INTRODUCTION

The process of referring patients to health care providers has been the subject of significant government scrutiny and regulation in recent years. Both the Federal and state governments have adopted laws limiting healthcare providers’ ability to refer patients to entities with which they have a financial relationship. Regulators and legislators believe that these referrals often result in overutilization, increased costs to health care programs, unfair competition, and questionable patient-care decisions, among other things. Below is an overview of some of the more commonly utilized “fraud and abuse” laws relating to referrals.

POLICY

It is CNGCS’ policy to make referral suggestions based on the best interest of patients while always respecting patient choice. No referral decisions are ever made based on business arrangements or in return for referrals to the agency.

1. COMPLIANCE STANDARDS RELATING TO REFERRALS

A. Compliance with Federal and State Anti-Referral Laws. In compliance with the laws discussed below, CNGCS does not pay incentives to any personnel based upon the number of persons admitted for treatment or the value of services provided. Nor does CNGCS pay physicians, or anyone else, either directly or indirectly, for client referrals. The decision to refer clients is a separate and independent clinical decision made by the referring physician or health care provider.

CNGCS also does not accept any form of remuneration in return for referring our clients to other health care providers. Rather, in discharging clients and referring them to other providers, it is CNGCS’ policy: (i) that such referrals will be based on the client’s documented medical need for the referred service and the ability of the referred provider to meet that need; and (ii) that the client’s freedom to choose the provider is at all times respected and honored.

B. Relationships with Other Healthcare Providers. All contracts, leases, and other financial relationships with other healthcare providers who have a referral relationship with CNGCS will be based on the fair market value of the services or
items being provided or exchanged, and not on the basis of the volume or value of referrals of Medicare or Medicaid business between the parties. CNGCS will not engage in any practice that violates the anti-referral laws or tend to create an appearance of illegality or impropriety, including but not limited to:

i) **Free Services.** Providing free services or items to, or accepting such services or items from, another provider with whom there is a referral relationship;

ii) **Above Fair Market Value.** Paying or charging excessive amounts above fair market value to another provider for the provision of equipment, space or personnel services;

iii) **Below Fair Market Value.** Paying or charging amounts below fair market value to another provider for the provision of equipment, space or personnel services;

iv) **Joint Ventures.** Entering into joint ventures with other providers or facilities for which applicable Safe Harbors or Exceptions under the anti-referral laws do not apply, or pursuant to which benefits are conferred on one party in a manner that could be interpreted as an inducement to refer.

2. **ANTI-KICKBACK LAWS**

A. **Federal Law.** A Federal law commonly known as the “Anti-Kickback Statute” prohibits the knowing and willful solicitation, receipt, offering or payment of any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind: (i) in return for or to induce the referral of an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (ii) in return for or to induce the purchasing, leasing, ordering or arranging (or the recommending of such) of any good, facility, item or service for which payment may be made in whole or in part under a Federal health care program. “Federal health care programs” under this law generally include health care programs that receive any funding from the United States government (e.g., Medicare and Medicaid), as well as certain specified state programs.

The Anti-Kickback Statute has been broadly interpreted by a number of courts to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals – even where there are other, wholly legitimate business purposes present.

i) **Penalties.** Violation of this law is a criminal offense that could result in significant fines and/or imprisonment for both sides of an illegal kickback arrangement. In addition, substantial civil monetary penalties and administrative penalties, including exclusion from Federal and state health
care programs, may also result from violations of the Anti-Kickback Statute.

ii) Exceptions/Safe Harbors. The law contains certain statutory exceptions. Regulations describing additional exceptions for certain business arrangements and payment practices – known as “safe harbors” – also exist (the “Safe Harbor Regulations”). Each exception/Safe Harbor has a number of specific requirements. Compliance with each requirement of all applicable Safe Harbors/statutory exceptions removes the risk of criminal, civil or administrative action pursuant to the Anti-Kickback Statute. Failure to fall squarely within a Safe Harbor or exception, however, does not necessarily render an arrangement illegal per se or otherwise actionable. Instead, in such cases, the arrangement will be analyzed in light of the governing law and regulations and, in particular, the intent of the parties (i.e., whether the arrangement is intended to pay for or to induce referrals, or to otherwise violate the law).

B. New York State Law. New York State’s Anti-Kickback laws are similar to the Federal Anti-Kickback Statute (and, indeed, compliance with the Federal law may well equate to compliance with New York’s law). New York’s laws prohibit a Medicaid provider or any person acting in concert with a Medicaid provider from soliciting, receiving, accepting, agreeing to receive or accept, or offering, agreeing to give, or giving, any payment or other consideration: (i) for the referral of services for which payment is made under the Medicaid program; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid program.

New York State law and regulations also provide that licensed professionals engaging in the foregoing activities have committed “professional misconduct” and an “unacceptable practice.” Indeed, professional misconduct may occur without regard to whether Medicaid beneficiaries/payments are involved.

Violation of these New York State laws may have civil, criminal and administrative consequences, including monetary fines, imprisonment and/or the loss of licensure or other disciplinary action against a licensed professional, as well as likely exclusion from government insurance programs and/or other penalties.
3. THE “STARK” PHYSICIAN SELF-REFERRAL LAWS.

A. Federal Law. Federal law contains significant prohibitions against certain physician referrals. These prohibitions are embodied in a law commonly known as “Stark.” Stark generally prohibits a physician from making referrals to an entity for the furnishing of certain “designated health services” reimbursable by Medicare if the physician (or an immediate family member of the physician) has a direct or indirect financial relationship (including an ownership or investment interest, or a compensation relationship) with that entity. If the referral is prohibited, so too is the submission of a claim for payment by the entity that receives the prohibited referral. In addition to the conduct directly prohibited by the law, the statute also prohibits “circumvention schemes,” i.e., those arrangements that are designed to obtain referrals indirectly that cannot be made directly.

i) Designated Health Services. The “designated health services” presently covered by the Stark law include: (a) clinical laboratory services; (b) physical therapy services, occupational therapy services and speech-language pathology services; (c) radiology services and certain other imaging services; (d) radiation therapy services and supplies; (e) durable medical equipment and supplies; (f) parenteral and enteral nutrients, equipment and supplies; (g) prosthetics, orthotics and prosthetic devices and supplies; (h) home health services; (i) outpatient prescription drugs (including all drugs covered by Medicare Part B or Part D); (j) inpatient and outpatient hospital services; and (k) nuclear medicine services.

ii) Penalties. The penalties for violating the Stark law include: (i) the denial or the required refund of any payments for services that resulted from an unlawful referral; (ii) civil monetary penalties; and (iii) exclusion from Federal health care programs.

iii) Exceptions. Stark contains a number of statutory and regulatory exceptions. These exceptions include, but are not limited to, exceptions for certain physicians’ services, certain in-office ancillary services, certain office space or equipment rental arrangements, certain personal services arrangements, certain bona fide employment arrangements, and certain fair market value compensation arrangements, among various others. Like the Anti-Kickback exceptions/Safe Harbors, the “Stark” exceptions are often very complex and very detailed. If the Stark law is implicated, all relevant exceptions must be squarely met, or the law will have been violated (i.e., Stark is a “strict liability” law. In other words, under Stark, the intent of the parties is irrelevant).

1 “Immediate family member” means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.
B. **New York State’s “Stark” Law.** In New York, a practitioner may not make a referral to a health care provider for clinical laboratory services, pharmacy services, radiation therapy services, x-ray or imaging services or physical therapy services if the practitioner or a member of his immediate family\(^2\) has a financial relationship (including an ownership interest, an investment interest or a compensation arrangement) with that provider, unless a statutory or regulatory exception is met (and again, there are a number of varied and quite complex exceptions that exist).

Unlike its Federal counterpart, the New York law covers all payors (*i.e.*, it is not limited to Medicare). If the referral is prohibited, so too is any demand for payment. The New York State law also covers any cross-referral scheme designed to make referrals indirectly that could not be made directly. A provider or practitioner that collects any amount under a prohibited referral is jointly and severally liable to the payor. In addition, such practitioner would likely be subject to disciplinary action (including license revocation) by the appropriate State licensing authority, among other things. As with the Federal law, if the State law is implicated, all applicable exceptions must be squarely met, or the law will have been violated (*i.e.*, the State “Stark” law, like its Federal counterpart, is a “strict liability” law. Unlike with the Anti-Kickback laws, the intent of the parties is irrelevant).

4. **QUESTIONS**

All questions regarding existing or potential referral relationships and how they implicate the Anti-kickback Statute, the Stark Law, and any applicable safe harbors and/or exceptions should be raised with the Compliance Officer, who will consult with legal counsel, as necessary.

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\(^2\)“Immediate family member” means spouse; natural and adoptive parents, children and siblings; stepparents, stepchildren and stepsiblings; fathers-in-law, mothers-in-law, brothers-in-law, sisters-in-law, sons-in-law and daughters-in-law; and grandparents and grandchildren.