Subpart 34-1 of 10 NYCRR

Health Care Practitioner Referrals

Statutory Authority: Public Health Law, sections 238-a(2)(g) and 238-a(10)

Sec.

34-1.1 Title
34-1.2 Definitions
34-1.3 Referrals prohibited
34-1.4 Disclosure: Clinical laboratory services, pharmacy services, radiation therapy services or x-ray or imaging services
34-1.5 Disclosure: other health or health related items or services
34-1.6 Disclosure form
34-1.7 Exceptions from compensation arrangement prohibitions

Section 34-1.1 Title. This Subpart shall be known and cited as "Health Care Practitioner Referrals."

Section 34-1.2 Definitions. Whenever used in this Subpart, unless the context of this Subpart clearly requires otherwise, the following terms shall have the following meanings:

(a) "Clinical laboratory services" shall mean the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body, for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease, or the assessment of a health condition.

(b) "Fair market value" shall mean the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes, not taking into account its intended use, and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(c) "Financial relationship" shall mean an ownership interest, investment interest or compensation arrangement.

(d) "General hospital" shall mean a hospital engaged in providing medical or medical and surgical services primarily to in-patients by or under the supervision of a physician on a twenty-four hour basis with provisions for admission or treatment of persons in need of emergency care and with an organized medical staff and nursing service, including facilities providing services relating to particular diseases, injuries, conditions or deformities. The term general hospital shall not include a residential health care facility, public health center, diagnostic center, treatment center, out-patient
lodge, dispensary and laboratory or central service facility serving more than one institution.

(e) "Group practice" shall mean a group of two or more practitioners organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan or similar association; and

(1) in which each practitioner who is a member of the group provides substantially the full range of services which the practitioner routinely provides, including medical care, consultation, diagnosis or treatment, through the joint use of shared office space, facilities, equipment and personnel; and

(2) for which substantially all of the services of the practitioners who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and

(3) in which the overhead expenses of the income from the practice are distributed in accordance with methods previously determined by members of the group; and

(4) provided, however, in the case of a faculty practice plan associated with a hospital with an approved residency training program in which practitioner members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, the provisions of paragraphs (1), (2) and (3) of this subdivision shall be applied only with respect to the services provided within the faculty practice plan.

(f) "Health care provider" shall mean a practitioner in an individual practice, group practice, partnership, professional corporation or other authorized form of association, a hospital or other health care institution issued an operating certificate pursuant to the public health law or the mental hygiene law, a certified home health agency or a licensed home care services agency, and any other purveyor of health or health related items or services including but not limited to a clinical laboratory, a physiological laboratory, a pharmacy, a purveyor of x-ray or imaging services, a purveyor of physical therapy services, a purveyor of health or health related supplies, appliances or equipment, or an ambulance service.

(g) "Health or health related items or services" shall include, but not be limited to, items and services available under the medical assistance program pursuant to title eleven of article five of the social services law.

(h) "Immediate family member" shall include spouse; natural and adoptive parents, children and siblings; stepparents, stepchildren and step-siblings; fathers-in-law, mothers-in-law, brothers-in-law, sisters-in-law, sons-in-law and daughters-in-law; and grandparents and grandchildren.

(i) "Interested investor" shall mean, with respect to a health care provider, an investor who is a practitioner in a position to make or to influence referrals or business
to the health care provider, or who is an immediate family member of such an investor.

(j) "Investor" shall mean, with respect to a health care provider, a person with a financial relationship with the health care provider, subject to the exceptions provided in paragraph (b) of subdivision three, subdivision four and paragraph (b) of subdivision five of section 238(a) of the Public Health Law.

(k) "Ownership interest" or "investment interest" shall mean an interest through equity, debt, or other means, but shall not include ownership of investment securities, including shares or bonds, debentures, notes or other debt instruments, which were purchased on terms generally available to the public and which are in a corporation that is listed for trading on the New York stock exchange or on the American stock exchange, or is a national market system security traded under an automated interdealer quotation system operated by the national association of securities dealers, and had, at the end of the corporation's most recent fiscal year, total assets exceeding one hundred million dollars.

(l) "Pharmacy services" shall mean the preparing, compounding, preserving or, the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority.

(m) "Practitioner" shall mean a licensed or registered physician, dentist, podiatrist, chiropractor, nurse, midwife, physician assistant or specialist assistant, physical therapist, or optometrist.

(n) "Rural" shall mean a county with population of two hundred thousand persons or less, or a town with a population density of one hundred fifty persons or less per square mile.

(o) "X-ray or imaging services" shall mean diagnostic imaging techniques which shall include but not be limited to the following:

1. conventional x-ray or radiology;
2. fluoroscopy;
3. digital radiography;
4. computed tomography;
5. magnetic resonance imaging;
6. nuclear imaging;
7. ultrasonography; and
8. angiography.

(p) "Radiation therapy services" shall mean the use of high-energy x-rays, particles, or radiation materials for the treatment of cancer and other diseases or conditions.

(q) Effective December 8, 2002, "physical therapy services" shall mean physical therapy as defined by section sixty-seven hundred thirty-one of the Education Law.
**Section 34-1.3 Referrals prohibited.** Except as provided in this Part or in Public Health Law Article 2 Title II-D, a practitioner authorized to order clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services may not make a referral for such services to a health care provider authorized to provide such services where such practitioner or immediate family member of such practitioner has a financial relationship with such health care provider. A referral shall not be construed to include an arrangement whereby a treating practitioner makes arrangements with another covering practitioner for the treatment and/or care of the treating practitioner’s patients for services routinely provided by the treating practitioner when the treating practitioner is unavailable to treat such patients.

(a) Effective December 8, 2002, physical therapy services shall be subject to all applicable provisions of this Subpart governing designated health services to the same extent that clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services are subject to this Subpart, including, but not limited to, provisions governing prohibited referrals, disclosure requirements, disclosure forms and financial relationships.

**Section 34-1.4 Disclosure: Clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services.**

(a) An ownership interest or investment interest shall not be subject to Public Health Law section 238-a(1)(a) or to section 34-1.3 of this Subpart if:

(1) the health care provider authorized to provide clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services is in a rural area, and the referring practitioner or the patient is in such rural area; or

(2) the clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services are provided by a general hospital, the referring practitioner is authorized to perform services at such general hospital, and the ownership or investment interest is in the general hospital itself and not merely in a subdivision thereof; or

(3) the clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services are provided by an ambulatory surgical center issued an operating certificate pursuant to Part 401 of this Title in conjunction with a surgical procedure performed by the referring practitioner at the ambulatory surgical center; and
(4) if each practitioner who is an interested investor in a health care provider within a category specified in paragraph (1), (2) or (3) of this subdivision discloses to the patient the practitioner’s, or family member’s, ownership interest or investment interest in the health care provider and the patient’s right to utilize a specifically identified alternative health care provider if any such alternative is reasonably available, in the disclosure form specified in section 34-1.6 of this Subpart. Such form shall also be posted prominently in the practitioner’s office.

(b) A practitioner shall maintain documentation of each instance of disclosure to a patient pursuant to this section.

Section 34-1.5 Disclosure: other health or health related items or services.

(a) With respect to referrals for health or health related items or services other than clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services, and except as provided in subdivision (c) of this section, a practitioner may not make a referral to a health care provider for the furnishing of health or health related items or services where such practitioner or immediate family member of such practitioner has any of the following financial relationships without disclosing to the patient such financial relationship:

(1) an ownership or investment interest with such health care provider; or

(2) a compensation arrangement with such health care provider which is in excess of fair market value, or which provides for compensation that varies directly or indirectly based on the volume or value of any referrals of business between the parties.

(b) The disclosure shall provide notice of any such financial relationship and shall also inform the patient of his or her right to utilize a specifically identified alternative health care provider if any such provider is reasonably available, and shall be in the form specified in section 34-1.6 of this Subpart. Such form shall also be posted prominently in the practitioner’s office.

(c) Disclosure pursuant to this section shall not be required for a referral for the furnishing of any health or health related items or services under circumstances for which a referral for clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services would not be prohibited pursuant to section 238-a of the Public Health Law, provided that any disclosure required by section 34-1.4 of this Subpart for clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services remains applicable to referrals for other health, or health related items or services under comparable circumstances.

(d) A practitioner shall maintain documentation of each instance of disclosure to a patient pursuant to this section.
Section 34-1.6 Disclosure form.

NOTICE TO PATIENTS
Because of concerns that there may be a conflict of interest when a physician refers a patient to a health care facility in which the physician has a financial interest, New York State passed a law. The law prohibits me, with certain exceptions, from referring you for clinical laboratory services, pharmacy services, radiation therapy services, or x-ray or imaging services to a facility in which I or any of my immediate family members have a financial interest. If certain of the exceptions in the law apply, or if I am referring you for other than clinical laboratory, pharmacy, radiation therapy, or x-ray or imaging services, I can make the referral under one condition. The condition is that I disclose this financial interest and tell you about alternative providers where you may go to obtain these services. This disclosure is intended to help you make a fully informed decision about your health care. I or my immediate family members have a financial relationship with the following providers:

________________________________________________________
________________________________________________________
________________________________________________________

For more information about alternative providers, please ask me or my staff. We will provide you with names and addresses of [places] providers best suited to your individual needs that are nearest to your home or place of work.

Name of Physician

Section 34-1.7 Exceptions from compensation arrangement prohibitions. The following shall not be considered to be compensation arrangements subject to Public Health Law section 238-a(1)(a) or to section 34-1.3 of this Subpart:

(a) Rental of equipment: Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment, if:

(1) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease;

(2) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee;

(3) the lease provides for a term of rental or lease of at least one year;

(4) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and

(5) the lease would be commercially reasonable even if no referrals were made between the parties.
(b) Bona fide employment relationships: Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services, if:

(1) the employment is for identifiable services;

(2) the amount of the remuneration under the employment

(i) is consistent with the fair market value of the services; and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and

(3) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer. Subparagraph (2)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(c) Personal service arrangements: Remuneration from an entity under an arrangement if

(1) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;

(2) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity;

(3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

(4) the term of the arrangement is for at least one year;

(5) the compensation to be paid over the term for the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

(6) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any state or federal law.

(d) Payments by a physician for items and services: Payment made by a physician

(1) to a laboratory in exchange for the provision of clinical laboratory services, or
(2) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

(e) Remuneration consisting of any of the following:

(1) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors;

(2) the provision of items, devices, or supplies that do not have any generally accepted use in health care practices other than to, and are actually used solely to

   (i) collect, transport, process, or store specimens for the entity providing the item, device or supply, or

   (ii) order or communicate the results of tests or procedures for such entity;

(3) a payment made by an insurer or a self-insured plan to a practitioner to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that practitioner to an individual who is covered by a policy with the insurer or by the self-insured plan, if

   (i) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the practitioner,

   (ii) the payment is made to the practitioner on behalf of the covered individual and would otherwise be made directly to such individual, and

   (iii) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

(f) Payments for services furnished in an ambulatory surgical center or a chronic renal dialysis center facility issued an operating certificate pursuant to Article 28 of the Public Health Law, if payment for those services is included in a rate that is substantially similar or equivalent to the ambulatory surgical center (ASC) rate reimbursable by the Medicare Program pursuant to 42 CFR Part 416 Subpart E, or a rate substantially similar to the End Stage Renal Disease composite rate reimbursable by the Medicare Program pursuant to 42 CFR Part 413 Subpart H, respectively.

(g) Payments for services provided by a hospice licensed pursuant to Article 40 of the Public Health Law, if payment for those services is included in a rate that is substantially similar or equivalent to the per-diem hospice charge reimbursable by the Medicare program set forth in 42 CFR Part 418 Subpart G.