Advantage Care Health Center Compliance Program Policies and Procedures	
SUBJECT: Compliance with Anti-Referral Laws	
APPROVED BY:	**EFFECTIVE:**
REVISED:	**PAGE 1 OF 4**

I. POLICY

It is the policy of Advantage Care Health Center ("Center") that all personnel shall comply with applicable Federal and State Anti-Referral laws and related regulations. Center has instituted various procedures to ensure compliance with these laws and to assist Center in preventing fraud, waste and abuse in Federal health care programs.

A. OVERVIEW OF THE FEDERAL ANTI-REFERRAL LAWS

1. The Federal Anti-Kickback Statute. Under the Federal Anti-Kickback Statute, it is a crime to knowingly and willfully solicit, receive, offer or pay 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 program" under this statute generally includes ***all*** health care programs that receive ***any*** funding from the United States government (including, but not limited to, Medicare and Medicaid), as well as certain specified State health care programs.

The Federal Anti-Kickback Statute has been broadly interpreted by a number of courts to prohibit remuneration which is offered or paid when the circumstances show that ***one*** purpose of the arrangement is to induce referrals or otherwise engage in the prohibited conduct - ***even if*** the arrangement has other, wholly legitimate, business aspects to it.

There are, however, a number of statutory exceptions as well as a series of regulatory "safe harbors" under the Federal Anti-Kickback Statute. If an arrangement meets every requirement of an applicable exception or "safe harbor" it will be protected from prosecution under the statute. On the other hand, the failure of an arrangement to fit squarely within a safe harbor or exception does not necessarily render the 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 induce referrals or otherwise violate the law).

Violation of the Federal Anti-Kickback Statute may result in significant fines (up to $100,000) and/or imprisonment (of up to ten years) for ***both sides*** of an illegal kickback arrangement. In addition, substantial civil monetary penalties and exclusion from Federal and State health care programs may also result from violations of the Federal anti-kickback statute.

2. The Federal "Stark" Law. In general terms, the Federal "Stark" law prohibits a physician from making a referral to an entity for certain specified "designated health services" that are paid for by Medicare[1] to an entity when the physician (or his or her immediate family member) has a "financial relationship" (that is, an ownership interest, an investment interest or a compensation relationship) with that entity, unless an exception to the law is squarely met. If the referral is prohibited, so too is the submission of a claim for payment by the entity that receives the prohibited referral.

Currently, the Federal "Stark" law covers the following "designated health services": (a) Clinical laboratory services; (b) Physical therapy services; (c) Occupational therapy services; (d) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; (e) Radiation therapy services and supplies; (f) Durable medical equipment and supplies; (g) Parenteral and enteral nutrients, equipment, and supplies; (h) Prosthetics, orthotics, and prosthetic devices and supplies; (i) Home health services; (j) Outpatient prescription drugs; (k) Inpatient and outpatient hospital services; and (l) Outpatient speech-language pathology services.

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.

The Federal "Stark" law contains a number of statutory exceptions. In addition, there are also a series of regulatory exceptions to the "Stark" law. A number of the "Stark" exceptions are similar (but not identical) to the Federal Anti-Kickback "Safe Harbors."

Unlike the Federal Anti-Kickback Statute, however, if the Federal "Stark" law is implicated, all relevant exceptions must be squarely met, or the law will have been violated. The Federal "Stark" law is a "strict liability" law. In other words, unlike with the Federal Anti-Kickback Statute, the intent of the parties is irrelevant from a "Stark" perspective.

The penalties for violating the Federal "Stark" law include: (i) the denial of, or the requirement to refund, any payments for services that resulted from an unlawful referral; (ii) civil monetary penalties of up to $15,000 for each service for which a person presents or causes to be presented a bill or claim that they know or should know results from a prohibited referral, or for which a required refund has not been made,[2] plus assessments of up to three times the amount

[1] On its face, the Federal "Stark" law only prohibits referrals for "designated health services" that are paid for by Medicare. However, the Social Security Act prohibits any Federal financial participation payment to a State for "designated health services" furnished on the basis of a referral that would result in a denial of payment under Medicare if Medicare covered the services in the same way as the State plan. In other words, arrangements that would be improper under the Federal "Stark" law may extend to State Medicaid Programs and prevent the State from receiving Federal matching funds for those services.

[2] Administrative penalties under the Civil Monetary Penalties Law may be imposed by the Federal Office of Inspector General. These penalties are subject to adjustments for inflation and have increased $27,750, for each service, as of March 17, 2022. For "circumvention schemes," a civil monetary penalty of up $185,009 (as of March 17, 2022) may be imposed on any physician or entity that knows or should know that the scheme/arrangement has a

claimed in lieu of damages; and (iii) exclusion from the Medicare and Medicaid programs as well as other Federal and/or State health-care programs.

B. OVERVIEW OF RELEVANT STATE ANTI-REFERRAL LAWS

1. New York's Anti-Kickback Statute. Similar to the Federal law, New York State also makes it a crime to offer, agree to give or give any payment or other consideration in any form to another person to the extent such payment or other consideration is given: (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. Medicaid providers who violate this statute may be found guilty of a misdemeanor crime punishable by fines of up to $10,000, or imprisonment for up to one year or both; except that Medicaid providers that violate this statute and obtain money or property having a value in excess of $7,500 may be found guilty of a class E felony.

2. The New York State "Stark" Law (the "Health Care Practitioners Referrals" Law). In New York State, 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 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 exceptions that exist).

Unlike its Federal counterpart, the New York State Stark law covers all payers. If the referral is prohibited, so too is any demand for payment. The New York State "Stark" 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 payer. In addition, disciplinary action (including license revocation) by the appropriate State licensing authority is also a possibility. As with the Federal "Stark" law, if the New York State "Stark" law is implicated, all applicable exceptions must be met, or the law will have been violated (i.e., it, too is a "strict liability" law and the intent of the parties is irrelevant).

C. COMPLIANCE WITH ANTI-REFERRAL LAWS

It is Center's intent to at all times comply with the anti-referral laws to which it is subject. Given the complexity of these laws, outside counsel will be consulted as necessary to ensure Center's on-going compliance.

The decision to refer a patient is a separate and independent clinical decision made by the referring physician or practitioner. Center will not knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward the referral of business reimbursable under any Federal or State health care program. Nor will Center otherwise engage in any relationship or arrangement

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principal purpose of assuring referrals by the physician to a particular entity that could not be directly made under the law.

that violates the anti-referral laws. Moreover, it is Center's policy to avoid relationships or arrangements that create an appearance of illegality or impropriety.

1. Marketing Activities. All marketing activities and advertising by Center personnel must be based on the merits of the services provided and *not* on any promise, express or implied, of remuneration for referrals. In addition, all marketing activities and advertising must be truthful and not misleading, and must be supported by evidence to substantiate any claims made and must comply with all applicable legal requirements. Center's best advertisements are the quality of the medical services we provide. Center personnel should not disparage the services or business of a competitor through the use of false or misleading representations. All marketing materials must be reviewed and approved by the Compliance Officer before they are disseminated. The Compliance Officer may consult with legal counsel, as necessary and appropriate.

D. QUESTIONS

To the extent that you have any questions regarding the propriety of an existing or prospective arrangement or relationship (whether under the laws discussed herein, under our compliance policies, or otherwise), you are encouraged to contact Center's Compliance Officer. She may be reached by email at dweissbrot@advantagecaredtc.org or by telephone at (516) 686-4400 Extension 2395. In addition, compliance concerns may be submitted via the Compliance Hotline at (516) 686-4450.