



IH Stark and Anti-Kickback Policy

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APPLIES TO: Infirmary Health and all affiliated corporations and employees

POLICY

It is the policy of Infirmary Health and its affiliates (“IH”) to fully comply with the Stark Law and Anti-Kickback Statute and their regulations at all times. To that end, each IH financial relationship with a physician or a physician’s immediate family member shall meet a Stark Law exception and, if possible, an Anti-Kickback Statute safe harbor where applicable. In addition, IH shall comply with the Stark Law by prohibiting a physician who has a financial relationship with an entity from making a referral to that entity for the provision of designated health services (“DHS”) unless an exception applies. The basic Stark Law prohibition applies to entities with which a physician or the physician’s immediate family member has a financial relationship. IH shall also comply with the Anti-Kickback Statute by prohibiting the solicitation, receipt, offer, or payment of any kind of remuneration in return for referring an individual or recommending or arranging the purchase, lease, or ordering of an item or service that may be wholly or partially paid for under a Federal health care program. The inducement of referrals to either IH or the other party to an arrangement shall never be an underlying purpose of the arrangement. This policy supplements the IH Standards of Business and Professional Conduct, which set forth appropriate legal and ethical behavior.

PURPOSE

To ensure compliance with, and promote awareness of, requirements under the Stark Law and Anti-Kickback Statute.

DEFINITIONS

The following definitions are provided as basic definitions emanating from the Stark Law.

Designated Health Services (DHS) – Shall have the meaning set forth in 42 C.F.R. § 411.351 and includes: physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; home health services; prosthetics, orthotics, and prosthetic devices and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

Entity – Shall have the meaning set forth in 42 C.F.R. § 411.351 and includes:

1. A physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it:
 - (i) Is the person or entity that has performed services that are billed as DHS; or



- (ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1)(employer) or (b)(2)(payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).
2. A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under §424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.
 3. “Entity” does not include a physician’s practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable.

Financial Relationship – Two types of financial arrangements are covered under the Stark Law (both direct and indirect):

1. Arrangements involving physician ownership or investment interest in a DHS entity; and
2. Compensation arrangements between a referring physician and a DHS entity to which the physicians make referrals.

Immediate Family Member – Shall have the meaning set forth in 42 C.F.R. § 411.351 and includes husband, wife, birth or adoptive child, parent, 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.

Physician – For the purposes of the Stark Law, a “physician” is defined in 42 C.F.R. § 411.351 as “a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.” A physician and the professional corporation of which he or she is a sole owner are the same for purposes of the Stark Law. Therefore, if a health care practitioner who is not a “physician” under this definition has a financial relationship with an entity, the Stark Law does not apply to the arrangement or any referrals made by that practitioner.

Referral – Shall have the meaning set forth in 42 C.F.R. § 411.351 and includes a request by a physician that includes the provision of any DHS, the establishment of a plan of care by a physician that includes DHS, the certifying or recertifying of the need for DHS, or the request for a consultation with another physician and any test or procedure ordered by or to be performed by that other physician. The definition specifically excludes DHS personally performed or provided by the referring physician.

PROCEDURES

1. The Stark Self-Referral Law

The Ethics in Patient Referrals Act, 42 U.S.C. §1395nn and the regulations promulgated thereunder (the “Stark Law”) prohibit a physician who has a financial relationship with an entity that provides or performs DHS:

- from making a referral for any DHS that is reimbursable by Medicare or Medicaid, and
- the entity that provides or performs the services may not bill Medicare or Medicaid for the services provided as a result of the prohibited referral.

A financial relationship can include an ownership or investment interest or a compensation arrangement. Any relationship involving the transfer of payments or benefits, including income guarantees, certain types of loans, free or discounted services, equipment or office space constitutes a compensation arrangement. The Stark Law is a civil statute with strict liability and no intent is required for a violation to occur. While a violation of the Stark Law does not subject violators to imprisonment, a violation may result in denial of payment for services, repayment of reimbursed services, and monetary penalties of up to \$15,000 per violation and \$100,000 per arrangement or scheme. Additionally, a knowing Stark Law



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violation may result in exclusion from Federal health care program participation and result in a false claim made to the United States Government. The Stark Law provides for several exceptions specific to compensation arrangements. The exceptions include:

- Rental of Office Space
- Rental of Equipment
- Employment Relationships
- Personal Service Arrangements
- Physician Recruitment
- Isolated Transactions (e.g., one time sale of property)
- Arrangements with Hospitals (unrelated to DHS)
- Group Practice Arrangement with Hospital
- Payments from Physicians
- Charitable Donations by Physicians
- Non-Monetary Compensation
- Medical Staff Incidental Benefits
- Risk-Sharing Arrangements
- Compliance Training
- Indirect Compensation
- Referral Service Programs
- Obstetrics Malpractice Coverage Assistance
- Professional Courtesy
- Retention Payments in Underserved Areas
- Community-Wide Health Information Systems
- Electronic Prescribing Services
- Donation of Electronic Health Record items and Services

Compensation arrangements that implicate the Stark Law shall fall within one of the exceptions listed above. The requirements of these exceptions are complicated and detailed, and each requirement must be fully met for the exception to apply. The General Counsel shall be consulted to determine whether there is an applicable exception for any proposed compensation arrangement.

2. The Anti-Kickback Law

The Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), is a criminal statute. It prohibits any knowing or willful solicitation or acceptance of any type of remuneration (in cash or in kind) intended to induce a person to: (a) refer an individual 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 (e.g., Medicare, Medicaid, etc.); or (b) purchase, order, or arrange for, or recommend purchasing or ordering any item or service for which payment may be made in whole or in part under a Federal health care program. The Anti-Kickback Statute can apply to remuneration provided to anyone in a position to induce referrals, purchases, or orders – whether or not such individual is a physician. Violation of the Anti-Kickback Statute is a felony and punishable with criminal penalties up to \$25,000 in fines and five years of imprisonment and \$50,000 in fines per violation. In addition, violations of the Anti-Kickback Statute can result in exclusion from Federal health care program participation.

IH Personnel are strictly prohibited from accepting gifts, favors, payments, services, or anything else of value, which might appear to influence the actions of IH or such Personnel. IH Personnel shall report any inappropriate offers to the IH Compliance Officer. IH Personnel are strictly prohibited from soliciting or accepting anything of value in exchange for individual referrals or in exchange for purchasing or leasing any item or service, which may be reimbursed, by Medicare,



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Medicaid, or any Federal or State health care program.

The Office of Inspector General (OIG) has published regulations outlining certain categories of activities referred to as “safe harbors” that are deemed not to violate the Anti-Kickback Statute. The failure of a particular business arrangement to comply with a safe harbor, however, does not make such conduct or activity illegal. Each such arrangement shall be analyzed by the General Counsel to determine whether anything of value is being offered or exchanged to induce referrals, recommendations or the purchase of goods or services reimbursable by a Federal health care program. Safe harbors are available for areas such as:

- Investments in large publicly held health care companies
- Joint ventures
- Space rental
- Equipment rental
- Personal services and management contracts
- Sales of retiring physicians’ practices to other physicians
- Referral services
- Warranties
- Discounts
- Employee compensation
- Group purchasing organizations
- Waivers of Medicare Part A inpatient cost-sharing amounts
- Physician recruiting in underserved areas
- Obstetrical malpractice insurance subsidies for underserved areas
- Sales of practices to hospitals in underserved areas
- Investments in ambulatory surgical centers
- Investments in group practices
- Referral arrangements for specialty services
- Cooperative hospital service organizations

3. Private Benefit/Private Inurement

As IH and many of its affiliates are tax-exempt charitable organizations, such entities may not engage in activities primarily serving private interests and may not enter into agreements in which the savings of IH pass to "Insiders" such as physicians such that private inurement results. IH may not pay physicians unreasonable or excessive compensation, whether the compensation is for goods or services.

4. Physician Recruitment

All agreements involving physician recruitment incentives shall be processed through the IH Contract Administration Policy and the Focus Arrangements Procedures for Contracting with Actual Sources of Health Care Business or Referrals to or From IH and adhere to the IH Physician Recruitment Policy. This includes agreements that provide: income guarantees, educational loan repayment assistance, and relocation assistance along with any other recruiting incentives. The recruitment incentives shall be structured so as to minimize risks of violating the Stark Law and the Anti-Kickback Statute, shall be consistent with fair market value and commercially reasonable and shall not be based on the volume or value of any referrals. In addition, all physician recruitment incentives shall be reviewed by General Counsel to ensure compliance with



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IRS guidelines on physician recruitment by tax-exempt corporations.

5. Employed and Independent Contractor Physicians

Employment arrangements or independent contractor arrangements between IH and physicians shall be structured to comply with an exception to the Stark Law where the ordering of designated health services is included. Any payments related to transactions between IH and such physicians shall be consistent with fair market value and commercially reasonable and shall not be based on the volume or value of any referrals. Arrangements with such physicians shall also be structured to comply with the Anti-Kickback Statute. Finally, in order to comply with the laws governing tax-exempt charitable organizations, such arrangements shall not result in private benefit or private inurement.

6. Discipline

Compliance with this policy is a required condition of employment or continued engagement with IH. Violations of this policy shall be reported in accordance with the IH Disclosure Program.

REFERENCES:

- 42 CFR § 411.350 et seq. Stark Law Regulations
- 42 USC §1395nn Stark Law Statute
- 42 USC §1320a-7b Anti-Kickback Statute
- 42 CFR § 1001.952 Anti-Kickback Statute Safe Harbor Regulations

IH Policies:

- Contract Administration Policy
- Focus Arrangements Procedures for Contracting with Actual Sources of Health Care Business or Referrals to or From IH
- Physician Recruitment Policy
- Disclosure Program