



Legal Standards -AKS

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- **Anti-Kickback Statute** prohibits knowingly & willfully paying, offering, soliciting or receiving remuneration in return for referral
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, sale of practice, bona fide employment, physician recruitment, etc.)
- “One Purpose” rule

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Legal Standards - Stark Law

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- **Stark law:** If physician (or immediate family member) has financial relationship with entity (e.g. hospital), physician may not make referral to entity for designated health service (“DHS”) and entity may not submit claims for such services.
- “Designated Health Services” = Lab services, therapy services, radiology/imaging, DME, prosthetics & orthotics, home health services, outpatient Rx drugs, inpatient & outpatient hospital services.
- “Financial relationship” under Stark? Any ownership or investment interest; Any compensation arrangement (defined as “any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity” with certain very limited exceptions..
- “Referral” is defined very broadly, and includes: A request for, or ordering of, DHS; Establishment of a plan of care, etc.
- Safe Harbors and Exceptions: Rental of office space & equipment, Bona fide employment, Personal service arrangements, Physician recruitment, Isolated Transactions, Remuneration unrelated to DHS, etc.

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Legal Standards - FCA

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- **False Claims Act** prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - Retention of overpayment
    - 60-day rule
- *Qui tam* actions

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Role of Compliance, In-House  
and Outside Counsel to Company

- Whistleblowers work with government to identify and prosecute cases
- Does the entity have an effective compliance program?
- Will it be necessary to conduct employee interviews?
- Who will handle them?
- How will interviews be memorialized?
- Will the company retain counsel for employees if requested?
- How will the company handle a refusal to cooperate?

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Investigation

- Take every complaint and allegation seriously.
- What are the issues?
- What is the applicable legal standard?
- Who at company/entity decides whether compliance will conduct initial investigation?
- What are the risks of compliance acting without direction of counsel?
- Making yourself a witness/accomplice/co-conspirator.
- Cost of outside counsel vs. cost of foregoing outside counsel.
- Pitfalls: waived privileges, binding admissions, payment suspension, loss of licenses or privileges, penalties, imprisonment, and government-wide exclusion.

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Questions

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