HINSHAW

Alerts

OIG Advisory Opinion 25-03: Navigating Anti-Kickback Rules and Safe Harbors in Telehealth Contractual Arrangements

June 30, 2025
Health Care Alert

Attorneys

Michael A. Dowell

Overview

On June 6, 2025, the Office of Inspector General (OIG) issued Advisory Opinion 25-03 (the "Opinion"), offering guidance for structuring telehealth collaborations in a manner that complies with the federal Anti-Kickback Statute (AKS).

The Opinion provides a framework for healthcare organizations seeking to expand telehealth services in a manner that promotes growth while maintaining compliance with federal and state anti-kickback laws, and state corporate practice of medicine and fee-splitting prohibition statutes.

The Proposed Arrangement

In the proposed arrangement, the Requestor Professional Corporation (the "Requestor PC") operates as a physician-owned entity maintaining extensive payor contracts (covering 80 percent of commercially insured lives and 65 percent of Medicare Advantage lives) and Medicaid programs through over 400 contracts.

Partner telehealth platforms exist in two configurations:

1. Professional corporations that employ clinicians but have limited insurance contracting capabilities (the **"Platform PCs"),** and

2. Management service organizations (the **"MSOs"**) that provide non-clinical administrative support, including accounting, marketing, scheduling, and telehealth technology infrastructure.

Platform Patients are patients, including Federal health care program enrollees, who visit a Platform PC's website to obtain various healthcare items and services and access telehealth services.

Each Platform PC provides telehealth services (e.g., urgent care services, rheumatology care, oncology care navigation, menopause care, obesity management care, and mental healthcare), including services that are reimbursable by a federal health care program to Platform Patients.

The Requestor PC leases healthcare professionals from each Platform PC on an hourly basis, with fees determined by provider type, such as physicians, nurse practitioners, or physician assistants. Simultaneously, the arrangement includes bundled administrative services from Platform MSOs to support the expanded telehealth operations.

Healthcare professional lease fees are paid on an hourly basis regardless of whether the requestor receives third-party reimbursement, and these fees remain unaffected by referral volume or business generation. Administrative fees cover non-clinical services and may be structured as flat fees, revenue-sharing arrangements, or cost-plus models, though all fee structures require independent validation to establish fair market value.

The OIG's Legal Analysis and Determination

Application of the Federal Anti-Kickback Statute ("AKS")

The AKS prohibits any form of remuneration designed to induce referrals for services reimbursable by federal healthcare programs. Under the Proposed Arrangement, the Requestor PC would offer and pay remuneration to the Platform MSO and Platform PC Entities in the form of the Service Fee. When a Platform PC refers Platform Patients to Requestor PC for services that are reimbursable by a federal health care program, the Federal anti-kickback statute is implicated.

Structural Safeguards Implemented by the Requestor

- **Formal Written Agreement:** A detailed, signed agreement specifying the scope of services, duration (minimum of one year), and all key terms.
- **Independent Valuation:** Fees must be set forth at fair market value and established in advance by an independent third-party valuator.
- **Independence from Referral Volume:** The compensation structure deliberately separates clinical and administrative components. Remuneration should not be influenced by the volume or value of referrals or business generated for items or services covered by federal programs.
- **Commercial Reasonableness:** Even if no referrals were generated, the arrangement would still be commercially reasonable on its own merits.

The OIG noted that the safeguards adopted align the arrangement with the "personal services and management contracts and outcomes-based payment arrangements" safe harbor provided at 42 C.F.R. § 1001.952(d)(1), which require that all services must be memorialized in detailed, written, and signed agreements that specify a fixed term of typically one year or longer.

In addition, the written agreement comprehensively described all services provided and established fee structures through arm's-length negotiations without basing compensation on referral volume or business generated through the relationship. The OIG concluded that fair market value compensation and independent assessment ensure that compensation reflects legitimate business purposes rather than inducements for referrals or other prohibited considerations.

The OIG emphasized that "compliance with a safe harbor is voluntary," but this arrangement "would be protected" by the safe harbor due to strict conformity with the requirements, especially the predetermined and independently validated fees and the clear segregation of clinical and non-clinical services.

The OIG determined that the arrangement **"**would not generate prohibited remuneration under the Federal anti-kickback statute" and "would not impose administrative sanctions on Requestors" under relevant federal statutes. The OIG's favorable determination aligns with previous advisory opinions that emphasize the importance of implementing safeguards to ensure that legitimate business arrangements will not be interpreted as potential inducements.

Compliance Takeaways and Best Practices

Healthcare organizations seeking to implement similar telehealth arrangements should prioritize comprehensive documentation and independent validation processes. Written agreements must be comprehensive and detailed, specifying the complete scope of both clinical and administrative services, establishing clear fee schedules, and defining fixed terms that provide operational stability while meeting regulatory requirements. Key recommendations include:

Structured Agreements and Fair Market Value Fee Validations:

- **Written, Fixed-Term Agreements:** Always ensure a complete and detailed written and signed agreement specifies the scope, services to be rendered, fee structures, and a minimum term of no less than one year.
- **Adhere Strictly to Safe Harbor Provisions:** Structure remuneration to comply with recognized safe harbor criteria. The arrangement must satisfy all six elements of the safe harbor for personal services and management contracts (42 C.F.R. § 1001.952(d)(1)). This includes using fees determined as commercially reasonable and necessary, setting terms in advance, ensuring compensation is based on an arm's-length transaction (verified by an independent valuation), and safeguarding that fees are not contingent on referral metrics or reimbursement outcomes.
- **Segregate and Define Clinical and Administrative Services:** Keep clinical arrangements (e.g., leasing of clinicians) structurally and financially separate from the administrative services provided. Ensure that payments for non-clinical services are not linked to any referral decision-making processes and are independent of referral volume or payer reimbursements.
- **Fair Market Value Validation:** Both the Clinical Fee and Administrative Fee should be independently validated and set in advance. They must be clearly segregated and not tied to referral incentives. Documentation of this valuation is critical for defending the arrangement against potential anti-kickback scrutiny.

Internal Controls and Ongoing Compliance:

- **Document Everything:** All services and relationships should be memorialized in written, signed agreements that detail the services and fees. Verbal or informal understandings do not suffice.
- **Avoid Control of Patient Allocation**: The Opinion notes that Requestors "would not control or influence decisions regarding how to allocate Platform Patients" when both Platform PCs and Requestor PC are contracted with the same payor. Telehealth organizations should adopt internal policies to uphold this principle to avoid conflicts of interest or referral manipulation.
- **Regular Reviews and Updates**: As the telehealth market evolves, ensure ongoing compliance through periodic valuation updates, contract audits, and legal review of any proposed modifications to service structures. Implement periodic valuation updates, contract audits, and legal reviews to promptly adjust to any changes in the telehealth landscape.

- **Monitor Scope and Necessity**: Services should not exceed what is "reasonably necessary to accomplish the commercially reasonable business purpose." Ensure the services contracted remain commercially reasonable and do not exceed what is necessary to support the business purpose of the arrangement.

Important Considerations for Telehealth Organizations and Contractors

Tailored Legal Analysis for Telehealth Models

The Opinion comes with a limitation that the "advisory opinion has no application to, and cannot be relied upon by, any other person" outside of the named parties. Entities seeking to adopt similar models should pursue individualized legal review and, if necessary, request their own advisory Opinion. In other words, the Opinion's safe harbor protection applies specifically to the disclosed arrangement, meaning that any additional or modified financial arrangements require their own compliance review.

Complex telehealth arrangements demand tailored legal analysis by competent health care law counsel to ensure each component maintains compliance. Whether involving clinical provider compensation or leasing fees, management services or administrative fees, or ancillary agreements, each component must be structured to avoid unintended inducements or legal risks. Periodic reviews of fee methodologies are particularly important as market trends evolve, and state corporate practice of medicine and fee-splitting law enforcement patterns change.

Ongoing Regulatory Developments and Operational Practices

Successful implementation requires ongoing attention to regulatory developments and operational practices. Telehealth organizations and contracted providers, telehealth platforms, and MSOs must regularly monitor both state and federal regulatory changes, including evolving approaches to private equity health care investments and corporate practice of medicine regulations that vary significantly across state jurisdictions.

Personalized Telehealth Care Requires Additional Compliance

The personalized nature of telehealth care, particularly in specialized areas such as mental health, obesity management, sexual health, or reproductive health, requires additional operational diligence to ensure compliance with both federal anti-kickback provisions and state professional practice requirements.

Thus, telehealth organizations and their contracted entities should fully disclose material facts to legal counsel when seeking regulatory guidance and should maintain ongoing legal oversight to address changes in operational practices or regulatory requirements.

Conclusion

The Opinion demonstrates that carefully structured telehealth arrangements can achieve regulatory compliance while expanding healthcare access, particularly in rural and underserved areas. The structure, centered on clear documentation, comprehensive written agreements, independent fee validation, and clear service segregation, provides a model for organizations seeking to leverage telehealth partnerships while minimizing regulatory risks. However, successful adaptation requires clients to consult with competent health care law legal counsel for a thorough legal review of the proposed arrangement to ensure full regulatory compliance.

Hinshaw's Health Care attorneys have extensive experience advising telehealth platforms, telemedicine providers, management services organizations, mail order pharmacies, remote patient monitoring, mobile health apps, and other digital health on corporate transactions and healthcare regulatory law matters.