



## **OIG's Compliance Program Effectiveness Resource Guide: Takeaways for AKS and Stark Law Risks**

On March 27, 2017, the Department of Health and Human Services, Office of Inspector General ("OIG-HHS"), in collaboration with the Health Care Compliance Association (HCCA), published *Measuring Compliance Program Effectiveness – A Resource Guide* (the "Guide"). The Guide was based on a series of discussions between healthcare compliance professionals conducted in January of this year to provide meaningful guidance and best practices for assessing the effectiveness of organizations' compliance programs, which is recommended by the United States Federal Sentencing Guidelines.

In one form or another, several governmental entities over the years have outlined the elements of an effective compliance program, which can be summed up as follows: (1) written policies and procedures, (2) compliance program oversight, (3) screening of ineligible persons, (4) training and communication, (5) monitoring and auditing, (6) appropriate enforcement of non-compliance, and (7) responding promptly and undertaking corrective action. The Guide represents the first regulatory guidance by OIG-HHS to provide specific details and examples of how and what can be measured to assess the effectiveness of compliance program elements.

While not intended to be a checklist, the Guide is intended to be a resource "to give health care organizations as many ideas as possible, be broad enough to help any type of organization and let the organization choose which [guidance] best suit its needs."

One of the many compliance topics discussed in the Guide is contracting with third parties. The Anti-Kickback Statute and the Stark Law are two measures that prohibit healthcare entities and individuals from providing patient referrals in exchange for anything of value to generate business from federal healthcare programs. These laws, along with the False Claims Act, have been referred to by the Department of Justice in numerous whistleblower cases involving inappropriate contracts between healthcare entities, vendors, contractors, physicians, etc. Most of these cases are settled and in many instances, the entities have entered into Corporate Integrity Agreements ("CIA's") with the OIG-HHS. CIA's generally require an organization to establish an effective compliance program and often subject the entity to annual reviews of their contracts with potential referral sources and the processes, policies, procedures and systems surrounding those contracts.

Given the increased scrutiny over violations of the Anti-Kickback Statute and the Stark Law in recent years, organizations must be aware of the regulatory requirements surrounding contracting with potential referral sources. The Guide offers some helpful questions that healthcare organizations can ask to begin to evaluate their contracting processes to determine if there are risks that need to be addressed. The exhibit below offers a summary of the applicable Guide sections and points to consider.

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Compliance Program Element	Section	Consideration
Screening of Ineligible Persons	3.39	Do third party contracts allow for the organization to review vendor files for compliance with screening requirements? Does the organization conduct reviews of third party contracts?
Monitoring and Auditing	5.21	Is the compliance department aware of the contracts with business partners, contractors, etc.? Is there an inventory of partners? Do the partners know how to contact the compliance department with issues?
Monitoring and Auditing	5.77	Are vendors' certifications reviewed? Are consequences for vendors not adhering to an organization's compliance program tracked? Do all vendor contracts include consistent compliance language?
Enforcement of Non-Compliance	6.15	Do employees, vendors and contractors know their responsibilities regarding code of conduct? Do they sign annual attestations relating to the code of conduct or other compliance responsibilities?
Effective Response and Correction Action	7.71	Are there standard terms that must be included in contracts or standard templates that must be utilized?

To review the complete Guide, [please click here](#).

While the above list of questions is important to consider, it is by no means exhaustive. Organizations should perform a comprehensive evaluation of their contracting processes and seek assistance from outside counsel and consultants with Anti-Kickback Statute and Stark Law expertise to ensure that any risks are appropriately identified and mitigated. Recent enforcement actions stemming from violations of these regulations have resulted in hundreds of millions of dollars in fines, and state and federal regulators have made it abundantly clear that they have no tolerance for non-compliance, regardless of intent or the size of the entity. Furthermore, organizations that have failed to take any action towards establishing effective compliance programs and implementing controls around contracting with potential referral sources have been punished the most severely. Ignorance is not an excuse in today's highly regulated healthcare environment, and proactive compliance with all applicable laws and regulations should be forefront priority for every organization.



These are just some of the many questions and points that your organization's leadership should be considering to gauge the effectiveness of its compliance program. When was the last time your organization reviewed its compliance program?

If you have questions about how your organization can evaluate the effectiveness of its compliance program or have matters that warrant the involvement of outside accountants or consultants, please contact Chris Roane or Patrick Braley by calling 770.396.2200.