POLICY

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Corporate Compliance and Audit Services

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Policy Title:
General Policy Statement and Standards on Prohibition on Self-Referrals, Kickbacks and Inducements to Refer

Manual Section:
Legal; Financial Arrangements

Approved by:
Dir. Corp Compliance and Audit Services

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PURPOSE

The purpose of this document is to communicate the general policy statement and related standards governing Halifax Health’s financial arrangements with patient referral sources and entities to which Halifax patients may be referred.

POLICY

Halifax Health will not enter into an arrangement, nor offer, accept or provide anything of value from/to a source of referrals, or an entity to which Halifax patients are referred, unless such arrangement is in compliance with all applicable laws, regulations, and Halifax’s legal compliance policies and standards.

The inducement of referrals to either Halifax or the other party to the arrangement shall never by an underlying purpose of a referral source arrangement.

SCOPE/APPLICABILITY

This policy is applicable to all Halifax entities and departments, and any agreement or financial relationship involving:

- A physician; or
- non-physician referral source, or
- Physician’s immediate family member; or
- An entity to which a Halifax patient may be referred.

Subject agreements and financial relationships include, but are not limited to, physician recruiting agreements, loans, guarantees of physician loans, management services agreements, professional service agreements, employment agreements, physician expense reimbursement agreements, other agreements for the provision of services or supplies (whether medically related or not), asset purchase and disposition agreements, equipment rentals, and office space leases.

BACKGROUND

Referral source regulation in the United States has a long history, growing out of concerns that financial relationships between providers of health care items or services and entities that refer healthcare items result in increased costs in government health programs such as Medicare and Medicaid. The principle sources of legislation governing Halifax relationships with referral sources are: the Physician Self-Referral Law (Stark Law) and the federal Anti-Kickback Statute. Anti-kickback legislation was first enacted in the Social Security Act of 1972. The first phase of self-referral legislation was enacted in 1989 by prohibiting physician ownership of clinical laboratories (Stark I). The legislation was later amended to apply to additional ancillary services, hospital services and home health services.

Sanctions and penalties for violations of these laws are very severe, and can include exclusion from participation in federal health programs, criminal penalties, civil money penalties, and treble damages liability under the Federal False Claims Act.

DEFINITIONS

“Immediate family member” includes spouse; natural 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 the spouse of a grandparent or grandchild.

“Financial source arrangement” or “Arrangement” means any offer, acceptance, or exchange of anything of value whether money or in-kind between Halifax and a party in a position to refer business to Halifax.
or to which Halifax patients may be referred. Most arrangements fitting this definition will also be considered a “focus arrangement” under the Corporate Integrity Agreement entered into 3/10/2014 with the HHS Office of Inspector General, thus triggering the corporate integrity obligations summarized below.

STANDARDS

1. General Prohibition on Non-Compliant Referral Source Financial Arrangements

   a. Halifax shall not enter into an Arrangement with a physician that refers or has the potential to refer patients to Halifax unless such Arrangement meets an exception to the referral and billing prohibition of the Stark Law;

   b. Halifax shall not enter into a relationship with any other person in a position to refer patients to Halifax, or to which a Halifax patient may be referred unless the Arrangement undergoes legal review and approval and either;

      (1) The relationship fits within a regulatory safe harbor of the Federal Anti-kickback statute; or;

      (2) The arrangement fulfils a legitimate business or clinical need and no purpose of the Arrangement is for the inducement of referral of healthcare business.

   c. All Arrangements are subject to Legal review and approval under the applicable contract policies and procedures.

   d. Approval for an Arrangement will be withheld if there exists any documents, or it appears that there have been any discussions, indicating intent to obtain or reward referrals by way of the Arrangement.

2. Authority and Responsibility for Entering into a Referral Source Financial Relationships

   Authority and responsibility to enter into an Arrangement shall be strictly controlled via separate signature authority policies and standards approved by the CEO.

3. General Requirements for Referral Source Financial Arrangements

   Arrangements with referral sources, generally:

   a. Must be in writing and signed by the parties before any remuneration can be paid;

   b. Must specify the services covered;

   c. Specify the timeframe for the arrangement;

   d. Specify the remuneration (i.e., salary, other compensation, rental rate, purchase price, etc.)

   e. Set the consideration in advance;

   f. Be consistent with fair market value, for services or items actually provided without taking into account the value or volume of referrals or other business generated by the other party; and

   g. Must be “commercially reasonable”, i.e., intended to obtain or provide an item or service that is reasonable and necessary for a legitimate business purpose, without regard to referrals generated between the parties

Notes:

Additional legal requirements may apply depending on the nature of the relationship. Other Halifax policies should be reviewed or the proposed arrangement discussed with legal counsel before the commencement of negotiations.
Some Arrangements, such as medical staff incidental benefits and certain physician non-monetary compensation subject to an annual or per occurrence dollar limit need not be in writing. Consult the policy listed under Related Policies applicable to the specific type of arrangement.

4. **Supporting Policies and Standards**
   
a. The Legal and Corporate Compliance Departments are jointly and collaboratively responsible for establishing and maintaining policies and standards relating to specific types of referral source financial arrangements, and the procedures for tracking existing relationships in a centralized database.

b. The policies and standards listed in the “Related Policies” section of this policy have been established for various types of financial arrangements, and covering key requirements common to more than one type of arrangement, such as “fair market value” and “commercially reasonable.”

c. Relationship-specific policies, standards and procedures will be maintained on Pulse, in the Legal section of the Compliance Manual.

d. To the extent a policy or standard has not been developed for a specific type of arrangement, this policy and Halifax’s corporate integrity obligations to regulatory authorities shall govern.

e. Any exception to a promulgated policy requirement must be approved by General Counsel. Exceptions are discouraged, and any exception must still meet applicable legal requirements.

5. **Responsibilities for Procedures for Management of Referral Source Financial Arrangements**

   Responsibilities of the procedures for management of referral source financial relationships are as follows:

   a. Service Line Administrators (SLAs) and Operations Vice Presidents (OVPs) are responsible for:

      (1) Determining the need for an Arrangement, and documenting the purpose and business rationale;

      (2) Recognizing an arrangement as a “focus arrangement” triggering certain corporate integrity obligations;

      (3) Facilitating meeting corporate integrity obligations such as the delivery and execution of supplemental compliance agreements, and overseeing completion of required compliance training by the other party to an arrangement;

      (4) Obtaining legal advice on Arrangements when an approved template Arrangement document is not available;

      (5) Obtaining a fair market fair analysis for an Arrangement from the Finance Department or a qualified third-party appraiser;

      (6) Negotiating the Arrangement with the other party;

      (7) Finalize the terms of the Arrangement in compliance with all applicable policies and standards and any legal advice obtained;

      (8) Adhering to the applicable Contract Management, Signature Requirements, and Review and Approval, and any Arrangement-specific standards and procedures.

      (9) Monitoring performance under the Arrangement and ensuring that adequate documentation exists to support performance and all payments made throughout the term of the Arrangement.
(10) Submitting performance documentation with each disbursement, when required.

b. The Legal Department is responsible for:
   (1) Legal review of Arrangements and advising SLAs and OVPs on applicable legal requirements, or engaging qualified outside counsel for same;
   (2) Maintaining template Arrangement documents for use by SLAs and OVPs;
   (3) Coordinating the Physician Arrangement Review Committee;
   (4) Managing the Arrangements Tracking System;
   (5) Issuing reminder notices and tasks to managers responsible for Arrangements; and
   (6) Following up on delinquent tasks and documents that are required to be logged into the Arrangements Tracking System.

c. The Physician Arrangements Review Committee is responsible for:
   (1) Reviewing all Arrangements with physicians and other Arrangements referred to the Committee by the Legal Department;
   (2) Recommending Arrangements for final execution or referring the Arrangement back to the responsible SLA or VP with recommended changes.

d. The Finance Department is responsible for
   (1) Performing fair market value analyses;
   (2) Collecting and evaluating documentation supporting the purpose of the Arrangement;
   (3) Reviewing and evaluating documentation supporting disbursement requests applicable to an Arrangement;
   (4) Forwarding approved disbursement requests to the Accounting Department for processing.

e. The Corporate Compliance and Audit Services Department is responsible for:
   (1) Maintaining the policies, standards, training materials, other documents and the delivery systems needed to meet arrangements-related corporate integrity obligations;
   (2) Scheduling, planning and performing reviews and audits of Arrangements procedures and the Arrangements Tracking System;
   (3) Monitoring and reporting on compliance with corporate integrity obligations (discussed below).
   (4) Reporting results of audits and reviews to the Compliance Committee, Audit Committee and Board of Commissioners;

6. Corporate Integrity Requirements Relating to Arrangements

   Halifax has a number of corporate integrity obligations to regulatory authorities, such as the HHS Office of Inspector General that are specific to financial arrangements with referring physicians and certain other arrangements. These include:

   a. Halifax must provide Stark Law and Anti-kickback Statue training to workforce members with Arrangement approval or oversight responsibilities and to parties to an Arrangement as follows:
      (1) Minimum of 2 hours of Arrangements training for workforce members and agents who are involved in the development, approval, management, or review of Halifax's Arrangements;
(2) Minimum of 2 hours of Arrangements training for each member of the Board of Commissioners;
(3) Minimum of 1 hour of Arrangements training to any member of the active medical staff that is a party to an Arrangement.
b. Halifax must maintain Arrangements policies and procedures that include:
   (1) Creating and/ or maintaining a centralized tracking system for all existing and new or renewed Arrangements (Arrangements Tracking System);
   (2) Tracking remuneration to and from all parties to Arrangements;
   (3) Tracking service and activity logs to ensure that parties to an Arrangement are performing the services required under the applicable Arrangement(s);
   (4) Monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
   (5) Establishing and implementing a written review and approval process for Arrangements, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following:
      (a) a legal review of all Arrangements by legal counsel with expertise in the Anti-Kickback Statute and Stark Law;
      (b) process for specifying the business need or business rationale for all Arrangements, and a process for determining and;
      (c) documenting the fair market value of the remuneration specified in the Arrangement;
   (6) The Compliance Officer must annually review the Arrangements Tracking System, internal review and approval process, and other Arrangements procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
   (7) Halifax must implement effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing the issues to the appropriate authorities and quantifying and repaying overpayments received from government health programs, when appropriate.
c. For any new or renewed arrangement, Halifax must:
   (1) Ensure that each Arrangement is set forth in writing and signed by an authorized Halifax official and the other parties to the Arrangement;
   (2) Include in the written agreement a requirement that each party to the Arrangement shall complete the training in the Stark Law and Federal Anti-kickback Statute provided by the Halifax Corporate Compliance and Audit Services Department;
   (3) Provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-kickback Statute Policies and Procedures; and
   (4) Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.
d. The Compliance Officer must review the entries in Halifax's Arrangements Tracking System at least annually and certify in writing to the OIG that, to the best of his or her knowledge,
the Arrangements Tracking System is complete and accurate, except for any discrepancies identified. The Compliance Officer must provide an explanation for:

1. any Arrangements found to have been missing from the Arrangements Tracking System; and
2. any entries in the Arrangements Tracking System found to have been incomplete or inaccurate.

e. Halifax must retain and make available to the OIG, upon request, the Arrangements Tracking System and all supporting documentation of the Arrangements, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

f. Halifax must engage a Legal Independent Review Organization (LIRO) to
   1. Periodically review and report to the OIG on the Arrangements Tracking System and Halifax’s Arrangements policies and procedures; and
   2. Annually review and report to the OIG on 75 Arrangements entered into or renewed by Halifax during the applicable reporting period.

IMPLEMENTATION GUIDANCE
For implementation guidance, contact the Legal Department or Corporate Compliance and Audit Services. Implementation guidance can also be found on Pulse at:

Departments > Department Home Pages > Compliance and Audit Services > Government Billing > Stark and Anti-Kickback

ENFORCEMENT & SANCTIONS

1. Responsibility for enforcement
   Team leaders shall enforce the standards of this policy within their areas or responsibility.

2. Discipline
   a. For employees, Team Leaders shall follow the progressive discipline policy outlined in the Employee Handbook.
   b. For Medical staff, the Medical Staff bylaws and the rules and regulation of the Medical shall be followed.
   c. For Volunteers, discipline shall be governed by the bylaws of the volunteer organization, or guidelines of the Volunteer Department.
   d. For Students, discipline shall be governed by the affiliation agreement with the educational institution.
   e. For vendors, sanctions shall be governed by the written agreement with the vendor. Termination of the vendor relationship should be considered depending on the frequency and severity of the violations and risk placed upon the organization.

3. Reports of Non-Compliance: Corrective Action
   a. A report of actual or suspected non-compliance with Halifax’s arrangements standards shall be forwarded to the Legal Department, regardless of the method of report (chain of command, Compliance Committee member, Compliance Officer or Ethics and Concerns Help Line, etc.)
b. Notwithstanding Halifax’s progressive discipline outlined above, corrective action shall be subject to review and approval by the CEO, Compliance Committee and Audit Committee.

c. An arrangement found to be non-compliant shall be immediately terminated or amended to be compliant, and any pending payments suspended until the plan of correction has been approved by the Legal Department.

REFERENCES
42 U.S.C. § 1320a-7b; 42 C.F.R. § 1001.952(a)-(v); (Federal Anti-kickback Statute)
42 U.S.C. § 1395nn (Stark Law Phase II);
63 Fed. Reg. 1659 (Jan. 9, 1998); Stark Law Phase II Proposed Rule

COMMITTEE APPROVAL
Compliance Committee approval pending.

EXHIBITS
Exhibit 1 Corporate Integrity Agreement Definitions of “Arrangement” and “Focus Arrangement”

RELATED POLICIES
Halifax Health Code of Conduct
COM-P-LL-050.00 Contract Management
COM-S-LL-100.00 Financial Relationships; Review; Approval
COM-S-LL-102.00 Physician Employment and Personal Services Arrangements
COM-S-LL-103.00 Financial Relationships; Physician Recruiting Agreements
COM-S-LL-104.00 Financial Relationships; Space and Equipment Leases, Rentals
COM-S-LL-108.00 Financial Relationships; Non-Monetary Compensation and Incidental Benefits
COM-S-LL-110.00 Financial Relationships; Non-Employed Physician CME Expenses
COM-S-LL-111.00 Honoraria and Expenses for Invited Speakers
COM-S-LL-125.00 Professional Courtesy Discounts
COM-S-LL-145.00 Fair Market Value Determinations; Commercially Reasonable Standard
COM-S-LL-160.00 Financial Arrangements; Preventive Care Services
# REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision/Review</th>
<th>By</th>
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<tbody>
<tr>
<td>4/25/2014</td>
<td>Created as overarching policy for dissemination to counterparties to Halifax arrangements and incorporating all other arrangements policies by reference.</td>
<td>G.Rousis</td>
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<tr>
<td>5/12/2012</td>
<td>Added definitions of arrangements and focus arrangements from CIA as Exhibit for reference purposes; added SLA/OVP responsibility to recognize an arrangement as within the scope of corporate integrity obligations.</td>
<td>G.Rousis</td>
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Last review: Refer to the document abstract on Pulse. If printed, document may be out of date.
Exhibit 1
Definitions of “Arrangement” and “Focus Arrangement”

The following are relevant definitions contained in the Halifax-OIG Corporate Integrity Agreement executed 3/10/2014. It has been reproduced here for reference purposes.

1. "Arrangements" shall mean every arrangement or transaction that:
   a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Halifax and any actual or potential source of health care business or referrals to Halifax or any actual or potential recipient of health care business or referrals from Halifax.

   The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term "recipient of health care business or referrals" shall mean any individual or entity: (1) to whom Halifax refers an individual for the furnishing or arranging for the furnishing of any item or service; or (2) from whom Halifax purchases, leases, or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
   b. is between Halifax and a physician (or a physician's immediate family member (as defined at 42 C.P.R. § 411.351) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Halifax for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Focus Arrangements" means every Arrangement that:
   a. is between Halifax and any actual source of health care business or referrals to Halifax and involves, directly or indirectly, the offer, payment, or provision of anything of value;
   b. is between Halifax and any physician (or a physician's immediate family member) (as defined at 42 C.P.R. § 411.351) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Halifax for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)); or
   c. is between Halifax and any physician (or a physician's immediate family member) or medical practice that involves, directly or indirectly, the offer, payment, or provision of anything of value in anticipation of that physician becoming an actual source of health care business or referrals (e.g., for purposes of recruitment).

   Notwithstanding the foregoing provisions of Section II.C.2 [of the OIG CIA], any Arrangement that satisfies the requirements of 42 C.P.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357 (g) (remuneration unrelated to the provision of designated health services); 42 C.P.R. § 411.357(i) (payments by a physician for items and services); 42 C.P.R. § 411.357(k) (non-monetary compensation); 42 C.P.R. § 411.357(m) (medical staff incidental benefits), 42 C.P.R. § 411.357(o) (compliance training), 42 C.P.R. § 411.357(q) (referral services), 42 C.P.R. § 411.357(s) (professional courtesy), 42 C.P.R. § 357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.