Policy AD516

Subject	AD516 - Physician Self-Referral and Anti-Kickback Laws		
Category / Section	Administration/Corporate Compliance		
Owner	Director, Corporate Compliance		
Stakeholder/ Reviewer(s)			
Effective Date	12/00	**Review Frequency**	3 years
Approval Date	08/21/2019		

Scope of Policy/Procedure *(applies to entities/locations marked below)*					
	This document applies to **all** entities/locations listed below				
Hospitals		**Ambulatory/Off-Campus locations**		**Other Carle Entities**	
	All Carle Hospitals listed below:		All Carle ambulatory/off-campus locations listed below:	X	All other Carle entities listed below:
X	Urbana (CFH)	X	CFH/CPG ambulatory locations *(also includes Home Health, Therapy Services, Medical Supply, Danville Surgicenter, Specialty Pharmacy)*		Arrow Ambulance, LLC
X	Carle Hoopeston Regional Health Center (CHRHC)	X	CHRHC ambulatory locations *(includes, CARMC, Cissna Park, Danv-Fairchild, Mattoon-Hurst, Milford, Rossville, Tuscola, Watseka)*		Carle Retirement Centers *(Windsor of Savoy & Windsor Court)*
X	Carle Richland Memorial Hospital (CRMH)	X	Champaign SurgiCenter, LLC		Health Alliance Medical Plans
	Carle Eureka Hospital (CEH)	X	Administration Building locations (includes Carle at the Fields)		FCC – First Carolina Care, Inc.
	Carle BroMenn Medical Center (CBMC)		Carle West Physician Group (CWPG)	X	CHPP—Carle Health Physician Partners
		X	CRMH Ambulatory locations (includes Bridgeport, Newton, West Salem, Olney, Specialty Services)		
	Scope Exclusions *(Mark this box and enter any departments or locations within a marked entity that are exempt from the policy/procedure.)*				

Attachments N/A

Purpose

A. To inform employees of The Carle Foundation about the potential for physician self-referral and anti-kickback violations in common health care business relationships and to establish guidelines to ensure compliance with federal and state self-referral and anti-kickback laws.

Definitions:

Remuneration: Anything of value including items, services, or payments, made in cash or in kind, directly or indirectly, overtly or covertly.

Statement of Policy

A. It is the Foundation's policy to comply with all applicable federal and state laws and regulations, including the Stark Physician Self-Referral Prohibition and the federal Anti-kickback Statute, which address the relationships between hospitals and physicians or other entities who are in a position to refer business that is reimbursable by any federal or state health care program, such as Medicare and Medicaid. Under no circumstances, will the Foundation offer any referral source any form of remuneration in exchange for referrals.

Legal Requirements

A. **Stark Physician Self-Referral Law**. This law prohibits **physicians** from referring Medicare or Medicaid patients for certain designated health services to entities in which the physicians or their immediate family members have a

Printed copies are uncontrolled documents. Refer to the intranet for the most current version.

financial relationship, unless a legal exception is met. In turn, any health care provider receiving improperly referred patients cannot submit claims for any designated health services provided to those patients. The term "financial relationship" is defined very broadly and includes many of the ownership, investment, and compensation relationships commonly found in health care between physicians and other health care providers. The following is a list of the designated health services to which the Stark Law applies:

1. Clinical laboratory
2. Physical therapy
3. Occupational therapy
4. Outpatient speech-language pathology
5. Radiology, including MRI, computerized axial tomography scans and ultrasound services
6. Durable medical equipment and supplies
7. Parenteral and enteral nutrients, equipment, and supplies
8. Prosthetics, orthotics and prosthetic devices and supplies
9. Home health services
10. Outpatient prescription drugs
11. Inpatient and Outpatient hospital services
12. Radiation Therapy Services and supplies

Since the Stark Law is a strict liability statute, it may be violated even if the parties do not intend to violate the law and are not aware that they are doing so. Possible penalties for violating the Stark Law include (1) fines of up to $15,000 per service or up to $100,000 for schemes with a principal purpose of assuring referrals (2) an assessment of up to three times the amount claimed, (3) exclusion from participation in any federal health care program, such as Medicare and Medicaid, and (4) $10,000 per day for failure to report required information.

B. **The Anti-kickback Statute**. This federal criminal statute prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration in exchange for referring an individual to another person or entity for the furnishing, or arranging for the furnishing, of any item or service that may be paid for in whole or in part by a federal health care program. Moreover, it is possible for an arrangement to violate the Anti-kickback Statute if just one purpose of the arrangement is to induce or encourage referrals even though all other aspects of the arrangement are otherwise legitimate. Unlike the Stark Law, the Anti-kickback Statute applies to remuneration paid to **any referral source** including patients. Like the Stark Law, the federal Anti-kickback Statute contains many statutory exceptions and regulatory Safe Harbors. A violation of the federal Anti-Kickback Statute may result in:

1. Criminal fines of up to $25,000 and imprisonment for up to five years
2. Civil fines of $50,000 per act or occurrence, or three times the remuneration (payment) offered
3. Mandatory exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid

C. **The Beneficiary Inducements (Civil Monetary Penalties Statute).** Past, present, or prospective patients shall not be given any gifts or remuneration for having received healthcare items or services nor as inducements to obtain healthcare items or services in the future. Certain incentives that do not exceed $15.00 per patient per visit or $75.00 per patient annually may be allowable as part of the nominal gifts exception to this statue. Any use of this exception shall be approved by the Director of Corporate Compliance and can never be advertised to patients.

1. **Accountable Care Organization Incentive Waivers:** As a participant in an ACO, certain in-kind gifts or services to beneficiaries may be permissible so long as the gift or service is implemented under an approved ACO Patient Incentive Waiver and all of the following are met:
    a. There is a reasonable connection between the items and services and the medical care of the beneficiary,
    b. The items or services are related to preventive care or advance a clinical goal for the beneficiary, including adherence to a treatment regime, drug regime, follow-up care plan, or management of a chronic disease or condition,
    c. The conditions under which the Incentive Waiver may be used is documented AND
    d. Each instance in which free or reduced items or services are documented.

D. **At-risk Relationships**. Business relationships that are at risk for violation of the Physician Self-Referral and/or Anti-Kickback laws include relationships, whether written or oral, between the Foundation or any of its employees and:

1. Individual physicians
2. Group practices
3. Ancillary healthcare providers
4. Post-acute healthcare providers
5. Management companies

Printed copies are uncontrolled documents. Refer to the intranet for the most current version.

6. Joint venture arrangements
7. Pharmaceutical companies and representatives
8. Medical equipment/supply companies and representatives, and
9. Any patient.

Printed copies are uncontrolled documents. Refer to the intranet for the most current version.

Procedure

A. Foundation employees must not offer, pay, solicit or receive money or anything of value in return for patient referrals or to persuade individuals or entities to purchase Foundation products or services. "Anything of value" includes, but is not limited to:
   1. Money
   2. Gifts
   3. Entertainment
   4. Discounted or free medical care, services or products
   5. Other free or discounted products or services.

B. Foundation employees must not make any monetary guarantees, or provide free services in order to induce referrals of business to the Foundation.

C. Foundation employees must not enter into agreements, whether oral or written, to pay an amount above fair market value for any items or services in return for referrals of patients or to persuade individuals or entities to purchase Foundation products or services. Similarly, Foundation employees must not enter into agreements to pay amounts below fair market value, or receive any other form of remuneration, for any item or service received by the Foundation when it is a referral source of other business payable by any federal or state health care program. **Prior to being entered into, any agreement with a referral source must be reviewed by the Contracts Attorney in coordination with the Office of Corporate Compliance. Any material amendments to existing agreements should also be reviewed by said parties.**

D. Ordinarily, all contracts, leases, and agreements made by the Foundation with individuals or groups who have the ability to refer patients or business to the Foundation must be:
   1. In a signed writing covering all of the items, services, or space to be provided
   2. For a term of at least one year
   3. Subject to review by legal counsel prior to execution
   4. Any compensation to be paid under any such arrangements should:
      a. Be set in advance
      b. For an amount that is consistent with fair market value
      c. Not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made under any federal health care program.
   5. Furthermore, in personal services and management contracts, the aggregate services contracted for must also not exceed those which are reasonably necessary to accomplish a commercially reasonable business purpose. In lease arrangements with physicians, any premises leased must be specified and must not exceed the space reasonably needed for the physician's legitimate purposes.

E. In all arrangements with referral sources, payments must be consistent with the terms of the agreement and performance of all of the terms of the agreements is required.

F. The Stark Law and Anti-Kickback statutes are incredibly complex, contain a number of statutory and regulatory exceptions, and make illegal practices that are perfectly common and legal in other industries. In some cases, the types of activities that violate the Stark Law and the Anti-Kickback Statute could also violate federal and state tax laws. Therefore, any employee who is concerned about whether an arrangement violates the Stark Law or Anti-Kickback statute, or otherwise implicates these statutes has a duty to report it to his/her supervisor, or contact the Corporate Compliance Officer, the Confidential Message Line, or Contracts Attorney. All good faith reports of Stark Law or Anti-Kickback violations will be investigated by the Corporate Compliance Department, in consultation with legal counsel, when necessary.

G. The Foundation will meet any violation of this Policy with fair and consistent discipline in accordance with HR609 - Employee Discipline and Misconduct

Attachments N/A

Other Related Links N/A

References – Applicable Laws and Penalties

- The Physician Self-Referral Law is located at Title 42, Section 1395nn of the United States Code
- The Federal Anti-Kickback Statute is located at Title 42, Section 1320a-7b(b) of the United States Code

Printed copies are uncontrolled documents. Refer to the intranet for the most current version.

- A violation of the Illinois Anti-Kickback Statute [305 ILCS 5/8A-3, et seq.] may also result in criminal penalties and imprisonment, civil monetary penalties, and/or revocation of healthcare license.
- 42 CFR §425.304(a)
- Civil Monetary Penalty – Beneficiary Inducements §1128A(a)(5) of the Social Security Act

Electronic Approval on File

Laurence J. Fallon, JD
Executive Vice President, Chief Legal Officer

Printed copies are uncontrolled documents. Refer to the intranet for the most current version.