

Opinion #	Date of Issuance	Entity Type	Proposed Arrangement	Outcome	OIG's Determination re: Prohibited Remuneration and Potential Sanctions
<a href="#">AO 22-22</a>	Dec. 22, 2022	Manufacturer of a Long-Acting Injectable Atypical Antipsychotic Drug	<ul style="list-style-type: none"> <li>Requestor would permit hospitals that do not dispense samples that comply with the Prescription Drug Marketing Act of 1987 in their facilities to request up to a maximum number of 20 units per month, limited to 2 free units of the drug (each of which provides medication coverage for 1 month) per eligible inpatient, per calendar year.</li> </ul>	Favorable; Low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>The OIG determined the risk under AKS would be low for three reasons: <ul style="list-style-type: none"> <li>(1) the risk of a hospital steering inpatients to the drug based on receipt of the drug for free is low because clinicians would make independent decisions about the appropriateness of the Drug for a particular patient and the arrangement would not give prescribers a financial incentive to prescribe the drug;</li> <li>(2) the arrangement is unlikely to increase costs to federal health care programs inappropriately and could reduce costs overtime if successful because it could reduce hospitalizations; and</li> <li>(3) the arrangement includes safeguards to minimize the risk of misuse of the free trial units, including requiring Participating Hospitals to a prohibition on selling or billing for the units.</li> </ul> </li> </ul>
<a href="#">AO 22-21</a>	Dec. 20, 2022	County Emergency Medical Services Division (Political Subdivision)	<ul style="list-style-type: none"> <li>Requestor is a political subdivision that manages EMS in a county and subleases space to its exclusive Ambulance Supplier (Supplier).</li> <li>Requestor does not pay the supplier for providing emergency ambulance transports except those for patients who fall under the county's financial responsibility, such as inmates and detainees.</li> <li>Payments from patients and third-party payors comprise the Supplier's primary compensation.</li> </ul>	Favorable; Minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>While the safe harbors for space rental, equipment rental, personal services and management contracts, and outcomes-based payment arrangements may apply, not all remuneration streams satisfy a safe harbor.</li> <li>For example, the Ambulance Supplier's rental payments to Requestor for the subleased space would not satisfy the space rental safe harbor because the aggregate rental charge for the subleased space is not set in advance.</li> <li>However, the arrangement appears to be a reasonable means for Requestor to fulfill its obligation to manage Emergency Medical Services in the County, with the only remuneration stemming from the subleased space and leased equipment.</li> </ul>

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			<ul style="list-style-type: none"> <li>Under the sublease, Requestor does not profit from leasing the space and passes through all costs, fees and bills between the Supplier and the landlord.</li> </ul>		
<a href="#">AO 22-20</a>	Dec. 14, 2022	Acute Care Hospital	<ul style="list-style-type: none"> <li>Requester is an acute care hospital that uses its employed nurse practitioners (NPs) to assist physicians in rendering care to patients who are inpatients or in observation status in two designated units.</li> <li>Although the NPs perform many tasks that would otherwise be done by the physician: (1) the duties performed by the NPs are done in communication and collaboration with physician treating the patients, while the physician must still round daily; (2) the physician is prohibited from billing for services furnished by the NP and the physician must generate their own documentation to bill for their services; and (3) the Requestor additionally pays for all services rendered by NPs and does not separately bill any payor for the NP's services.</li> </ul>	Favorable; Minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>The risk of fraud and abuse is minimal because the arrangement is restricted to two non-surgical, non-specialty units, and participating physicians are mostly primary care physicians rather than specialists that could be positioned to make more lucrative referrals to Requestor.</li> </ul>
<a href="#">AO 22-19</a>	Sept. 30, 2022	C-Corp that applied for 501(c)(3) status	<ul style="list-style-type: none"> <li>Requestor is funded entirely by pharmaceutical manufacturers that produce oncology drugs reimbursed by Medicare Part D.</li> </ul>	Unfavorable; More than a minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS.</li> <li>The OIG determined that the proposed arrangement presents more than a minimal risk of fraud and abuse because it would target a class of drugs that present</li> </ul>

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			<ul style="list-style-type: none"> <li>• Requestor proposes a new patient assistance model in response to studies that show the negative relationship between treatment delays and oncology patients incurring out-of-pocket costs for treatments that are a product of benefit designs. The arrangement requires each of the funding manufacturers supporting Requestor to subsidize three categories of costs: (1) cost sharing incurred by eligible Part D enrollees when filling prescriptions for that funding manufacturer's oncology drugs; (2) specified programs designed to increase health equity and clinical trial participation and certain beneficiaries' health insurance premiums; and (3) Requestor's operating costs.</li> <li>• The arrangement produces three distinct streams of remuneration designed to remove barriers to enable eligible Part D enrollees to purchase the funding manufacturer's drugs, or about 90% of Part D oncology products.</li> </ul>		<p>limited price negotiability for plan sponsors and price increases that exceed inflation.</p> <ul style="list-style-type: none"> <li>• The OIG also stated the arrangement circumvents a key price control and could impede the ability of sponsors to control costs for oncology drugs because it essentially insulates beneficiaries from high prices.</li> <li>• The arrangement also risks penalizing non-participating manufacturers who do not subsidize cost sharing for their products. However, the remuneration is not likely to induce a beneficiary to select a specific provider, practitioner, or supplier for items that may be covered by Medicaid or State healthcare programs.</li> </ul>
<p><a href="#">AO 22-18</a></p> <p><a href="#">AO 22-12</a></p>	<p>Sept. 15, 2022</p> <p>May 26, 2022</p>	<p>PHO and Network Hospitals</p>	<ul style="list-style-type: none"> <li>• Requestor seeks to incentivize Medigap Plan policyholders to seek inpatient care from a hospital within the network of a preferred hospital organization (PHO).</li> <li>• Under the arrangement, each network hospital provides a</li> </ul>	<p>Favorable; Minimal risk of fraud and abuse</p>	<ul style="list-style-type: none"> <li>• The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions, despite the arrangement not falling within any safe harbor.</li> <li>• The OIG would not impose civil monetary penalties.</li> <li>• The arrangement is not likely to result in overutilization of healthcare items or services or to increase costs to</li> </ul>

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			<p>discount on the Medicare Part A inpatient deductible that the Plan would ordinarily cover, and the Plan gives the policyholder a \$100 premium credit. Additionally, the Medigap Plan pays the PHO monthly administrative fees as compensation for establishing the hospital network and for arranging the deductible discount program.</p> <ul style="list-style-type: none"> <li>This involves three streams of remuneration: (1) the discount to inpatient deductibles; (2) the premium credit; and (3) the administrative fees paid by the Plan to the PHO.</li> </ul>		<p>Federal healthcare programs and the administrative fee is consistent with fair market value.</p> <ul style="list-style-type: none"> <li>The arrangement does not impact patient choice and has minimal potential to harm patients or impact competition.</li> </ul>
<a href="#">AO 22-17</a>	Aug. 31, 2022	501(c)(3) not-for-profit healthcare system and clinic	<ul style="list-style-type: none"> <li>Requestor proposes to restructure existing financial agreements (a credit line note, a lease, and a master services agreement) between the health system and the clinic.</li> <li>The health system would forgive in full the outstanding amounts under all three agreements and would enter into a new lease that would permit the clinic to use the premises for free and a new arrangement that would require the clinic to pay the health system fair market value for all services and supplies.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>The clinic is not a federally qualified health center (FQHC), and therefore it does not qualify for the FQHC safe harbor. However, the clinic is a FQHC "look alike" and poses a sufficiently low risk of fraud and abuse because the structure of the arrangement would align with the requirements under the safe harbor, and would reduce the risk of inappropriate patient steering from the clinic to the health system.</li> </ul>
<a href="#">AO 22-16</a>	Aug. 16, 2022	Third party entity that provides an online shared decision-	<ul style="list-style-type: none"> <li>Requestor contracts with certain Medicare Advantage Organizations to offer an online shared decision-making tool that aims to improve</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>The arrangement poses a low risk because it likely will not: increase costs to Federal programs, induce a</li> </ul>

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		making tool for patients considering surgery	<p>patient literacy and decrease inappropriate surgeries by educating patients on potential risks, benefits, and expectations relating to surgeries.</p> <ul style="list-style-type: none"> <li>Enrollees who complete this module of the program receive a \$25 gift card to a retailer a maximum of once per year.</li> </ul>		beneficiary to select one provider over another, or impact competition among providers. The program could even decrease costs by reducing inappropriate utilization.
<a href="#">AO 22-15</a>	June 29, 2022	University A (including University A School of Medicine and University A Management Entity); (2) University B (on behalf of University B Medical Group)	<ul style="list-style-type: none"> <li>Both Universities provide specific treatments and specialty TBI and PTS care to U.S. military veterans through their "Intensive Outpatient Program. Any out-of-pocket costs a veteran would incur as a result of their screening for or participation in this program are covered by charitable donations from donors outside of the medical field.</li> <li>The Requestor would bill an insurer (including Federal healthcare programs) for all covered expenses.</li> <li>Notably, all veterans who meet clinical criteria would receive treatment from the programs regardless of financial need or insurance and the risk of "leapfrogging" between this and other benefit programs is very low due to its niche offerings of the program.</li> </ul>	Favorable; minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG found minimal risk of fraud and abuse and would not impose sanctions.</li> </ul>
<a href="#">AO 22-14</a>	Jun. 23, 2022	Ophthalmology practice specializing in	<ul style="list-style-type: none"> <li>Requestor would offer annual continuing education (CE) courses about new technology</li> </ul>	Favorable with respect to financing	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS and the OIG would impose sanctions.</li> </ul>

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		cataract and refractive surgery	<p>and treatment protocols and be open to all local optometrists within approximately 20 miles.</p> <ul style="list-style-type: none"> <li>Requestor proposed several financing options: (A) Requestor would charge a FMV registration fee for all attendees to cover expenses of putting on the program; (B) Requestor would not charge any registration fee and would fund the entire CE program themselves; (C) Requestor would not charge any fee but, would cover the program expenses with funding from industry sponsors consistent with ACCME guidelines; or (D) Requestor would charge a registration fee to attendees and solicit industry funding.</li> </ul>	option A; unfavorable with respect to financing options B, C, and D	<ul style="list-style-type: none"> <li>Financing option A would pose a sufficiently low risk under AKS because it lacks industry sponsors or sources of funding other than the registration fees. However, the other financing options would convey a benefit to attendees, and create a risk for attendees to refer surgical patients, thus causing patient steering.</li> </ul>
<a href="#">AO 22-13</a>	Jun. 17, 2022	Durable medical equipment manufacturer	<ul style="list-style-type: none"> <li>Requestor manufactures and sells durable medical equipment (DME) to supplier customers, some of whom provide DME products to beneficiaries of Federal healthcare programs.</li> <li>Requestor entered agreements with two third-party financial institutions (Lenders) to make zero-interest financing available to qualifying supplier customers.</li> <li>The customers do not receive discounts on the products, and the Lenders play a detached and neutral role.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>The terms of the arrangement do not increase the possibility of fraud and abuse, and the arrangement is unlikely to increase costs to Federal healthcare programs because it will not impact utilization.</li> </ul>

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<a href="#">AO 22-11</a>	May 20, 2022	Medical group practice specializing in pain management	<ul style="list-style-type: none"> <li>Requestor hired an excluded individual as an administrative employee three years after the individual pled guilty to conspiracy to illegally receive kickbacks for referring workers compensation (WC) patients to a particular hospital for spinal surgery.</li> <li>Two years later, the Requestor placed this employee on unpaid administrative leave and now seeks to reinstate the individual's employment as a WC payor relations representative.</li> </ul>	Favorable	<ul style="list-style-type: none"> <li>The arrangement does not compel CMP since the Requestor has arranged to pay the excluded employee from a segregated payroll not connected with WC funds or paid by Federal healthcare programs.</li> <li>However, given the employee's history of fraud and abuse, their employment represents a serious compliance risk for Requestor.</li> </ul>
<a href="#">AO 22-10</a>	Apr. 27, 2022	Non-profit organization dedicated to providing resources, services, and support with a certain disease	<ul style="list-style-type: none"> <li>Requestor proposes to modify an existing program, which only covers future MRI scans, to provide financial assistance to low-income individuals for MRIs they received.</li> <li>The modifications would include the cost of an individual MRI if: (1) the date of service of the scan is within 6 months of the application for financial assistance, and (2) the individual met the current eligibility requirements on the date of service.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>This modification is a low risk of fraud and abuse because it is narrowly circumscribed and does not increase the cost to Federal healthcare programs.</li> </ul>
<a href="#">AO 22-09</a>	Apr. 25, 2022	Operator of a network of clinical laboratories that collect and handle specimens for testing	<ul style="list-style-type: none"> <li>Requestor operates clinical laboratories. Under the proposed arrangement, Requestor would contract with hospitals and pay them per-patient-encounter to collect and process specimens then sent to the clinical laboratories.</li> </ul>	Unfavorable; poses more than a minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS and would constitute grounds for sanctions.</li> <li>This compensation is tantamount to remuneration to an organization who is in a position to refer patients. Labs are particularly susceptible to steering practices and the compensation scheme reflects the volume or value of referrals.</li> </ul>

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			<ul style="list-style-type: none"> <li>Request would pay contract hospitals only for services performed in connection with individuals who present with orders for testing who are not currently inpatients or registered outpatients for the contract hospital, and would not pay for services performed for current patients.</li> </ul>		
<a href="#">AO 22-08</a>	Apr. 22, 2022	FQHC that serves low-income beneficiaries	<ul style="list-style-type: none"> <li>Requestor provides telehealth services to low-income patients and has currently arranged to loan 3,000 smartphones for existing patients to use for the limited purpose of telehealth visits.</li> <li>Requestor taught patients how to apply for funding under the FCC's Affordable Connectivity Program and encourages patients who do not qualify to find other similar programs.</li> </ul>	Favorable; minimal risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions.</li> <li>This arrangement meets the requirements for the Promotes Access to Care Exception during the PHE because it increases patients' access to telehealth services, which are covered by State Medicare Programs.</li> <li>In addition, it is not likely to interfere with clinical decision making, to increase costs to Federal health care programs or beneficiaries, or to pose any concerns regarding safety or quality of care.</li> </ul>
<a href="#">AO 22-07</a>	Apr. 20, 2022	Physicians with an ownership interest in a medical device company which manufactures devices ordered by the physician owners and one of the physician owner's spouse	<ul style="list-style-type: none"> <li>Requestors are orthopedic surgeons and owners of a medical device company creating upper extremity surgical technologies.</li> <li>They have certified that in using their products: (1) they will not attempt to influence hospitals and ASCs to use their devices; (2) their referrals to hospitals will not be contingent upon a hospital purchasing their devices; and (3) they provide disclosures to patients about the arrangement at pre-surgery consultations.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse.</li> <li>The risk is low is due to the diluted financial incentives for the physicians and the limited amount of business generated by the physicians and other members.</li> </ul>



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<a href="#">AO 22-06</a>	Apr. 6, 2022	Genetic testing service	<ul style="list-style-type: none"> <li>Requestor offers free genetic testing for a common mutation only to those who meet certain eligibility requirements, contracts with a third-party laboratory to conduct the testing, and arranges for free counseling services before and after testing provided by counselors under a third-party contract.</li> <li>Requestor has marketed the services to certain cardiologists who are likely to treat the disease, and provide them with specimen collection kits, as the tests must be ordered by a physician.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse.</li> <li>The OIG made its determination based on the following factors: (1) detection of the mutation does not affect the treatment; (2) the arrangement poses no risk to patient safety or quality of care, and may help patients receive better care than they otherwise would have; and (3) marketing or testing is not likely to induce physicians to order additional items or services from the Requestor and Requestor does not pay the ordering physician.</li> </ul>
<a href="#">AO 22-05</a>	Mar. 11, 2022	Medical device manufacturer	<ul style="list-style-type: none"> <li>Requestor manufactures an investigational therapy device that uses a patient's own cells for the treatment of ischemic systolic heart failure.</li> <li>Requestor intends to enroll 260 subjects in the study of this therapy. Requestor would directly pay cost-sharing obligations that Medicare beneficiaries participating in the study otherwise would owe, and which would be cost-prohibitive for many beneficiaries, for Medicare-reimbursable items and services provided during the study.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse.</li> <li>The arrangement generates a low risk of fraud and abuse because: (1) it is a reasonable means of promoting enrollment in the study; (2) the cost-sharing subsidies are specifically aimed at preventing inappropriate utilization of the Federal healthcare program; and (3) the scope limited to the duration of the study avoids the risk that the Requestor would benefit financially from follow-up beneficiaries.</li> </ul>
<a href="#">AO 22-04</a>	Feb. 25, 2022	Privately held digital health company	<ul style="list-style-type: none"> <li>Requestor's program uses smartphone and smart debit card technology to implement contingency management</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse for the reasons provided below.</li> </ul>

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			<p>(CM) for individuals with substance use disorders.</p> <ul style="list-style-type: none"> <li>Requestor is not enrolled as a provider or supplier in any Federal healthcare program and, therefore does not bill any Federal healthcare program for items or services furnished through the Program.</li> </ul>		<ul style="list-style-type: none"> <li>The process is protocol driven, proven to be useful, and bolstered by appropriate safeguards.</li> <li>The incentives are fairly low in value, capped at \$200 per month, or \$599 per year; a substantial portion of incentives are for services ineligible for federal payment; and many of the varied types of customers lack incentive to induce a member to receive federally reimbursed services.</li> </ul>
<a href="#">AO 22-03</a>	Feb. 9, 2022	Owner and operator of several Home Health Agencies (HHAs)	<ul style="list-style-type: none"> <li>Requestor employs CNAs to serve its patients, most of whom are medically fragile children.</li> <li>The State has a plan that provides Medicaid reimbursement for services provided by parents or other relatives to these children if the parents are both State certified CNAs and employed by an HHA.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The Requestor's payment of salaries to, and program tuition costs on behalf of, employees who are parents or relatives of medically fragile children constitutes remuneration that could induce parents or relatives to refer children to Requestors' HHAs for services that are eligible for federal reimbursement programs.</li> <li>Since the parents are employees, and the remuneration would be the payment of their salary for furnishing services which may be covered in part or in whole by Federal healthcare programs, they fall within the statutory exception and regulatory safe harbor for employees. Thus, the arrangement does not involve prohibited remuneration.</li> </ul>
<a href="#">AO 22-02</a>	Feb. 4, 2022	501(c)(3) operator of multiple hospitals including pediatric hospitals	<ul style="list-style-type: none"> <li>Donor A and B have entered into an agreement to make a donation to be used to establish a restricted endowment fund with Requestor as beneficiary.</li> <li>Pursuant to the proposed arrangement, Requestor and the fund would pay all out-of-pocket costs owed to Requestor by families with children who have an existing treatment relationship with physicians at the Children's Hospital and receive services provided under certain programs.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse.</li> <li>The risk of fraud and abuse is low: (1) because of the fund will be available to almost all families who need it regardless of the payor; (2) the fund will not be advertised prior to treatment; and (3) there are other existing safeguards to prevent overutilization.</li> </ul>

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<a href="#">AO 22-01</a>	Jan.13, 2022	Web-based marketplace that sells a wide variety of consumer goods and services to the general public	<ul style="list-style-type: none"> <li>• Requestor has a pharmacy-subsiary that is enrolled in Medicare Part B and Medicaid programs in several states.</li> <li>• A retailer offers two discount programs to customers who can demonstrate that they currently receive benefits from one of the accepted benefit programs.</li> <li>• The proposed arrangement would add Medicaid to this list as a category to determine eligibility but, Requestors would not target Medicaid beneficiaries or track utilization of the subsidiary pharmacy by its customers.</li> </ul>	Favorable; low risk of fraud and abuse	<ul style="list-style-type: none"> <li>• The arrangement would generate prohibited remuneration under AKS. However, the OIG would not impose sanctions because of the low risk of fraud and abuse.</li> <li>• The OIG reached this conclusion because: (1) the nexus between the discount program and a Medicaid beneficiary's potential ordering drugs is attenuated; (2) the eligibility process is primarily for convenience for individuals and retailers; (3) the arrangement is unlikely to result in overutilization; (4) the arrangement does not pose a risk to patient safety or quality of care; and (5) the risk of patient steering is minimal.</li> </ul>