

FRAUD, WASTE, & ABUSE (FWA) POLICY



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POLICY STATEMENT

Dominion requires that all its business practices be conducted in a lawful and ethical manner. Dominion Diagnostics follows all applicable state and federal laws in regards to Fraud, Waste, and Abuse. The following are some (but not limited to) of the key federal laws and statutes that are noted as Fraud, Waste, & Abuse.

DEFINITIONS

- **Fraud** – Intentionally submitting false information in order to receive money or a benefit.
- **Waste** – Practices that directly or indirectly, result in unnecessary costs to the Medicare Program, such as overusing services or misuse of resources.
- **Abuse** – Actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program. Abuse involves paying for items or services where there is no legal entitlement to the payment and the provider has misrepresented facts to obtain payment.

SUMMARY

- **Federal Anti-Kickback Statute** – The Statute prohibits employees from offering, paying, soliciting, or receiving compensation to persuade or reward persons for referring or generating Federal Health Care business. Additionally, many states have similar anti-kickback laws, some of which are based in whole or in part upon Federal law.
- **Stark Law** – The physician self-referral or Stark Law the Stark Law prohibits a physician from making a referral for specified designated health services (“DHS”) to an entity that will furnish or bill the Medicare program for that DHS, if the physician has a financial relationship with or ownership interest in that entity. DHS is defined to include a wide variety of ancillary services including clinical laboratory services. A financial relationship includes an ownership or compensation relationship with the physician. The Stark Law includes a number of exceptions for financial relationships with referring physicians; however, these are narrowly drawn. Failure to meet an applicable exception would preclude a laboratory from seeking payment for any laboratory tests ordered or referred by such physician.
- **False Claims Act** – The federal statute establishes liability for any person who knowingly presents or causes to be presented a false or fraudulent claim to the U.S. government for payment (Medicare and Medicaid). The term “knowing” is defined to mean that a person with respect to information:
 - a. Has actual knowledge of falsity of information in the claim.
 - b. Acts in deliberate ignorance of the truth or falsity of the information in a claim; or acts in reckless disregard of the truth or falsity of the information in a claim. Penalties for knowingly submitting or causing the submission of false claims may result in damages up to 3 times the erroneous payment plus civil penalties for each false claim.
- **Qui Tam “Whistleblower” provisions of the False Claims Act** – To encourage individuals to come forward and report misconduct involving false claims, the False Claims Act includes a “Qui Tam” or whistleblower provision. The provision essentially allows any person with actual knowledge of false claims activity to file a lawsuit on behalf of the U.S. government.

POLICY

- **Federal Anti-Kickback Statute** – Dominion Diagnostics requires all employees to comply with the Federal Anti-Kickback Statute. Therefore, no employee may offer, pay, solicit, or receive any form of return in exchange for referrals or the generation of Federal Health Care Program business. “Reckless disregard” or “deliberate ignorance” of the law can be construed as intent. The AKS provides specifically defined “safe harbors” which describe activities that may implicate the Act but have been deemed not to violate the AKS. However, the Office of the Inspector General has recognized that failure to meet an applicable safe harbor does not mean that the arrangement is illegal and, in such instances, the facts and circumstances of the financial arrangement may be evaluated on a case-by-case basis.
- **Stark Law** – Dominion Diagnostics requires all employees to comply with the Stark Law. Therefore, no medical professional who currently

is in a financial relationship with Dominion Diagnostics may refer clients to Dominion Diagnostics unless an exception exists and the financial relationship has been reviewed and approved by the Chief Compliance Officer and the General Counsel of the company.

- **False Claims Act** – Dominion Diagnostics requires that all employees shall not present or cause to be presented claims that are knowingly false, fictitious, or fraudulent.

EMPLOYEE RESPONSIBILITIES

- Dominion Diagnostics requires all employees to report any violation or suspected violation of the Anti-Kickback Statute, Stark Law, or False Claims Act. There are several ways to report violations or suspected violations.
 - The suspected violation should be reported to the Compliance Officer either directly or via a Supervisor or Manager.
 - The suspected violation can also be reported to the Compliance Hotline by leaving a voicemail at 1-401-667-0374.
- Compliance with the Anti-Kickback Statute, Stark Law, and False Claims Act is a required condition of employment or continued engagement with Dominion. Violations of this policy should be reported in accordance with Dominion's Compliance Program and Code of Conduct.
- Employees will not be retaliated against for reporting any violation or potential violation.
- Dominion Diagnostics will identify, resolve, and return funds, as well as potentially report, if suspected fraud, waste, or abuse have occurred.

ANTI-KICKBACK EXAMPLES

- Payment that is not "fair market value" when purchasing or leasing space, equipment, or professional services from referral sources.
- Excessive discounts on commercial business to customers in exchange for referrals.
- Providing excessive gifts and entertainment to referral sources conditional upon current or future referrals.
- Providing free services conditional upon current or future referrals.

STARK LAW EXAMPLES

- Lease or rental of space from or with referral sources.
- Contracted professional services with referral sources.
- Provision of supplies (other than those used directly for specimen collection and test information transmission).
- Partnerships and joint ventures with referral sources.
- Discount arrangement for services with a referral source other than discounts based upon financial need.

FALSE CLAIMS ACT EXAMPLES

- Billing for services not rendered/performed
- Altering claim forms or medical records to receive higher payment
- Ordering excessive laboratory tests
- Excessively charging for services or supplies
- Misusing codes on a claim, such as upcoding or unbundling codes
- Changing the rendering physician and/or services to get the claim paid (after the claim was denied)
- Overcharging for a service
- Billing multiple times for the same service (duplicate billing)

RELATIONSHIPS/ARRANGEMENTS WITH REFERRAL SOURCES OR POTENTIAL REFERRAL SOURCES INCLUDING REFERENCE LAB ARRANGEMENTS

As stated above, the Federal Anti-Kickback Statute prohibits anyone from either paying or being paid any form of remuneration in exchange for the referral of patients or specimens covered by a Federal Healthcare Program, and the recommendation of Dominion for testing services. The broad language of the Federal Anti-Kickback Statute implicates a wide array of relationships between providers of laboratory services and their customers. While the Office of the Inspector General has issued a variety of safe harbors that protect some financial arrangements with parties in a position to refer or recommend business, the safe harbors are narrowly drafted and many commonplace arrangements do not fit within each criterion of an applicable safe-harbors. However, the OIG has made clear that arrangements that do not meet a safe harbor are not per-se illegal as each arrangement can be evaluated based upon the facts and circumstances of such arrangement.

SPECIMEN COLLECTION & SALES COMMISSION ARRANGEMENTS

Specimen Collection and Sales Commission arrangements may implicate the Federal or a state Anti-Kickback Statute depending upon multiple factors including whether the party being paid is in a position to refer or recommend patients to Dominion and whether the compensation paid to such organization or individual is paid to an employee or independent contractor. Whenever Dominion enters (or contemplates entering) into any contractual arrangement with a referral source or potential referral source the relationship and all written agreements shall be reviewed by the Chief Compliance Officer and General Counsel to evaluate compliance with the Anti-Kickback Statute. If necessary, the Chief Compliance Officer and General Counsel may request the assistance of outside consultants or counsel. All reasonable steps will be taken to structure the arrangement does not violate the Federal Anti-Kickback Statute. Examples or arrangements that will not be approved:

- The payment of percentage-based compensation to any referral source including but not limited to sales representatives or marketing companies, independent contractors and referring laboratories.
- The rental of space from a referral source unless otherwise approved and consistent with regulatory guidance (including safe harbor, fraud alerts or other informal OIG guidance).
- An arrangement with any referral source that is excluded or disbarred from federally funded health care programs: HHS/OIG List of Excluded Individuals/Entities (<http://oig.hhs.gov>).

REFERENCE LABORATORY ARRANGEMENTS

A reference laboratory arrangement is one in which Dominion provides testing services for another laboratory who will then seek payment for the testing services. Reference laboratory agreements may be established when another laboratory either lacks the experience to perform a particular test or is unable to meet volume requirements. While reference laboratory arrangements are commonplace in the laboratory industry, the structure of any reference laboratory agreement may present compliance issues. As a result, all reference laboratory agreements shall be reviewed by the Chief Compliance Officer and General Counsel to ensure compliance with applicable legal requirements. Examples of reference laboratory agreements that will not be approved:

- The performance of reference testing for a laboratory where Dominion knows that the ordering laboratory is not permitted by law, regulation or policy to bill a Federal Healthcare Program for the tests performed by Dominion by applicable state law direct billing requirements. A direct billing requirement is one in which only the testing laboratory may bill for the laboratory service.
- The performance of reference testing for a laboratory where Dominion knows that the ordering laboratory is not permitted by law, regulation or policy to bill for services when furnished to certain types of individuals—such as in the case of an applicable Medicaid rule, regulation or policy that prohibits the testing for individuals who are residents of a sober living home if the sole purpose of the test is for residential monitoring.
- The performance of reference testing for a laboratory where Dominion knows that the volume of testing being performed for individual patients including Medicare or Medicaid beneficiaries is likely to exceed applicable testing threshold requirements (i.e., the number of UDT tests that patients may receive on a monthly or annual basis).

On an Annual Basis, the Chief Compliance Officer will audit and review any financial arrangements with referral or potential referral sources. The audit will include reviews of any specimen collection, physician compensation, sales and marketing and reference laboratory arrangements. The annual audit shall evaluate whether the arrangements implicate the Anti-Kickback Statute, the Stark Law or any other federal or state law including laws or regulations relating to the prohibition or any frequency limitation of laboratory services furnished to Medicaid beneficiaries who are residents of a sober living home. Arrangements that raise compliance concerns shall be presented to Dominion's General Counsel or Dominion's outside legal counsel for further evaluation.

Questions relating to whether a specific arrangement is implicated by the Federal Anti-Kickback Statute or a similar state law prohibition should be directed to the Chief Compliance Officer and/or the General Counsel. No individual in the Company has the authority to negotiate or execute any arrangements of the nature described above without approval of the Company's General Counsel.

VERSION HISTORY

Release Date	Revision Number	Reason for Change	Sections Affected	Next Review Date
9/23/2022	1.0	Initial Policy Release	All	Annually