employee safe harbor's scope. OIG also determined that the arrangement would violate the Beneficiary Inducements CMP.

The requestors operate a home care agency that participates in state Medicaid in-home support programs. Beneficiaries receiving services under these programs may select attendants of their choice, who need not be licensed or certified. The requestors proposed to market attendant positions and publicly advertise a sign-on bonus. The requestors certified that attendants often are family members of beneficiaries and serve as the decision-makers with respect to the agency that would furnish Medicaid-reimbursable services to those beneficiaries. Once hired, attendants would be bona fide W-2 employees of the agency. The stated purpose of the sign-on bonus was to entice prospective attendants to choose the requestors' agency over competing agencies for the provision of services to the beneficiaries for whom the attendants are responsible.

When recruiting payments are directed at individuals who are simultaneously the beneficiary's agent and the near-certain source of the beneficiary's business, OIG may treat those payments as referral inducements rather than protected employee compensation.

OIG concluded that offering and advertising the bonus to prospective attendants would implicate the AKS because, in most cases, the prospective attendants act as decision-makers with respect to the agency that will provide Medicaid-reimbursable services to the beneficiaries. In OIG's view, this dynamic creates an inextricable link between the proposed employment and an all-but-certain referral of the beneficiary. The agency's marketing of the bonus to those decision-makers operates as a solicitation for a referral before any employment begins, rather than as an "amount paid by an employer to an employee for employment" within the meaning of the statutory exception and regulatory safe harbor for employees. On that basis, OIG determined that the exception and safe harbor do not apply.

OIG emphasized the heightened risk of inappropriate steering and unfair competition created by publicly advertising the bonus amount to caregiver decision-makers. OIG expressed concern that the proposal could drive a bonus "arms race," divert resources from patient care, and encourage agency selection based on bonus size rather than quality indicators such as training or back-up coverage. Separately, OIG concluded that the Beneficiary Inducements CMP would be violated because the offer of a bonus to the beneficiary's agent is likely to influence the beneficiary's selection of a provider, and no CMP exception applies.

Advisory Opinion 25-12 is noteworthy because it delineates a boundary condition: when recruiting payments are directed at individuals who are simultaneously the beneficiary's agent and the near-certain source of the beneficiary's business, OIG may treat those payments as referral inducements rather than protected employee compensation. OIG's analysis turns on the timing and purpose of the remuneration and the dual role of the recipient. The bonus is offered and advertised pre-employment and is aimed at securing the beneficiary's business through the caregiver-decision-maker, rendering it qualitatively different from routine workforce recruiting, where any referral benefit is speculative.

Significant Provider Self-Disclosure Protocol (SDP) Settlements

Throughout the year, OIG publishes settlements with healthcare providers and suppliers who have submitted disclosures through the Health Care Fraud SDP. The disclosures provide summaries of potential violations of the fraud and abuse laws and offer insight into the importance of monitoring compliance issues. In 2025, OIG posted 106 enforcement actions resolved through the SDP. The most common alleged violations involved excluded individuals (26), unlicensed individuals (25), inadequate documentation or failure to meet Medicare requirements (19), and billing for medically unnecessary services or services not rendered (18).

In total, these 106 enforcement actions accounted for nearly $65.5 million in settlement payments, with individual settlements ranging from $20,000 to

$18.8 million. In the largest settlement, a Florida health system agreed to pay $18,848,530.40 for allegedly employing two individuals that it knew or should have known were excluded from participation in FHCPs, and also for allegedly submitting claims for transcatheter aortic valve replacement procedures that were not performed or failed to meet coverage criteria.

Several of the largest settlements resulted from allegations of improper billing of Medicare services or insufficient documentation for services under Medicare:

- A hospital and medical group located in Washington agreed to pay $10,043,555.40 for allegedly submitting claims to FHCPs for items and services provided in inpatient and outpatient clinical research studies that should have been paid for by the research study sponsor or provided for free to the research participant.
- Another medical center in Washington agreed to pay $8,993,725.50 for allegedly submitting claims to the Medicare Part A program for inpatient hospital stays that did not meet coverage criteria under the Medicare "two-midnight" rule. The medical center also allegedly submitted claims to the Medicare Part B program for intravenous hydration administration for hospital outpatients in the emergency department that did not meet Medicare coverage criteria.
- A health system in North Carolina agreed to pay $4,796,424 for allegedly submitting claims to Medicare for chronic care management that failed to comply with Medicare requirements.
- A medical group in New York agreed to pay $2,836,219 for allegedly falsely representing the rendering provider on claims to FHCPs when the services were actually performed by other providers who were not enrolled.
- A health system in New York agreed to pay $411,184.70 for allegedly submitting office-based evaluation and management (E/M) claims on behalf of a physician for services that were not performed or otherwise did not meet coverage criteria, as well as allegedly submitting claims for E/M services for which the physician overstated the amount of time spent with patients to increase reimbursement.
- A medical group in South Carolina agreed to pay $225,113.29 for allegedly submitting claims for telehealth psychotherapy services for longer psychotherapy sessions than were provided.

Other settlements noted instances where allegedly improper remuneration was offered or received in return for the referral of FHCP beneficiaries:

- A medical system in Arizona agreed to pay $2,831,733 for allegedly paying remuneration to a physician in the form of excessive rental fees; making excessive compensation payments to an oncologist that were outside the scope of the oncologist's employment; and receiving free staffing services from two local hospices.
- A health system in Georgia agreed to pay $1,006,192.01 for allegedly paying remuneration to certain primary care physicians if the primary care physicians' Medicare Advantage and commercially insured patients received services from a specialist physician within the health system's network.
- A medical center in Nevada agreed to pay $945,993.36 for allegedly submitting claims for mid-level practitioner services at the physician rates. The medical center also allegedly paid remuneration to: a physician and practice in the form of additional payments for professional services; a physician in the form of free space to see private dental patients; and a practice and two physician managers in the form of free space, purportedly leased by the practice from the medical center.
- A hospital in Minnesota agreed to pay $214,661.78 for allegedly paying remuneration to a referring orthopedic physician practice in the form of free information technology services and without a written agreement in place.

Several settlements involved services allegedly provided by uncredentialed providers but billed under another credentialed individual:

- A physical therapy provider in California agreed to pay $1,239,599.66 for allegedly submitting claims to FHCPs that purportedly were furnished by a credentialed physical therapist when, in fact, a physical therapist who was not enrolled or credentialed with the applicable FHCP actually rendered the services. The provider's managing entities also agreed to pay $636,118.16 for their role in the alleged conduct.
- A multi-state medical group agreed to pay $749,702.51 for allegedly submitting claims for E/M services that were not medically necessary and not provided as billed. Additionally, the group allegedly submitted claims to Medicare for the services of a non-credentialed provider under the credentials of another provider.

Other settlements involved potential violations of billing rules, upcoding, and the provision of medically unnecessary services.

- A health system in Oregon agreed to pay $709,462.14 for allegedly billing outpatient sleep study services by a physician that were not provided and paying remuneration to that physician in the form of compensation for the services that the physician did not provide.
- An urgent care provider in New Jersey agreed to pay $614,137.34 for allegedly submitting non-physician practitioner "incident to" claims for reimbursement that incorrectly identified the rendering physician and were upcoded to higher levels of service than warranted.
- A health system in New Jersey agreed to pay $528,937.50 for allegedly submitting claims to FHCPs for remote physiologic monitoring that did not meet the requirements for coverage and payment.
- A medical group in New York agreed to pay $455,408.16 for allegedly submitting claims for services provided by nurse practitioners in the office setting, which were billed as "incident to" the services of physicians employed by the group. The services did not satisfy incident to billing requirements because the nurse practitioners providing the services were not employed by, or under contract with, the medical group.
- A gastroenterology group in New York agreed to pay $352,442.46 for allegedly submitting claims to FHCPs for E/M services that had been furnished as split/shared visits between group physicians and hospital-employed advanced practice gastroenterology providers (APPs). These claims were allegedly improper because the group physicians were not in the same group practice as the APPs, and the billing provider did not perform the substantive portion of the visit.
- A community mental health center in Ohio agreed to pay $165,532.37 for allegedly billing FHCPs for psychotherapy services by an employed licensed clinical social worker that were not provided as billed.
- A dermatology practice in California agreed to pay $140,547.68 for allegedly submitting claims for "incident to" services that did not satisfy the "incident to" requirements because they were provided during initial visits with new patients or during visits with existing patients during which a new plan of care was established. OIG also contended that some of the "incident to" services were provided by providers who were not yet enrolled at the time of the service.

In a number of settlements, OIG alleged that compensation arrangements took into account the volume or value of referrals or other business generated by the party:

- An infusion services provider based in Illinois agreed to pay $719,265 for allegedly paying remuneration to a healthcare system and a physician practice in the form of compensation for physician services that varied with the volume of parenteral infusion therapy services referred to the provider by the healthcare system and the physician practice, where the physician services were reimbursable separately.
- A hospice agency in Texas agreed to pay $430,752 for allegedly paying remuneration to two physicians in the form of medical director compensation that took into account the physicians' volume or value of referrals.
- A multi-specialty medical group in Oregon agreed to pay $108,964.56 for allegedly paying remuneration to an ophthalmologist and his practice in the form of the routine referral of Medicare patients requiring intraocular lens (IOL) implant surgery; and receiving remuneration from the ophthalmologist and his practice in the form of per-patient referral fees and the routine referral of IOL surgery patients back to the clinic for post-operative services billed and paid for by Medicare.

Medicare Advantage Industry Segment-Specific Compliance Program Guidance

On February 3, 2026, OIG issued new Medicare Advantage Industry Segment-Specific Compliance Program Guidance (MA ICPG) for the MA industry and individuals and entities participating in or engaging with the MA program (collectively, MA Parties). The MA ICPG is intended to be read together with OIG's General Compliance Program Guidance (GCPG), which applies to all individuals and entities involved in the healthcare industry and describes the seven elements of an effective compliance program. As OIG's first update to its 1999 Medicare+Choice compliance program guidance, the MA ICPG

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OIG repeatedly characterizes the MA ICPG as nonbinding guidance that does not create any new legal obligations or standards. However, MA oversight has been a top OIG priority for years, and MA's growing popularity and OIG's recent experience pursuing fraud, waste, and abuse within the MA program motivated OIG to issue the MA ICPG. Consequently, MA organizations (MAOs) may be expected to look to the MA ICPG as a benchmark for effective compliance practices.

The MA ICPG identifies the following seven compliance risk areas and provides recommendations to mitigate these risks:

1. Access to care
2. Marketing and enrollment: improper financial incentives and deceptive marketing practices
3. Risk adjustment
4. Quality of care
5. Oversight of third parties
6. Compliance programs within vertically integrated organizations and other ownership structures
7. Submission of accurate claims

For each of these risk areas, the MA ICPG provides detailed recommendations. Among the most notable are: (1) enhanced network adequacy monitoring and documentation requirements; (2) specific safeguards for marketing practices, including broker and agent oversight; (3) comprehensive risk adjustment compliance programs addressing chart review practices and diagnostic coding; (4) quality metrics integrity protocols; (5) robust third-party due diligence and monitoring frameworks; and (6) compliance considerations for private equity and other outside investors in MAOs.

The MA ICPG reflects a notable evolution in the government's understanding of, and views toward, compliance in the MA space. The MA ICPG is more detailed and operationally prescriptive than earlier guidance, drawing on years of audits, evaluations, enforcement actions, data analyses and industry engagement. It signals that regulators have become significantly more sophisticated in understanding how MAOs and their related entities operate.

At the same time, the guidance sweeps more broadly in scope. Rather than focusing solely on MAOs, it applies to a wider array of "MA Parties," including providers, MSOs, downstream vendors and other entities—including investors—that play a role in the MA ecosystem. OIG makes clear that it views compliance risks as extending across the constellation of relationships and ownership structures within the MA sector.

Overall, the document serves as both a roadmap and a warning: OIG is paying close attention, expects MA Parties to build mature and proactive compliance programs, and is prepared to evaluate conduct across the full lifecycle of MA operations—including how organizations grow, structure themselves, deploy technology, and partner with investors and vendors.

Additional information about the MA ICPG can be found here: From 1999 to Prime Time: OIG Revamps Medicare Advantage Guidance for Today's—and Tomorrow's—Evolving Market.

Conclusion

As we reflect on OIG's 2025 activities and guidance, it is evident that the agency has remained unwavering in its commitment to safeguarding the integrity of FHCPs and the health and welfare of FHCP beneficiaries. The agency's focus on proactive compliance, transparent guidance and continued collaboration with stakeholders highlights the ongoing need for healthcare providers to stay engaged with regulatory developments and strengthen their compliance programs.

About the Bass, Berry & Sims Healthcare Industry Practice

Marked by an integrated approach and unmatched regulatory knowledge, the healthcare industry practice of Bass, Berry & Sims is a team of more than 300 experienced attorneys who leverages their diverse strengths to meet the unique demands of our clients. Our team encompasses the multitude of legal specialties necessary to service one of the largest, most highly regulated industries in the U.S. The firm has been recognized by leading healthcare and legal industry outlets, including being **nationally ranked** by Chambers USA for the last ten years (2016-2025), named a **Healthcare Practice Group of the Year** by Law360 (2025) and recognized as the **third largest healthcare law firm** in the U.S. by the American Health Law Association (2025). Additionally, the Healthcare Private Equity Team at Bass, Berry & Sims has served as counsel in hundreds of private equity-backed deals across the healthcare industry and recently was ranked as the **#6 most active law firm in healthcare private equity transactions** (PitchBook, Q3 2025). Read more here.

Named Healthcare Practice Group of the Year (2025, 2020)

Ranked 3rd Largest Healthcare Law Firm in the U.S. (2025)

Healthcare & Healthcare Government Investigations and Fraud Attorneys Recognized (2025)

#6 Most Active Law Firm in Healthcare Private Equity Transactions (Q3 2025)

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