



**Garfunkel Wild**

# **ASC and Healthcare Management Symposium**

**The OIG's Focus: What Healthcare Providers Need to Know**

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# Agenda

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- OIG's New Frequently Asked Questions (FAQ) Process
- Anti-Kickback Statute and Safe Harbor Refresher
- The New FAQ for Ambulatory Surgery Centers
- Recent OIG and DOJ Settlements

# OIG's Frequently Asked Questions

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- Historically, OIG's FAQ page only addressed procedural issues about various topics.
- During the pandemic, OIG used the FAQ to communicate information about its administrative enforcement authorities in a new way.
- And, it started asking questions about how the provider community and others used its publicly-available information and guidance.
- Feedback from these questions led to a re-engineered FAQ page that tries to balance competing provider needs.

# The New FAQ Process

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- Providers can now submit questions electronically to OIG on topics that were previously reserved for the formal advisory opinion process.
- OIG's attempt to balance the detailed analysis seen in advisory opinions with a more expeditious and less detailed alternative that promotes economy, efficiency, effectiveness, and program integrity.
- **CAVEATS:**
  - ❖ Informal, non-binding guidance
  - ❖ No prospective immunity from administrative sanctions
  - ❖ No opinions on potential liability
  - ❖ Subject to FOIA

# Anti-Kickback Statute: Paying for Referrals is a Crime

AKS is a **criminal law** that prohibits the **knowing and willful** payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.

- Remuneration is anything of value and can take many forms.



## **Applies To:**

- Those who offer or pay
- Those who solicit or receive
- All referral sources, even patients

# AKS Safe Harbors

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- Describes payment or business scenarios that would give rise to potential AKS liability, but are not treated as offenses under the statute
  - ✓ Compliance with safe harbor is voluntary
  - ✓ No protection for partial compliance with safe harbor conditions
  - ✓ Failure to comply with safe harbor  $\neq$  illegal per se

# The ASC FAQ

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**Question:** If all other elements of the single-specialty ASC safe harbor are satisfied, can an ASC offer an investment interest in a single-specialty ASC to a physician who derives less than one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from the performance of “procedures” ?

- Remuneration to a physician in the form of a return on an investment interest in an ASC implicates the AKS if the physician-investor makes referrals to the ASC.
- **Practice Income Test:** at least one-third of each physician-investor’s medical practice income from all sources for the previous fiscal year or previous 12-month period be derived from the performance of “procedures”

# So What?

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- Failure to satisfy ASC safe harbor's Practice Income Test (PIT) means that investment income either distributed or received is not protected from potential AKS liability.

## WHY?

- Physicians satisfying PIT are more likely to use the ASC as an extension of their physician office space, which reduces the risk that his or her investment interest would induce or reward referrals for ASC procedures that the physician does not personally perform.
- OIG evaluates risk on a spectrum. Meeting all of the ASC safe harbor conditions except PIT triggers look at **totality of circumstances** (e.g., referrals for services not personally performed; use of ASC for own procedures; reasons for not meeting the PIT, etc.)



# Recent Settlements

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**April 2022 (FCA, N.D. GA):** Two physicians and the company they created, Care Plus Management, LLC , along with 18 anesthesia entities that Care Plus owned and operated, agreed to pay \$7.2 million to resolve allegations that they entered into kickback arrangements with referring physicians in exchange for the referral of the physicians' patients for anesthesia services.

- Shared revenue from anesthesia services with referring physicians
- Provided subsidies for drugs, supplies and equipment to the referring physicians' outpatient surgical centers

**July 2022 (OIGSDP, MI):** Gastro practice group received remuneration from a sports medicine practice and a surgery center in the form of an ownership interest in the surgery center and reimbursement of related legal fees. Resolved CMP kickback liability for \$261K

# Wrap-Up

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- In the ever-changing healthcare landscape, the new FAQ process may offer more timely guidance to stakeholders. Remember, however, the limitations we discussed earlier.
- Formal advisory opinion process is still the only way to obtaining binding, conclusive guidance from HHS-OIG.
- Assessing compliance with ASC safe harbor conditions is complex and comes with risk as shown by recent settlements. Seek guidance from an experienced healthcare attorney.

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David's unique expertise in health care enforcement and compliance provides clients with specialized insight into federal investigations and enforcement actions based on his knowledge of the government's case identification strategies, its legal theories, and its interpretation of the applicable laws, rules, and regulations. His HHS-OIG experience also allows him to share critical information with clients about the government's corporate governance expectations and compliance best practices.

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