



POLICY INFORMATION

Policy Title: Compliance with Anti-Kickback Statutes and Stark Laws Policy and Procedure

Departmental Owner: Chief Compliance, Audit, and Privacy Officer

Version Effective Date: March 7, 2025

Last Reviewed: March 7, 2025

SCOPE

This policy applies to the following individuals and/or groups:

All Covered Individuals (e.g., all Nuvance workforce members, business affiliates, and agents) as defined below under Definitions.

This policy applies to all above listed Nuvance Health Covered Individuals including but not limited to the following locations:

All of the below entities

- Nuvance Health Systems
- Danbury Hospital (including New Milford Hospital Campus)
- Northern Dutchess Hospital
- Norwalk Hospital
- Putnam Hospital
- Sharon Hospital
- Vassar Brothers Medical Center
- Health Quest Systems, Inc. "(HQSI)"
- Health Quest Home Care, Inc
- Hudson Valley Cardiovascular Practice, P.C. (aka The Heart Center) ("HVCP")
- Other HQSI-affiliated Entities Not Listed
- Western Connecticut Home Care, Inc ("WCHN")
- Western Connecticut Health Network Physician Hospital Organization ACO, Inc.
- Western Connecticut Home Care, Inc
- Other WCHN-affiliated Entities Not Listed
- Nuvance Health Medical Practices (NHMP PC, NHMP CT, ENYMS & HVCP)

POLICY STATEMENT/PURPOSE

To ensure compliance with, and promote awareness of, requirements under the federal Anti-Kickback Statute, Eliminating Kickbacks in Recovery Act of 2018 and the Physician Self-Referral Law, commonly referred to as the Stark law, and similar New York and Connecticut requirements.

Covered Individuals who believe there is an Anti-Kickback Statute ("AKS") or Stark concern should report the concern to the Compliance Office.

DEFINITIONS

For purposes of this policy, the terms listed below shall have the following meanings:

Covered Individual: This term refers to all Nuvance Health workforce members, business affiliates, and agents. Workforce members shall include any of the following individuals at Nuvance Health: Members of the Nuvance Health Board and the boards of any Nuvance Health related entity; administrators; managers; officers; employees; affiliates; medical staff members; appointees; volunteers; personnel; interns; students; trainees; and any individual whose conduct is under direct control of Nuvance Health whether or not they are paid by Nuvance. Business Affiliates shall include certain non-workforce members contractors, independent contractors, vendors, persons, subcontractors or third parties. Agents include individuals or entities that have entered into an agency relationship with Nuvance.

For the full definition and applicability of Covered Individuals, please refer to the Nuvance Health Compliance and Ethics Program Charter which can be found internally on Ellucid at: [Nuvance Health Compliance and Ethics Program Charter](#), or externally at <https://www.nuvancehealth.org/NHcomplianceandethicsprogramcharter>.

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: 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. An "Entity" includes the person or Entity billing for the DHS as well as the person or Entity that performs the service that is billed by another as DHS.

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 or 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 Entity of which he or she is a sole owner are the same for purposes of the Stark Law. Therefore, if a healthcare 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. "Personally performed" is to be taken literally; a service that is performed by a technician or a non-Physician practitioner at the direction of a Physician is not personally performed by that Physician.

Remuneration: Shall have the meaning set forth in 42 C.F.R. § 1003.101, and refers to the transfer of anything of value, including any items or services, for free or for other than fair market value.

POLICY

Any Nuvance Covered Individual who participates in the referral of patients or business transactions is responsible for understanding the statutes and laws governing these activities and is required to abide by the legal restrictions on these

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activities. Members of Nuvance’s medical staff are expected to be knowledgeable about the Anti-Kickback Statute and Stark Law including the associated restrictions surrounding the referral of Nuvance patients. All Nuvance management personnel are expected to be knowledgeable about the Anti-Kickback Statute and Stark Laws when engaging in the referral of patients or business transactions on behalf of the System.

I. Anti-Kickback Prohibition:

- A. Nuvance Health (“Nuvance”), Covered Individuals shall not knowingly and willingly engage in activities that solicit, offer or receive payment of any kind of Remuneration for:
- Referring an individual/patient to a person for the furnishing or arranging of an item or service;
 - Purchasing leasing, ordering, or arranging for, or recommending purchasing, leasing, or ordering any good, facility item or service, for which, Medicare, Medicaid or another Federal healthcare program pays; or
 - Referring a patient to a laboratory, clinical treatment facility or recovery home, for items or services paid by any payor; or
 - In exchange for referring an individual with a substance use disorder to a clinical service provider for clinical services.
- B. Nuvance, Covered Individuals who engage in potential anti-kickback activities, could be subject to penalties, which include fines, imprisonment and exclusion from Medicare, Medicaid and/or other Federal healthcare programs.
- C. Nuvance, Covered Individuals must contact and consult with in-house legal counsel prior to engaging in any referral of patients or business arrangements involving statutory exceptions or Anti-Kickback Statute “safe harbors” 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 healthcare program. The list of available “safe harbors” includes, but are not limited to:
- Investments in large, publicly held healthcare 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
- D. The inducement of Referrals to Nuvance or to the other party shall never be an underlying purpose of the arrangement. Under no circumstances should a Nuvance Covered Individual solicit, either directly or

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indirectly, any remuneration in order to induce the referral of any patient or business transaction for which payment may be made, in whole or in part, by a federal healthcare program.

- E. Refer to the “Compliance Disclosure Program” policy and procedure for guidance for reporting a potential concern or violation concerning the referral of patients or business transactions.

II. Stark Law:

- A. A Physician or a Physician’s Immediate Family Member who has a Financial Relationship with Nuvance shall not make a Referral to Nuvance for the provision of DHS paid by Medicare, Medicaid or other Federal healthcare programs unless the provisions of this policy are met.
- B. Each Nuvance Financial Relationship with a Physician or a Physician’s Immediate Family Member shall be in writing, reviewed by in-house legal counsel, signed by an Nuvance officer and currently in effect.
- C. Each arrangement involving a Financial Relationship with a Physician shall meet a Stark Law exception listed below, and, if possible, an Anti-Kickback Statute safe harbor, identified above in Section I C, where applicable.
- Rental of Office Space
 - Rental of Equipment
 - Employment relationships
 - Personal service arrangements
 - Physician recruitment
 - Isolated transactions (e.g., onetime sale of property)
 - Arrangements with hospitals (unrelated to DHS)
 - Group practice arrangements with hospitals
 - 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
- D. Nuvance, Covered Individuals must contact in-house legal counsel before engaging in business arrangements with a Physician or a Physician group to determine if a Stark Law exception under Section II C permits payments to the Physician or Physician group.
- E. Violations of the Stark Law may subject Nuvance, Covered Individuals to False Claim Act liabilities, which include treble damages, civil monetary penalties and possible exclusion from Medicare, Medicaid and/or other Federal healthcare programs.

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REPORTING CONCERNS:

Activities which are (or appear to be) in violation of this policy should be immediately reported to the Corporate Compliance Office at 203-739-7110 or anonymously to the Compliance Helpline at (844) 395-9331 or (844) 937-9326, or the Office of General Counsel.

DOCUMENT RETENTION:

Nuvance will retain all documents relating to this process for a period of seven (7) years after their creation.

PROCEDURE

1. The Chief Compliance, Audit, and Privacy Officer or designees will log the allegation in the incident management database within two (2) business days, as required by the Compliance Disclosure Program Policy and Procedure.
2. They will also acknowledge the complainant via phone/email/in-person meeting within three (3) business days.
3. Investigation will begin promptly, will be completed within six (6) months, and will follow procedures outlined in the disclosure policy.
4. General Counsel will be notified of the concern and investigation will be jointly coordinated.
5. If found to be an AKS-Stark violation, the parties involved will be subject to the Nuvance Compliance Misconduct and Sanctions Policy and Procedure.
6. If it is determined that there is a violation of the AKS-Stark Law, once the amount is identified, voluntary refunds will be made within sixty (60) days and in accordance with applicable regulatory requirements.
7. Appropriate actions shall be taken against any Workforce Member who knowingly makes a false report of a violation or who fails to report an actual violation.

ENFORCEMENT

All Nuvance Covered Individuals whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this process. Failure to comply with this policy will be subject to appropriate remedial and/or disciplinary action, up to and including termination of any employment or other relationship, in accordance with this process.

REFERENCES

42 CFR § 411.350 et seq. Stark Law Regulations
 42 USC §1395nn Stark Law Statute
 New York Public Health Law §§ 238 to 238-e; §4501
 New York Education Law §6530
 10 NYCRR Part 34
 42 USC §1320a-7b Anti-Kickback Statute
 42 CFR § 1001.952 Anti-Kickback Statute Safe Harbor Regulations
 New York Education Law§ 6530(18),(19)
 Social Services Law§ 366-d
 18 NYCRR 515.2
 Conn. Gen. Stat. § 20-579 and § 53a-161d
 Eliminating Kickbacks in Recovery Act of 2018
 Compliance Disclosure Program Policy and Procedure
 Compliance Misconduct and Sanctions Policy and Procedure

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APPROVAL

Signed by:

Jared B Gaynor
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Signature

3/7/2025

Date

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