BASS BERRY SIMS

HHS-OIG YEAR IN REVIEW

2022

Introduction

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) continues to offer valuable insights to the healthcare industry as to how best to approach increasingly complex healthcare fraud and abuse issues.

Bass, Berry & Sims is pleased to share this **HHS-OIG Year In Review (HHS-OIG YIR)** that highlights key guidance OIG issued in 2022, as well as other items of import involving the agency.

Our intention is not to exhaustively cover every bit of guidance OIG published last year. Rather, we have used our decades of collective experience inside and outside OIG to focus on the items we think are of the greatest importance to the healthcare industry.

When evaluating the relevance of any particular guidance document, it is important to understand its context. For example, Special Fraud Alerts inform the public of practices that OIG considers to be of particular concern and reflect the agency's enforcement priorities. On the other hand, OIG cannot control the types of arrangements for which individuals and entities seek advisory opinions, so these opinions do not necessarily reflect the agency's enforcement priorities or the matters it believes are most significant.

It is also important to understand OIG's approach to issues raised in the advisory opinion context. OIG tends to view the federal Anti-Kickback Statute (AKS) expansively and typically is reluctant to conclude that an arrangement does not implicate the AKS. However, because the AKS is an intent-based criminal statute, OIG is judicious when issuing favorable advisory opinions. To issue 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, the fact that an arrangement may not receive a favorable advisory opinion does not necessarily mean the arrangement violates the AKS. Rather, it means only that OIG was not comfortable enough with the arrangement to provide prospective immunity under the AKS.

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

- Significant changes to the advisory opinion process as well as several noteworthy advisory opinions.
- OIG's Special Fraud Alert warning against the dangers of fraudulent telehealth arrangements.
- Provisions of legislation through which Congress established a new exception for physician wellness programs and directed OIG to study contingency management interventions.
- Implications of some process updates to OIG's self-disclosure protocol (SDP) and some noteworthy SDP settlements.
- Pfizer's efforts to obtain a favorable advisory opinion and its subsequent attempts to convince federal courts to overturn OIG's unfavorable advisory opinion.
- Key personnel changes at OIG.
- Although it occurred in early 2023, we mention OIG's expanded informal FAQ guidance process for questions related to the AKS and other authorities.

We hope that this HHS-OIG YIR will assist you in understanding and determining how best to navigate fraud and abuse issues in an increasingly complex environment.

OIG's Modernization Initiative Request for Information Yields Significant Changes to the Advisory Opinion Process

OIG's Modernization Initiative Request for Information (RFI)

One of OIG's key compliance priorities is modernizing the agency's program integrity and compliance information. In late 2021, in furtherance of its goals, OIG issued an RFI seeking input from the healthcare industry and the public on a wide range of issues, including how stakeholders use OIG's resources and how to improve their value and timeliness.

OIG's request for feedback was wide-ranging and included requests for feedback on advisory opinions, compliance program guidance, the list of excluded individuals and entities, and frequently asked questions. For example, OIG noted that it has received criticism that the advisory opinion process is too restrictive, slow, and cumbersome and sought input on how to balance the value of including a detailed analysis in each opinion with the value of a more expeditious approach, without a detailed legal analysis.

The RFI comment period concluded on January 31, 2022. Certain updates, such as any changes to the advisory opinion process, may require notice-and-comment rulemaking, while other changes would not require a formal process. OIG was careful to calibrate expectations, noting that this initiative likely would be a multi-year effort.

OIG's Update to the Advisory Opinion Regulations and Related Enforcement Policy Statement

On January 3, 2022 – before the conclusion of the RFI's comment period – OIG updated its advisory opinion regulations to remove the procedural provision requiring OIG to reject an advisory opinion request when "the same or substantially the same course of action is under investigation or has been the subject of a proceeding involving HHS or another governmental agency." This provision was a frequently cited basis for rejection, and its application resulted in requestors receiving rejection letters from OIG without any analysis or transparency as to the underlying investigation or proceeding that served as the basis for rejection.

OIG removed a constraint in its advisory opinion regulations that was a frequently cited basis for rejection.

OIG claimed that the amendments would provide the agency with more flexibility to issue advisory opinions and could provide stakeholders with greater transparency regarding factors that the government may consider in evaluating compliance with certain fraud and abuse laws and distinguishing between similar arrangements.

Additional information from our client alert can be found here: OIG Amends the Advisory Opinion Process to Remove a Frequently Cited Basis for Rejection | Bass, Berry & Sims PLC (bassberry.com).

New Advisory Opinion Template

In September, OIG released a template that parties may use when preparing advisory opinion requests. The four-page, voluntary template lays out the basic information OIG requires for an advisory opinion request, including the identity of the requesting party, the particular legal issue on which the requestor seeks an advisory opinion, a complete description of the arrangement, and a statement certifying the accuracy and completeness of the information provided.

The template also provides for an "optional" legal analysis, in which the requestor describes how it evaluates the arrangement under the relevant law and why it believes OIG should issue a favorable opinion. OIG regulations do not require such an analysis; however, in most cases, this portion of the advisory opinion request is the most consequential.

Although the template provides a simple framework that can serve as a useful starting point for advisory opinion requests, it may not accommodate every request. Parties requesting an advisory opinion may wish to refer to the template and use it as a starting point or checklist.

Additional information from our client alert can be found here: https://www.bassberry.com/news/oig-advisory-opinion-request-template/

OIG's Expanded Informal FAQ Guidance Process

Finally, shortly before the publication of this HHS-OIG YIR, the agency expanded the scope of subject matters on which it is willing to issue informal FAQ guidance, including questions regarding the AKS and the civil monetary penalty (CMP) provision prohibiting certain remuneration to Medicare and state healthcare program beneficiaries (the Beneficiary Inducements CMP). Building on its success with COVID-19 FAQ responses, which terminate at the end of the public health emergency declaration, OIG will entertain a broader scope of FAQs and, when appropriate, issue non-binding guidance with several caveats. Importantly, stakeholders can now seek informal feedback regarding the application of fraud and abuse laws to specific fact patterns—an area traditionally reserved for advisory opinions. OIG has already updated the FAQ page with several new responses.

Additional information from our client alert can be found here: OIG Offers Stakeholders a New Avenue for Informal Fraud and Abuse Guidance | Bass, Berry & Sims PLC (bassberry.com)

Stakeholders can now seek informal feedback regarding the application of fraud and abuse laws to specific fact patterns—an area traditionally reserved for advisory opinions.

Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies

OIG issued a Special Fraud Alert on July 20 regarding the growing use of fraudulent schemes involving telehealth, telemedicine, and telemarketing service companies. These fraudulent schemes often include aggressive kickback arrangements whereby the telehealth company arranges for practitioners to prescribe or order medically unnecessary items or services, coupled with a fee that correlates to the volume of services provided. Frequently, the practitioners are not given an opportunity to independently assess the patient or are not provided with the patient's true medical records.

Rapid changes in telehealth payment policies and a dramatic increase in the use of the telehealth all but ensure a continued emphasis on telehealth arrangements by government enforcement agencies.

Several federal laws may be implicated under these schemes and could result in liability under the AKS, the Beneficiary Inducements CMP, the federal criminal healthcare fraud statute, and the False Claims Act. OIG encourages practitioners to exercise caution when entering into arrangements with telemedicine companies that reflect suspect characteristics. OIG did acknowledge that there are legitimate uses of telehealth and did not seek to discourage practitioners from using such means to provide legitimate care.

Apart from the Special Fraud Alert, OIG is exercising oversight with respect to the impact of telehealth flexibilities granted during the COVID-19 public health emergency. In September, OIG issued a data brief analyzing program integrity risks associated with Medicare telehealth services during the first year of the pandemic.[1] And in November, the Pandemic Response Accountability Committee released a report examining the emerging program integrity risks identified by six participating Offices of Inspectors General related to the expansion of telehealth across federal programs during the pandemic.[2] Rapid changes in telehealth payment policies and a dramatic increase in the use of the telehealth all but ensure a continued emphasis on telehealth arrangements by government enforcement agencies.

1 HHS-OIG, Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks, OEI-02-20-00720 (Sept. 2, 2022), *available at* https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf.

2 Pandemic Response Accountability Committee, Insights on Telehealth Use and Program Integrity Risks Across Selected Health Care Programs During the Pandemic (Nov. 30, 2022), *available at* https://www.pandemicoversight.gov/media/file/telehealthfinal508nov30pdf.

Consolidated Appropriations Act, 2023: New Statutory Exceptions for Physician Wellness Programs and Direction to OIG on Contingency Management Incentives

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (the Act), providing nearly $1.7 trillion in funding across a wide range of domestic initiatives. Tucked into the Act are new exceptions to the AKS and the physician self-referral law, section 1877 of the Social Security Act (Stark Law), for physician wellness programs.[3] In addition, the Act directs OIG to conduct a review on whether to establish a safe harbor for evidence-based contingency management incentives.[4]

Statutory Exceptions

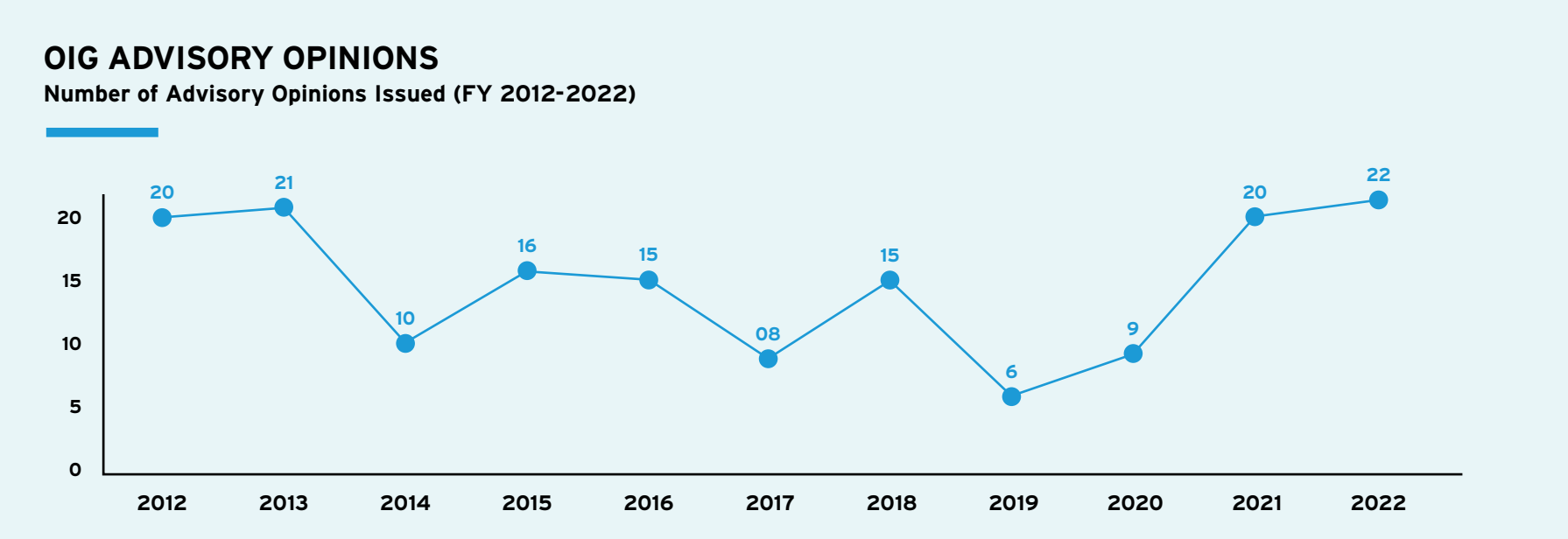
The new AKS and Stark Law statutory exceptions are substantially similar, with only minor changes reflective of the differences in the statutes' scope. The exceptions protect remuneration in the form of a *bona fide* mental health or behavioral health improvement or maintenance program that meets the following conditions:

1. The program must consist of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;
2. The program must be made available to a physician (or, in the case of the AKS, another clinician) for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of the physician (or other clinician);
3. The program must be set out in a written policy that is approved in advance of the operation of the program by the governing body of the entity providing the program that includes (a) a description of the content and duration of the program, (b) a description of the evidence-based support for the design of the program, (c) the estimated cost of the program, (d) the personnel conducting the program (and their qualifications), and (e) the method by which the entity will evaluate the use and success of the program;
4. The program may be offered by only certain types of entities with a formal medical staff, including hospitals, ambulatory surgery centers, community health centers, rural emergency hospitals, skilled nursing facilities, and other entities specified by regulation;
5. The program must be offered to all physicians (and, in the case of the AKS, other clinicians) who practice in the entity's geographic service area, including all physicians who have clinical privileges at the entity;
6. The program must be offered to all physicians (and, in the case of the AKS, other clinicians) on the same terms and conditions and without regard to the volume or value of referrals or other business generated by the individual for the entity (and, relatedly, neither the provision of the program nor the value of the program may be contingent on the number or value of referrals or other business generated by the individual for the entity);
7. The program must be evidence-based and conducted by a qualified health professional; and
8. The program must meet any other requirements imposed by regulation.

The exceptions enable hospitals and other healthcare organizations to provide comprehensive wellness programs for physicians and other clinicians in their communities by assuring that, if all of the elements are met, such programs will not constitute remuneration under the AKS or Stark Law.

The exceptions enable hospitals and other healthcare organizations to provide comprehensive wellness programs for physicians and other clinicians in their communities by assuring that, if all of the elements are met, such programs will not constitute remuneration under the AKS or Stark Law.

3 Consolidated Appropriations Act, 2023, Pub. L. 117-328, § 4126 (Dec. 29, 2022).
4 *Id.* at § 4127.



Review of Evidence-Based Contingency Management Incentives

The Act also directs OIG to conduct a review on whether to establish a safe harbor for evidence-based contingency management incentives. The review is to be conducted not later than one year after the date of enactment (i.e., December 29, 2023). In addition, not later than two years after the date of enactment (i.e., December 29, 2024), OIG is to submit to Congress recommendations for improving access to evidence-based contingency management interventions while ensuring quality of care and fidelity to evidence-based practices and including strong program integrity safeguards.

It is worth noting that OIG previously considered contingency management interventions in the the rulemaking in connection with the Regulatory Sprint to Coordinated Care.[5] Although OIG declined to expand the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions, OIG noted that such payments are not necessarily unlawful. The agency further observed that in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions could receive protection under the patient engagement and support safe harbor. It remains to be seen whether the Act will cause the agency to revisit the conditions under which such interventions may receive safe harbor protection.

5 *See generally* 85 Fed. Reg. 77684, 77791 (Dec. 2, 2020).

Significant Advisory Opinions

The industry witnessed a decline in the number of OIG advisory opinions issued in 2019 and 2020 while the agency focused on priorities such as the Regulatory Sprint to Coordinated Care, the response to the COVID-19 public health emergency, and various litigation against HHS and OIG. That trend reversed in 2021, and 2022 marked the second consecutive year in which the number of issued advisory opinions increased. OIG issued 22 advisory opinions in 2022, more than in any year since 2010. We highlight several noteworthy advisory opinions in this section and provide a chart summarizing all 2022 advisory opinions at the end of this HHS-OIG YIR.

2022 marked the second consecutive year in which the number of issued advisory opinions increased.

22-01

On January 13, OIG issued Advisory Opinion 22-01, approving an online retailer's proposal to extend its discount programs to Medicaid beneficiaries. The requestor, which operates an online marketplace, offers two discount programs to certain low-income individuals: (1) a discount on the monthly fee to its membership program, which provides benefits including free expedited shipping on orders from the requestor's wholly owned pharmacy, and (2) discounts on particular food and grocery items. The requestor proposed to extend these discount programs to Medicaid enrollees.

OIG concluded the proposed arrangement would implicate the AKS and the Beneficiary Inducements CMP because the discount programs, which include free expedited shipping of prescriptions, could induce Medicaid beneficiaries to purchase their Medicaid-reimbursable drugs from the requestor's wholly owned pharmacy. OIG determined that the arrangement would not satisfy any AKS safe harbor and would fail to satisfy the second element of the retailer rewards exception to the Beneficiary Inducements CMP, which requires rewards to be offered to the public on equal terms, regardless of health insurance status.

OIG nevertheless stated it would not pursue administrative sanctions because the arrangement would present a minimal risk of fraud and abuse under the AKS. Among the safeguards OIG cited were: (1) the attenuated nexus between the discount programs and the potential for a Medicaid beneficiary to order a prescription from the requestor's pharmacy; (2) the fact that the program does not target Medicaid beneficiaries and is unlikely to result in inappropriate use or overutilization of Medicaid-reimbursable drugs; and (3) the fact that the arrangement does not pose a patient safety or quality of care concern.

This opinion differs from other opinions that address the retailer rewards exception to the Beneficiary Inducements CMP. (*See Advisory Opinion Nos. 19-06, 17-05, 12-14, 12-05.)* In Advisory Opinion 22-01, OIG found that although the arrangement would not meet all elements of the retailer rewards CMP exception, the arrangement posed a low level of risk, and OIG would not impose sanctions.

22-04

On February 25, OIG issued Advisory Opinion 22-04, approving a digital health company's proposal to provide certain individuals digital contingency management tools and incentives—including the use of cash equivalents—to treat substance use disorders. This opinion is noteworthy because the program involves the use of cash equivalents (which have been a longstanding concern of OIG), and the total value of those cash equivalents may exceed the $500 cap (adjusted for inflation) OIG imposed in the new patient engagement and support safe harbor. Under the evidence-based, protocol-driven program, patients would receive incentives to motivate and sustain behavioral health efforts, such as attending treatment sessions or achieving certain behavioral goals. While the arrangement would implicate both the federal AKS and the civil monetary penalty provision prohibiting inducements to beneficiaries, OIG concluded that there was a low risk of fraud and abuse because (1) the program is protocol-driven and consistent with government-funded, evidence-based research; (2) the individual incentives are low in value and capped monthly and annually; (3) many of the requestor's customers have no incentive to induce members to receive federally reimbursable services; and (4) the smart debit card used to provide patients with rewards has anti-relapse protections.

Additional information from our client alert can be found here: OIG Approves Arrangement that Provides Cash Equivalents to Patients in Latest Advisory Opinion.

22-07

On April 20, OIG issued Advisory Opinion 22-07, approving an arrangement whereby physicians hold ownership interests in a medical device company that manufactures devices that the physicians or their family members may order for their patients. The requestors included three related orthopedic surgeons, their medical group, and a medical device company. The company was formed by one of the requestor physicians, who invented the company's intellectual property and has an ownership interest in an ambulatory surgery center (ASC) where the requestor-physicians and others in their medical group perform surgeries in which they may use company products.

Under the arrangement, the company granted a majority ownership interest to the inventor physician and his spouse in exchange for the assignment of his ownership interest in proprietary technology to the company. The physician and his spouse later contributed the majority interest in the company in two irrevocable trusts benefiting each other and their children, including one of the other requestor-physicians. The requestor-physicians' purchases of the company's products make up a very small percentage of the company's overall revenues, and revenues generated by the requestor-physicians and their medical group would be carved out from distributions to the trusts.

OIG distinguished the arrangement from its 2013 Special Fraud Alert on Physician-Owned Entities and concluded that the arrangement included safeguards sufficient to mitigate the risks of fraud and abuse. Of particular importance was the company's legitimacy, as evidenced by its range of operations and the carve-out of the physicians' and their medical groups' orders from the distributions to the trust.

Additional information from our client alert can be found here: OIG Approves Arrangement Involving Physician-Owned Device Manufacturer– Distinguishes Prior Special Fraud Alert on Physician-Owned Entities | Bass, Berry & Sims PLC (bassberry.com).

22-08

On April 22, OIG issued Advisory Opinion 22-08, approving a federally qualified health center's (FQHC) one-time loan of limited-use smartphones to existing patients to facilitate telehealth services. The requestor, an FQHC serving primarily low-income patients, offers telehealth services to its patients through a telehealth smartphone application. The smartphones, funded by a Federal Communications Commission COVID-19 telehealth grant and a local charity, were restricted to making and receiving telephone calls, sending and receiving text messages, looking at medical records, and using the telehealth application.

OIG concluded that the arrangement implicated the AKS by permitting patients to keep the smartphones under certain circumstances, and the Beneficiary Inducements CMP by likely influencing patients to select requestor for the receipt of federally-reimbursable items and services. The OIG declined to impose administrative sanctions and concluded that the provision of smartphones posed a minimal risk of fraud and abuse under the AKS. The OIG also found that during the public health emergency, the arrangement satisfied the "promotes access to care" exception to the Beneficiary Inducement CMP. Under this exception, the Beneficiary Inducement CMP is not violated by "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." The smartphones were provided to patients who did not already have a device capable of running the necessary telehealth application, the smartphones did not appear to interfere with clinical decision-making or otherwise increase the cost of federal healthcare programs (FHCPs) through overutilization or inappropriate utilization and the smartphones did not pose patient safety or quality of care concerns.

This opinion is noteworthy because it helps clarify the scope of the "promotes access to care" exception, noting that it applies only to a beneficiary's ability to obtain "items or services payable by Medicare or a State health care program." OIG noted that although the Beneficiary Inducement CMP exception may not shield the requestor's activities after the public health emergency ends, as it was not clear if the services would continue to be reimbursable by Medicare or Medicaid, no sanctions would be imposed.

22-09

On April 25, OIG issued Advisory Opinion 22-09, declining to approve a clinical laboratory's proposal to pay hospitals a per-patient-encounter fee to collect, process, and handle specimens that the hospitals send to the laboratory. The hospitals' phlebotomists would collect specimens, and fees would be paid only for patients who are not inpatients or registered outpatients of the hospital. The laboratory, in turn, would bill the applicable third-party payors (including FHCPs) for the testing.

OIG declined to approve the arrangement for two key reasons. First, OIG views laboratory services as particularly susceptible to inappropriate steering. Second, the "per-click" fee structure, even if consistent with fair market value, inherently reflects the business hospitals would send to the laboratory. Together, these dynamics created risks that the fees were intended to induce hospitals to steer business to the laboratory. The laboratory's proposed safeguards—prohibiting hospitals from billing payors for specimen collection and prohibiting hospitals from requiring referrals to the laboratory—were inadequate to overcome these risks.

An extension of earlier guidance and enforcement actions from OIG and the U.S. Department of Justice (DOJ), Advisory Opinion 22-09 reiterates the government's concern over arrangements where laboratories pay referral sources in a manner that varies with the business they send the laboratory. It also demonstrates that when fees are directly tied to volume, fair market value may not be enough to overcome this risk.

Additional information from our client alert can be found here: OIG Declines to Approve Lab's Payment of Specimen Collection Fees to Hospitals.

Advisory Opinion 22-09 reiterates the government's concern over arrangements where laboratories pay referral sources in a manner that varies with the business they send the laboratory. It also demonstrates that when fees are directly tied to volume, fair market value may not be enough to overcome this risk.

22-13

On June 17, OIG issued Advisory Opinion 22-13, approving an arrangement under which a durable medical equipment (DME) manufacturer maintains arrangements with financial institutions to offer zero-interest financing to the manufacturer's qualifying customers who are unwilling or unable to pay the requestor's total invoiced amounts. Under the arrangement, the lenders have the exclusive right to seek payment from the manufacturer's customers and administer, enforce, collect, litigate, settle, waive, or compromise on any defaulted transaction. The manufacturer certified that it does not advertise zero-interest financing or guarantee zero-interest financing to any customer.

OIG approved the arrangement for a number of reasons, including that (1) the customers ultimately end up paying the same amounts they would have paid, just over a longer time; (2) the lenders are not healthcare providers or suppliers; and (3) the arrangement is unlikely to increase costs to FHCPs because DME is reimbursed pursuant to a fee schedule.

This opinion serves as an important reminder that loans constitute remuneration under the AKS and that OIG will carefully consider the facts and circumstances surrounding loans between parties in a position to generate FHCP business.

Additional information from our client alert can be found here: OIG Approves DME Manufacturer Loan Program in Latest Advisory Opinion

Advisory Opinion 22-13 serves as an important reminder that loans constitute remuneration under the AKS and that OIG will carefully consider the facts and circumstances surrounding loans between parties in a position to generate FHCP business.

22-14

On June 23, OIG issued Advisory Opinion 22-14, approving in part and denying in part a request from an ophthalmology practice regarding four variations of its proposed continuing education (CE) programs designed for local optometrists. The requestor, an ophthalmology practice with one ophthalmologist and three optometrists, specializes in cataract and refractive surgery and receives half of its surgical referrals from local optometrists, with 30% of those patients returning to the referring optometrist for post-operative care co-managed by requestor's ophthalmologist. The practice proposed to offer two annual CE programs to local optometrists, designed to address new ophthalmic technology and pharmaceutical practice treatment protocols. The CE programs would be open to all local optometrists, regardless of historical or anticipated referral patterns, and would include modest food and non-alcoholic refreshments. The practice proposed various registration fee and payment structures for the CE programs. Under one proposal, the practice would charge attendees a fair market value registration fee; under another, the practice would not charge any fee and would cover the cost of the programs itself. Under the other proposals, the practice would solicit funding from pharmaceutical and device manufacturers and use the funding to subsidize all or some portion of the registration fee.

Advisory Opinion 22-14 is notable because it reinforces OIG's concerns with free CE programs, applies recent OIG guidance related to speaker programs funded by pharmaceutical and device manufacturers to programs organized by physicians, and generates confusion regarding why the opportunity to pay a fair market value fee for CE may constitute an inducement.

OIG concluded that each of the proposed arrangements implicated the AKS because, under each, the requestor would give something of value (the CE programs) to potential referral sources. OIG first looked to its November 2020 Special Fraud Alert for Speaker Programs and determined that the proposed CE programs did not exhibit any suspect characteristics. OIG went on to approve the proposal to charge a fair market value fee for the CE but did not analyze the arrangement under the personal services safe harbor. However, OIG found that each of the other three proposals presented too high of a risk to approve because the free or subsidized CE could induce attendees to refer surgical patients to the requestor or to order the sponsoring companies' products.

This opinion is notable because it reinforces OIG's concerns with free CE programs, applies recent OIG guidance related to speaker programs funded by pharmaceutical and device manufacturers to programs organized by physicians, and generates confusion regarding why the opportunity to pay a fair market value fee for CE may constitute an inducement .

Additional information from our client alert can be found here: Sponsoring Continuing Education Programs—OIG Weighs in with Advisory Opinion 22-14.

22-16

On August 16, OIG issued Advisory Opinion 22-16, approving an online patient education company's request to provide gift cards to certain Medicare Advantage (MA) enrollees who complete an online patient education program. The requestor is a company that operates a shared decision-making, online learning tool designed to educate patients on potential risks, benefits, and expectations related to surgeries. The tool includes two modules intended to increase patient understanding of surgical treatment options, reduce inappropriate surgeries, and lead to better outcomes when surgery is required. It does not refer to, recommend, or even reference specific healthcare providers, suppliers, practitioners or services. Enrollees who complete the first module (along with a survey) receive a $25 gift card. Participation is voluntary, and enrollees need not choose a particular treatment option or demonstrate surgical literacy to receive the gift card.

OIG concluded that the arrangement presents a sufficiently low risk of fraud and abuse under the AKS because, among other reasons, (1) it is unlikely to increase costs to FHCPs or result in inappropriate utilization; and (2) is unlikely to impact competition among healthcare providers, practitioners, or suppliers. Furthermore, although the $25 gift cards constitute remuneration to Medicare beneficiaries, OIG concluded that the arrangement does not implicate the Beneficiary Inducements CMP because it does not refer enrollees to, recommend, or even reference any particular provider, practitioner, or supplier.

This favorable opinion provides an avenue for MA plans and downstream contractors to educate patients through limited-frequency, modest rewards—including cash equivalents—as long as the entities implement appropriate safeguards and do not reference, refer to, or recommend any specific provider, practitioner, supplier, or service.

Additional information from our client alert can be found here: OIG Approves Educational Program that Provides Cash Equivalents to Patients.

22-19

On September 30, OIG issued Advisory Opinion No. 22-19, finding that a proposal by an entity funded entirely by manufacturers of oncology drugs to provide cost-sharing assistance to Medicare Part D beneficiaries for the funding manufacturers' own drugs, as well as certain other assistance, could violate the AKS.

The requestor is a C-corporation actively applying for 501(c)(3) status, with an independent board of directors comprised of individuals with expertise in healthcare policy, management, and operations. Under the proposed arrangement, participating manufacturers, through the requestor, would subsidize cost-sharing amounts for their own products, as well as assist with health insurance premiums for eligible Part D beneficiaries. Part D beneficiaries would be eligible for cost-sharing assistance if they have a cancer diagnosis, have a household income between 150-300% of the federal poverty level (FPL), and have been prescribed an oncology drug manufactured by a participating manufacturer that is covered by the beneficiary's Part D plan. The health insurance premium subsidies would be available to qualifying Part D beneficiaries regardless of whether they have been prescribed an oncology drug manufactured by a funding manufacturer. All manufacturers of branded or generic oncology drugs covered under Part D would be eligible to participate in the proposed arrangement and would reimburse the requestor for the amount of the cost-sharing subsidies attributable to their own products as well as their share of the premium subsidy amounts.

Unfavorable Advisory Opinion 22-19 follows Pfizer's loss in the U.S. Court of Appeals for the Second Circuit, where Pfizer challenged OIG's issuance of an unfavorable advisory opinion involving Pfizer's direct copayment assistance program.

OIG acknowledged that facilitating access to medically necessary oncology drugs "is of paramount concern" but declined to approve the proposed arrangement, finding that the cost-sharing subsidies likely would influence beneficiaries' decisions regarding whether to purchase the participating manufacturers' drugs. Despite having acknowledged the possibility of a "coalition model" patient assistance program in its 2005 Special Advisory Bulletin on Patient Assistance Programs, OIG noted that its enforcement experience has led it to conclude that allowing manufacturers to subsidize copayments for their own drugs may encourage manufacturers to increase the list prices of their drugs.

This unfavorable advisory opinion follows Pfizer's loss in the U.S. Court of Appeals for the Second Circuit, where Pfizer challenged OIG's issuance of an unfavorable advisory opinion involving Pfizer's direct copayment assistance program, and appears to foreclose another potential avenue for pharmaceutical manufacturers to provide cost-sharing assistance for their own drugs.

Additional information from our client alert can be found here: OIG Closes the Door on Coalition-Model Patient Assistance Programs in its Latest Advisory Opinion.

Advisory Opinion 22-20 is noteworthy because it represents a departure from OIG's typical approach to arrangements involving remuneration from hospitals to referring physicians.

22-20

On December 14, OIG issued Advisory Opinion 22-20, approving an acute care hospital's arrangement under which its employed nurse practitioners perform certain services that the patients' attending physicians traditionally perform.

The requestor, an acute care hospital, uses its employed nurse practitioners to perform various tasks for the patients of participating physicians who are inpatients or in observation status in two designated general care medical units. The participating physicians are predominantly primary care physicians, and the nurse practitioners perform a variety of tasks the physicians normally would perform in collaboration with the participating physicians. The treating physicians cannot bill for the nurse practitioners' services and remain ultimately responsible for their patients' care; however, the arrangement allows their patients to be treated and diagnosed more quickly. OIG considered this arrangement low risk because it is limited to non-surgical and non-specialty hospital units and incorporates several safeguards, including the fact that physicians may not bill for the work the nurse practitioners perform. OIG also determined that the arrangement may improve patient care through more timely evaluations.

This favorable opinion is noteworthy because it represents a departure from OIG's typical approach to arrangements involving remuneration from hospitals to referring physicians. However, the opinion addresses only the AKS and does not address the potential hurdles such arrangements may face under the Stark Law, thus limiting its potential relevance.

Additional information from our client alert can be found here: OIG Approves Hospital Provision of Nurse Practitioner Services in Advisory Opinion.

A Recap: OIG Updates to the Self-Disclosure Protocol and Significant 2022 Self Disclosures

Self-Disclosure Protocol (SDP) Process Updates

In November 2021, OIG published an update to its Health Care Fraud Self-Disclosure Protocol.[6] The SDP is a reporting tool that allows healthcare providers and suppliers to voluntarily identify, disclose and resolve instances of potential fraud involving FHCPs.

In its update, OIG noted the SDP's success in resolving more than 2,200 self-disclosures between 1998 and 2020, resulting in recoveries of more than $870 million to the FHCPs. Disclosing parties benefit from making a self-disclosure through the SDP by reaching a settlement at a lower multiplier than would be required in resolving a government-initiated investigation and receiving a release of OIG's permissive exclusion authority without requiring any additional integrity measures.

While OIG did not change the timelines and content requirements for disclosures or methods for the calculation of damages, the updated SDP included several changes.

Assessment of Penalties and Calculation of Damages. One of the most notable changes related to the minimum penalties to be assessed in resolving a matter through the SDP. In its update, OIG doubled the minimum settlement amounts for the resolution of self-disclosed matters, requiring a minimum amount of $100,000

In its update, OIG doubled the minimum settlement amounts for the resolution of self-disclosed matters, requiring a minimum amount of $100,000 to settle all kickback-related submissions.

6 OIG's Health Care Fraud Self-Disclosure Protocol (2021), *available at* https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf. The SDP was previously named the "Provider Self-Disclosure Protocol." The November 2021 update included renaming the SDP to the "Health Care Fraud Self-Disclosure Protocol." The new name clarifies that the SDP is available to any entity subject to CMPs, not just healthcare providers.

to settle all kickback-related submissions and a minimum amount of $20,000 to resolve all other matters to match the new statutory minimum penalty amounts under the Civil Monetary Penalties Law.[7]

OIG's update also clarified that all disclosures must include an estimate of damages for each affected FHCP *and* the sum of estimated damages for all affected healthcare programs. If a disclosing party can determine actual damages, the disclosure must include the actual damages calculations rather than an estimated amount. A disclosing party unable to include estimated or actual damages must include a certification that the estimate will be completed and submitted to OIG within 90 days of the submission date.

Online Submissions Only. OIG now requires disclosing parties to submit all disclosures through OIG's online portal. OIG also clarified that parties subject to Corporate Integrity Agreements (CIAs) may use the SDP process to report a "Reportable Event" as defined in the CIA. When disclosing a Reportable Event, the disclosure must reference that the disclosing party is subject to a CIA and send a copy of the disclosure to the disclosing party's OIG monitor.

Matters Not Eligible for SDP. OIG reiterated matters that would not be eligible for resolution under the SDP. OIG noted the SDP is only available to resolve matters involving potential violations of federal criminal, civil, or administrative law for which CMPs are authorized. As an example, OIG noted that matters involving only overpayments or errors should be disclosed directly to the appropriate Centers for Medicare & Medicaid Services (CMS) contractor for resolution under the contractor's voluntary refund process. The SDP also may not be used to obtain an opinion from OIG regarding whether an actual or potential violation has occurred. Finally, the SDP is not available to resolve matters involving liability only under the physician self-referral law, commonly known as the Stark Law, or for disclosures related to receipt of HHS grants or for federal contractors. Potential Stark Law violations may be disclosed to CMS through its Self-Referral Disclosure Protocol. Disclosures related to HHS grants or federal contractor matters may be disclosed through OIG's Grant Self-Disclosure Program[8] or OIG's Contractor Self-Disclosure Program[9], respectively.

In matters where DOJ declines to participate, OIG will handle the disclosure under its CMP authorities. Because OIG does not have the authority to settle claims under the False Claims Act (FCA), a resolution solely by OIG would not include a release of FCA liability.

DOJ Settlement of SDP Matters. OIG's final revision to the SDP clarified its coordination with DOJ in resolving SDP matters. In matters where DOJ declines to participate, OIG will handle the disclosure under its CMP authorities. Because OIG does not have the authority to settle claims under the False Claims Act (FCA), a resolution solely by OIG would not include a release of FCA liability. For matters where DOJ elects to participate, DOJ's intervention in the matter will result in a settlement consistent with the agency's resolution in FCA cases. OIG may ask DOJ for leniency in the process by requesting the disclosing party receive a benefit from disclosing the violation, and DOJ may resolve the matter under OIG's approach. While OIG's opinion may influence DOJ, DOJ ultimately determines the resolution of the matters in which it participates. Notably, OIG deleted language previously included in its prior version of the SDP encouraging disclosing parties to disclose criminal conduct through the SDP and its commitment to advocate for lenient treatment from DOJ in criminal matters disclosed to OIG.

Significant SDP Settlements

OIG regularly publishes summaries of settlements resulting from voluntary self-disclosures made pursuant to the SDP. Although OIG's summaries of these matters are often short on details, they offer insight into potential violations of the fraud and abuse laws and can serve as a useful compliance tool. In 2022, OIG posted 70 enforcement actions resolved through the SDP. The most common alleged violations involved excluded persons (28), billing under another practitioner's name (9), kickbacks (7), and unlicensed persons (5).

These 70 enforcement actions resulted in more than $66 million in settlement payments. Individual settlements ranged from $10,000 to over $14 million. The average was just shy of $1 million. Ten settlements accounted for over $53 million. The remaining 60 settlements totaled $13 million and averaged $225,000.

Several of the settlements are noteworthy, including one due to its damages calculation and others due to the disclosed conduct:

- A skilled nursing facility agreed to pay $17,000 to resolve allegations that it furnished nursing services through unlicensed nurses. Rather than calculating damages based on all tainted claims, OIG calculated single damages based on the full salary and benefits of the two nurses. Although the SDP describes this methodology for excluded persons who

7 *See* Section 1128A(a)(7) of Social Security Act; *see also* OIG's Health Care Fraud Self-Disclosure Protocol (2021), *available at* https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf.

8 https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/.

9 https://oig.hhs.gov/compliance/self-disclosure-info/contractor-self-disclosure-program/.

provide items or services that are not separately billed to FHCPs, it does not for those provided by unlicensed persons. Extending this logic to unlicensed persons avoids harsh claims-based damages, which can be vastly disproportionate to the portion of the item or service furnished by the unlicensed person.

- A health system in Missouri agreed to pay $100,000 to resolve allegations that it provided unlawful remuneration to over 100 community physicians in the form of free continuing medical education and meals in violation of the AKS, an issue OIG addressed in Advisory Opinion 22-14, which we summarize on page 8.
- A clinical laboratory in Arizona agreed to pay nearly $3.5 million to resolve several allegations, including billing for pathology services not provided, waiving copayments, accepting per-referral payments from a pharmaceutical manufacturer for referring patients to a clinical trial, and paying kickbacks to referring physicians in the form of improper registry payments.
- An ambulatory surgery center in Ohio agreed to pay $50,000 to resolve allegations that it paid unlawful remuneration to three physician owners in the form of profit distributions based in part on the facility fees generated by the owners.
- A physician practice in Michigan agreed to pay $50,000 to resolve allegations that it received improper remuneration from another physician practice and a surgery center in the form of an ownership interest in the surgery center and payment of related legal fees.

Two others are noteworthy simply for the size of the settlement amounts:

- A hospital in Washington agreed to pay over $14 million to resolve allegations that claims for inpatient rehabilitation stays did not satisfy Medicare coverage criteria. This self-disclosure resulted from an OIG Office of Audit Services audit.
- A hospital in Florida agreed to pay nearly $13 million to resolve allegations that claims submitted for pain management procedures and evaluation and management procedures performed by two physicians did not meet coverage criteria.

Other Significant Matters

Pfizer's Suit Against OIG

Pfizer's challenge to OIG's interpretation of the AKS and its unfavorable advisory opinion came to a close in early 2023. Pfizer first filed suit against HHS and OIG in 2020, seeking a declaratory judgment that its proposal to directly subsidize copayments for patients who had been prescribed its costly drug to treat a rare heart condition would not violate the AKS.[10] Before filing suit, Pfizer requested an advisory opinion from OIG with respect to its proposed copayment assistance program. Pfizer filed suit after OIG informed Pfizer that the opinion would be unfavorable, but before OIG issued the opinion, asserting that, to violate the AKS, the program must be administered with a corrupt intent that improperly skews the patient's decision-making. The district court rejected Pfizer's argument, concluding that nothing in the AKS's text requires a corrupt intent, and dismissed Pfizer's claims. Pfizer appealed the district court's decision to the Second Circuit, which rejected Pfizer's argument that the word "induce," as used in the AKS, requires or implies an element of corruption and affirmed summary judgment .[11] After failing to persuade the lower courts, Pfizer filed cert with the United States Supreme Court, asking the Court to decide whether the AKS is violated only if the person offering "remuneration . . . to induce" the purchase of a federally reimbursable item *intends to corrupt* the recipient's medical decision making.[12]

The district court rejected Pfizer's argument, concluding that nothing in the AKS's text requires a corrupt intent, and dismissed Pfizer's claims. Pfizer appealed the district court's decision to the Second Circuit, which rejected Pfizer's argument that the word "induce," as used in the AKS, requires or implies an element of corruption and affirmed summary judgment. The Supreme Court denied Pfizer's petition for a writ of certiorari.

10 *Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.*, No. 1:20-cv-04920 (S.D.N.Y. Jun. 26, 2020).
11 *Pfizer Inc. v. United States Department of Health and Human Services*, No. 21-2764-cv (2d Cir. July 25, 2022).
12 Petition for Writ of Certiorari, *Pfizer Inc., v. U.S. Dep't of Health & Human Servs.*, No. 22-339 (2022).

In its petition, Pfizer argued that the lower courts' and OIG's interpretation of the AKS was overbroad and thus prohibits a wide swath of routine, beneficial conduct in connection with federally funded healthcare. The Supreme Court denied Pfizer's petition for a writ of certiorari on January 9, 2023.

PCPA Advisory Opinion and Suit Against OIG

Shortly after OIG issued Advisory Opinion 22-19 (summarized on page 9), the requestor— Pharmaceutical Coalition for Patient Access (PCPA)—sued OIG on a number of grounds related to OIG's handling of its request and also directly challenged the framework of the AKS.[13] In this live controversy, PCPA asserts that its proposed coalition assistance program cannot violate the AKS because a needy cancer patient receives assistance with oncology drugs only after the patient's treatments have been determined and approved by an independent medical provider, which does not satisfy the "in return for" and "to induce" requirements of the AKS. In short, PCPA argues that its program does not involve a *quid pro quo*, which PCPA asserts is required to trigger AKS liability. Additionally, PCPA asserts similar "corruption" theories observed in the Pfizer litigation, arguing that the AKS requires an element of "corruption." PCPA essentially alleges that its proposed program does not result in prohibited remuneration because it does not involve any element of corruption.

This case is noteworthy because it represents a continuation of the pharmaceutical industry's attack on the AKS—a statute that PCPA reads as requiring both a *quid pro quo* exchange and an element of corruption. The outcome of this case and any appeal to the Fourth Circuit could set up a potential circuit split with the Pfizer decision in the Second Circuit—a split the Supreme Court may be more likely to review. The case has been assigned to the Eastern District of Virginia, and briefing is underway.

The outcome of this case and any appeal to the Fourth Circuit could set up a potential circuit split with the Pfizer decision in the Second Circuit—a split the Supreme Court may be more likely to review.

13 *Pharmaceutical Coalition for Patient Access v. U.S. Dep't of Health and Hum. Servs.*, No. 3:22-cv-00714 (E.D.Va. Jun. 26, 2020).

OIG Front Office and Office of Counsel Leadership Changes

In February, Christi Grimm was sworn in as OIG's 6th Inspector General after serving as Principal Deputy Inspector General (PDIG), performing duties of the Inspector General since January 2020. Juliet Hodgkins was elevated to PDIG, and Megan Tinker was named Chief of Staff. In early 2023, Robert DeConti was named OIG's Chief Counsel.

Appendix - 2022 Advisory Opinions

OIG issues advisory opinions on whether a requesting party's existing or proposed business arrangements violate certain fraud and abuse authorities. This appendix provides a summary of all of OIG's 2022 advisory opinions. If you are interested in advisory opinions from prior years, you may access them on OIG's website.

Date Issued	Advisory Opinion No.	Result (Favorable/ Unfavorable)	Arrangement Description
1/13/2022	22-01	Favorable	A proposal by a retailer operating a web-based marketplace that sells a wide variety of consumer goods and services to the general public to expand its discount programs for low-income individuals. The retailer also has a wholly-owned pharmacy subsidiary operating in a number of states.
2/4/2022	22-02	Favorable	A proposed arrangement between a charitable organization that operates a children's hospital and two individuals, pursuant to which the charitable organization and the individuals would reduce and subsidize certain costs incurred by qualifying patients of the charitable organization's children's hospital.
2/9/2022	22-03	Favorable	A proposal by an owner and operator of home health agencies that employ certified nurse aides (CNAs) who provide home health aide services to the agencies' patients to pay salaries to and nurse aide certification program tuition costs on behalf of new employees who the organization has hired to work as CNA's for the organization's home health agencies.
2/25/2022	22-04	Favorable	A proposal by a digital health company to operate a program providing individuals meeting specified criteria with access to digital contingency management and related tools to treat substance use disorders. The program is funded by customers, which could include individuals' healthcare providers or suppliers.
3/11/2022	22-05	Favorable	A medical device manufacturer's proposal to subsidize certain Medicare cost-sharing obligations in the context of a clinical trial.
4/6/2022	22-06	Favorable	A proposal for the provision of free genetic testing and genetic counseling services to individuals who meet specified clinical criteria.
4/20/2022	22-07	Favorable	A proposed arrangement in which certain physicians have an ownership interest in a medical device company that manufactures products that may be ordered by the physician owners and a physician spouse of one of the physician owners.

Date Issued	Advisory Opinion No.	Result (Favorable/ Unfavorable)	Arrangement Description
4/22/2022	22-08	Favorable	A federally qualified health center's proposal to loan limited-use smartphones to current patients to facilitate access to telehealth services.
4/25/2022	22-09	Unfavorable	A proposed arrangement pursuant to which an organization operating a network of clinical laboratories would compensate hospitals for certain specimen collection services for laboratory tests furnished by the organization.
4/27/2022	22-10	Favorable	A proposal requested by a nonprofit organization dedicated to providing resources, service, and support to individuals with a specified disease state regarding (1) a modification to OIG Advisory Opinion 15-14, issued to the nonprofit organization on November 13, 2015, to include within the scope of that opinion, the nonprofit organization's proposal to provide financial assistance for certain past magnetic resonance imaging tests; and (2) a second arrangement regarding the distribution of certain cooling and mobility items, ancillary to the arrangement addressed in OIG Advisory Opinion 15-14.
5/20/2022	22-11	Favorable	A medical group practice's proposal to employ an individual who is excluded from participation in federal healthcare programs to perform marketing tasks relating to workers' compensation programs.
5/26/2022	22-12	Favorable	A proposal to use a "preferred hospital" network as part of Medicare Supplemental Health Insurance (Medigap) policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.
6/17/2022	22-13	Favorable	A durable medical equipment manufacturer's arrangements with two financial institutions to make zero-interest financing available to qualified customers.
6/23/2022	22-14	Favorable and Unfavorable	An ophthalmology practice's proposal for continuing education programs for local optometrists and four financing options to fund the programs.
6/29/2022	22-15	Favorable	A proposal between two universities located in different states to use donations to cover: (1) specialized care furnished to veterans who meet certain criteria; and (2) certain out-of-pocket expenses related to that specialized care.
8/16/2022	22-16	Favorable	A proposal for the provision of gift cards to certain Medicare Advantage plan enrollees who complete specific steps in an online patient education program.

Date Issued	Advisory Opinion No.	Result (Favorable/ Unfavorable)	Arrangement Description
8/31/2022	22-17	Favorable	A health system's proposal to restructure its financial relationships, which include the forgiveness of debt, between a health system and a nearby clinic.
9/15/2022	22-18	Favorable	A proposal for the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance (Medigap) policies, whereby an insurance company would contract with a preferred hospital organization to provide discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.
9/30/2022	22-19	Unfavorable	A nonprofit's proposal to allow pharmaceutical manufacturers to (1) fund, through the nonprofit, cost-sharing subsidies for the manufacturers' Part D oncology drugs; (2) fund, through the nonprofit, specified programs and eligible beneficiaries' health insurance premiums; and (3) finance the nonprofit's operating costs.
12/14/2022	22-20	Favorable	A hospital's proposal to use its employed nurse practitioners to perform services that traditionally have been performed by a patient's attending physician in certain medical units.
12/20/2022	22-21	Favorable	A county and its department of public health's emergency medical services division proposal to sublease certain space and lease certain furniture and equipment to a private ambulance company that has been granted an exclusive contract for the provision of emergency ambulance transports in certain parts of the county.
12/22/2022	22-22	Favorable	A pharmaceutical manufacturer's proposal to provide up to a specified number of trial units of a long-acting antipsychotic drug to certain hospitals for inpatient use.

About Bass, Berry & Sims

Marked by an integrated approach and unmatched regulatory knowledge, the Healthcare Practice of Bass, Berry & Sims is a team of more than 260 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 nationally ranked by Chambers USA for the last seven years (2016-2022) and recognized as the fourth largest healthcare law firm in the U.S. by the American Health Law Association (2022).

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.

AMERICAN HEALTH LAW ASSOCIATION

Ranked 4th Largest Healthcare Firm in U.S. 2022

Modern Healthcare

Ranked 5th Largest Healthcare Firm in U.S. 2022

TOP RANKED Chambers USA 2022

Nationally Ranked Elite Healthcare Practice 2022

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.

*Justin Brown is admitted to practice in Alabama and Massachusetts; Tennessee bar application pending

ANNA M. GRIZZLE

Member | 615.742.7732 | agrizzle@bassberry.com

Anna Grizzle focuses her practice exclusively on helping healthcare clients address enforcement, fraud and abuse, and compliance issues through the structuring of arrangements and in responding to potential legal and regulatory matters and government investigations. Anna routinely advises on the reporting and repayment of overpayments and in responding to payor audits and has advised a number of healthcare clients in self-disclosures, including disclosures made through the Stark Law and HHS-OIG disclosure protocols.

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.

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.

ANGELIQUE M. SALIB

Associate | 202.827.7978 | angelique.salib@bassberry.com

Angelique Salib provides healthcare regulatory counsel as it relates to compliance, operational, and transactional matters through applicable components of the Stark Law, the federal Anti-Kickback Statute, Medicare reimbursement, and managed care, in addition to clinical research and life sciences matters. She also works with hospital and health system clients on contractual arrangements and a broad range of compliance matters.