

Subpart 34-2 of 10 NYCRR
Laboratory Business Practices

Statutory Authority: Public Health Law, sections 586(3) and 587(6)

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Section 34-2.1 Title. This Subpart shall be known and cited as "Laboratory Business Practices".

Section 34-2.2 Definitions. Whenever used in this Subpart, the following terms shall have the following meanings:

(a) Agent means an individual who agrees, pursuant to a written agreement with another, the principal, to act on behalf of, instead of, and subject to the authority and control of, the principal with regard to acts described in the agreement and to perform such acts with individual good faith, loyalty and fidelity to the principal.

(b) Clinical laboratory means a facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention or treatment of disease, or the assessment of a health condition, or for identification purposes. Such examinations shall include procedures to determine, measure, or otherwise describe the presence or absence of various substances, components or organisms in the human body. Clinical laboratory does not mean any facility or activity specifically excluded by section 579 of the Public Health Law.

(c) Clinical laboratory services means examinations, tests and/or analyses performed by a clinical laboratory.

(d) Consideration means anything of value or benefit, in cash or in kind.

(e) Contract for laboratory management services means a legally enforceable written agreement between a clinical laboratory under department permit and a hospital or a health maintenance organization, whereby the contracting clinical laboratory:

(1) agrees to provide laboratory management services at fair market value at a facility of a contracting hospital; or

(2) agrees to provide laboratory management services at fair market value at a facility of a contracting health maintenance organization; or

(3) agrees to provide clinical laboratory services at the laboratory's facility, and directly related services, all at fair market value, pursuant to a referral by the contracting hospital or health maintenance organization.

(f) Department means the New York State Department of Health.

(g) Directly related equipment and supplies means equipment and supplies provided by a clinical laboratory to a referring health services purveyor of a size, type and quantity reasonably related to the type and number of specimens being referred by the health services purveyor to the clinical laboratory, and which are used by the referring health services purveyor solely and exclusively for the collection, processing, storage, preservation, transport, or disposal of specimens, and which have no generally accepted use in health care practices other than solely for the collection, processing, storage, preservation, transport, or disposal of specimens.

(h) Directly related services means the following services, which are or can be performed by a clinical laboratory and are integral to the clinical laboratory services performed on referred specimens:

(1) the collection, processing, storage, preservation, transport, acceptance, or disposal of referred specimens;

(2) the reporting of test results to the referring health services purveyor; or

(3) the receipt, storage and transmittal of information between the clinical laboratory and the health services purveyor necessary for test ordering, requisitioning, reporting or billing.

(i) Fair market value means that value, calculated in monetary terms and not by bartering, in arms length transactions, consistent with general market value. The fair market value of clinical laboratory services is deemed to include the value of directly related equipment and supplies, and directly related services. With respect to rentals or leases of property and space, fair market value shall be:

(1) consistent with the value of rental property for general commercial purposes, not taking into account the property's intended use; and

(2) 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.

(j) Financial relationship means an ownership interest, investment interest or compensation arrangement, as those terms are defined or used in Public Health Law sections 238 and 238-a.

(k) Functions directly related to clinical laboratory operations means functions which are necessary and integral to, and have as their sole and exclusive purpose, the operation of a clinical laboratory, and may include clinical laboratory services and directly related services.

(l) Governmental agency means a department, board, bureau, division, office, agency, public benefit or other corporation, or any other unit, however described, of a state or of a political subdivision of a state, or the federal government.

(m) Health maintenance organization (HMO) means an organization operating in accordance with article 43 of the Insurance Law or article 44 of the Public Health Law, and includes an agent of the health maintenance organization.

(n) Health or health related services includes, but is not limited to, items and services available under the New York State Medical Assistance Program (Medicaid).

(o) Health services purveyor (HSP) means any person, firm, partnership, group, association, business corporation, not-for-profit corporation, professional corporation, limited liability company, or any agent, employee, fiduciary, employer or representative thereof, including, but not limited to, an entity that provides health related services, a physician, dentist, podiatrist, chiropractor, either in individual practice, group practice or employed in a facility owned by any person, group, association, firm, partnership, business corporation, not-for-profit corporation, professional corporation, limited liability company, hiring any one of the aforementioned practitioners who provides health or health related services.

(p) Hospital means a facility or institution defined in Public Health Law section 2801(1).

(q) Immediate family member means any of the following, whether natural or adoptive: spouse; parent; child and sibling; stepparent, stepchild and stepsibling; father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law and daughter-in-law; or grandparent and grandchild.

(r) Industrial firm means any employer, including, but not limited to:

(1) an agent of an employer; or

(2) an employer or employers who establish(es) or maintain(s) a single-employer or multi-employer employee benefit plan under the Employee Retirement Income Security Act of 1974 as amended (ERISA); or

(3) or an agent of an employee benefit plan.

(s) Insurance carrier includes, but is not limited to:

(1) an insurance carrier used by an employer; or

(2) the agent of an insurance carrier.

(t) Laboratory management services means some or all services necessary for the operation of a clinical laboratory, including but not limited to:

(1) directly related services; or

(2) services performed by a clinical laboratory employee, provided the services are directly related to clinical laboratory operations, and, provided that phlebotomy services, if rendered, are accompanied by actual clinical laboratory services by the laboratory providing the employee.

(u) Legal relative means an individual with legal authority to act on behalf of the recipient of services.

(v) Patient service center (PSC) is synonymous with collecting station or collecting depot, and means a facility, fixed or mobile, operated by a clinical laboratory for the collection, drawing and temporary storage of materials derived from the human body until such material is forwarded to a clinical laboratory for clinical laboratory services.

(w) Purveyor, as used in section 586 of the Public Health Law, means a clinical laboratory that does not receive from any health care practitioner or private medical practice having an ownership interest in the clinical laboratory any referrals for clinical laboratory services for patients of such health care practitioner or private medical practice. Notwithstanding any provision to the contrary, the term purveyor shall include any clinical laboratory owned by a hospital licensed pursuant to Article 28 of the Public Health Law or any clinical laboratory that is owned and operated by a publicly traded corporation.

(x) Residence means the location at which a test subject resides, whether on a temporary or permanent basis, and whether or not the living arrangement is voluntary, and is not necessarily the subject's legal residence.

(y) Trade union health facility means:

- (1) a facility owned and operated by trade union to provide health or health related services to its members or their families; or
- (2) an agent of a trade union health facility.

Section 34-2.3 Prohibited business practices by health services purveyors – general.

(a) No health services purveyor shall solicit, receive, accept, or agree to receive or accept any payment or other consideration from a clinical laboratory, or its agent, employee or fiduciary for the referral of specimens for the performance of clinical laboratory services.

(b) No health services purveyor shall participate in the division, transference, assignment, rebate, or splitting of fees with any clinical laboratory, or its agent, employee or fiduciary, or with any other health services purveyor, in relation to clinical laboratory services.

Section 34-2.4 Prohibited business practices by clinical laboratories.

(a) No clinical laboratory, its agent, employee or fiduciary shall make, offer, give, or agree to make, offer or give, any payment or other consideration to a health services purveyor for the referral of specimens for the performance of clinical laboratory services.

(b) No clinical laboratory, its agent, employee or fiduciary, shall participate in the division, transference, assignment, rebate, or splitting of fees with any health services purveyor, or with another clinical laboratory, in relation to clinical laboratory services.

Section 34-2.5 Equipment, supplies and services.

(a) The provision at less than fair market value of equipment and supplies by a clinical laboratory to a health services purveyor is prohibited, except that a clinical laboratory may offer to provide, and a referring health services purveyor may accept, directly related equipment and supplies.

(b) A clinical laboratory may offer to perform, and a referring health services purveyor may accept, directly related services, unless prohibited by this Subpart.

(c) Any equipment and supplies provided to a health services purveyor by a clinical laboratory, which is used in a manner prohibited by this Subpart and which is in the possession of the health services purveyor at the time this Subpart becomes effective, shall be returned to the clinical laboratory by the health services purveyor or reclaimed by the clinical laboratory within sixty (60) days of the effective date of this Subpart.

Section 34-2.6 Space. (a) The rental of space by a clinical laboratory from a referring health services purveyor, or an immediate family member of such purveyor, for more than fair market value, or under circumstances where the rental amount is affected by the volume or value of tests ordered by the health services purveyor shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(b) The rental of space by a clinical laboratory from a referring health services purveyor for storage of supplies provided by the laboratory to the health services purveyor shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(c) The location of a PSC by a clinical laboratory, within or sharing space in any part of the practice, administrative, office or waiting area of any health services purveyor that refers specimens to the clinical laboratory, shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(d) A PSC may be located in a building in which a health services purveyor that refers specimens to the clinical laboratory operating the PSC has a direct or indirect ownership, investment or leasehold interest, under the following circumstances:

(1) the PSC is the subject of a signed written lease, available to the department, which conforms to the requirements of Public Health Law section 238-a(5)(b)(i)(A) and implementing regulations; and

(2) the PSC is open to and actually serves the general public and operates independently from the health services purveyor, and meets all of the following criteria:

(i) the PSC actually collects a substantial number of specimens from patients of other health services purveyors which do not have a direct or indirect financial relationship with a referring health service purveyor who has an ownership, investment or leasehold interest in the building;

(ii) the PSC has its own entrance, exit, and waiting area, except that the PSC may use a waiting area that is generally shared by all tenants or occupants of the building or an entire floor of the building, provided there are two or more tenants renting separate office spaces who are not referring health services purveyors;

(iii) the PSC is identified on signs, consistent with signage of other tenants or occupants, on the outside of the building and within the building;

(iv) the PSC has its own telephone line, separate and distinct from that of any referring health services purveyor, and telephone listings for the clinical laboratory include the PSC's telephone number;

(v) advertisements and other public notices by the clinical laboratory list the address and telephone number of the PSC;

(vi) the hours the PSC is open are independent and not restricted to the hours of one or more referring health services purveyors in the building; and

(vii) the PSC patients of health services purveyors not located in the building have access to a restroom other than those of health services purveyors in the building.

(e) A clinical laboratory shall, within sixty (60) days from the effective date of this Subpart, bring any PSC which it operates at locations as described in subsection (d) of this section, into compliance with the requirements of paragraphs (d)(1) and (2) of this section, or shall cease operation of the PSC. However, a clinical laboratory may request in writing to the department an extension of time for complying with this Subpart with respect to a PSC. Such request shall be made within thirty (30) calendar days from the effective date of this Subpart, shall state the reason(s) that the PSC cannot be brought into compliance with the requirements of this Subpart, and shall document a plan of correction acceptable to the department. The department may extend the grace period granted pursuant to this subdivision for a period not to exceed one hundred eighty (180) days from the effective date of this Subpart.

Section 34-2.7 Employees. (a) Except as provided in subdivision (b) below, employees, agents or other fiduciaries of any clinical laboratory, when supplied by the clinical laboratory to a referring health services purveyor to perform functions and duties in the facility of the health services purveyor, shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(b) Nothing in Public Health Law section 587 or in this Subpart shall be construed as prohibiting a hospital or an HMO and a clinical laboratory from entering into a contract for laboratory management services, including provision of technical services and employees for the performance of functions directly related to clinical laboratory operations.

(c) Payment or reimbursement by a clinical laboratory to a health services purveyor for clinical laboratory services and/or directly related services, which had been rendered by the health services purveyor or such purveyor's employees, agents or fiduciaries, shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited. However, a clinical laboratory may enter into a written contract with a hospital, HMO or another clinical laboratory for the provision of phlebotomy services, clinical laboratory services, or directly related services to the contracting clinical laboratory, provided such services are rendered at fair market value and not in connection with individuals who are patients or clients of the hospital, HMO or other clinical laboratory.

(d) Nothing in this Subpart shall prohibit the employees, agents or fiduciaries of a clinical laboratory from visiting a residence for the purpose of drawing blood, or otherwise obtaining or collecting specimens, provided that:

(1) such visits shall not result in a substantially permanent presence and shall be established according to a schedule, available in the laboratory, or upon specific request of the health care provider or other authorized person responsible for care of the patient, and documented by the laboratory; and

(2) while at the residence, the employees, agents or fiduciaries of the laboratory do not provide any supplies, services or assistance, directly or indirectly, to the operators, nursing or medical staff or other individuals other than as stated in this Subpart; and

(3) during such visits, the activities of the employees, agents or fiduciaries of the laboratory are limited to:

(i) reviewing the orders for laboratory tests from the patient's health services purveyor, without reviewing the patient's chart;

(ii) scheduling the collection of specimens for future tests, without reviewing the patient's chart;

(iii) collecting specimens;

(iv) labeling the collected specimens;

(v) recording the number and kinds of specimens collected;

(vi) taking steps necessary to ensure that the test requisition forms are properly completed pursuant to orders from the patient's health care provider;

(vi) centrifuging blood specimens;

(vii) causing adequate and sanitary equipment and supplies to be maintained, when appropriate, at a residence, solely for the collection, preservation and transport of specimens; and

(viii) taking steps necessary to ensure the integrity of specimens which are stored, when appropriate, at a residence awaiting transport to the clinical laboratory; and

(4) no rent is paid by the clinical laboratory for the storage of equipment and supplies or specimens, or for any other purpose.

Section 34-2.8 Professional courtesy. The provision of clinical laboratory services by a clinical laboratory for health services purveyors, their families, or their employees, agents, or fiduciaries at a charge which is below the lower of the applicable Medicare fee schedule amount or the national limitation amount as defined by the Medicare program for such services is consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

Section 34-2.9 Computers. (a) The provision, at less than fair market value, of computers, including hardware, hard drives, or monitors; or of computer equipment or supplies such as stands, tables, printers, printer stands, interfacing telephone lines, or modems; or of software, by a clinical laboratory to a health services purveyor, is prohibited, except as stated below.

(b) Nothing in Public Health Law section 587 or in this Subpart shall be construed to prohibit a clinical laboratory from providing a computer, computer equipment, computer supplies and/or software, and/or developing and providing software, to a health services purveyor, under the following circumstances:

(1) the computer, computer equipment, computer supplies and/or software are solely and exclusively used for, and are solely and exclusively dedicated to, enabling the health services purveyor to:

(i) make referrals of specimens for the performance of clinical laboratory services to the clinical laboratory; or

(ii) receive, access, print and/or store test results from the clinical laboratory, including cumulative test results concerning a particular patient, and including test related information stored by the clinical laboratory; or

(iii) transmit data to the clinical laboratory necessary for preparation of laboratory requisition forms and/or billing invoices; or

(iv) transfer laboratory related data from the clinical laboratory to any computer system maintained by the health services purveyor; and

(2) the clinical laboratory takes reasonable steps to ensure that the computer, computer equipment, computer supplies and/or software are solely and exclusively used as set forth in this Subpart; and

(3) the clinical laboratory reasonably monitors the use of the computer, computer equipment, computer supplies and/or software; and

(4) ownership of the computer, computer equipment, computer supplies and/or software remains in the clinical laboratory; and

(5) the clinical laboratory is responsible for all repair and maintenance of the computer, computer equipment and/or software; and

(6) the clinical laboratory maintains reasonable documentation that the computer, computer equipment, computer supplies and/or software is being used solely and exclusively as set forth in this Subpart.

(c) Nothing in Public Health Law section 587 or in this Subpart shall be construed to prohibit a general hospital licensed pursuant to Article 28 of the Public Health Law from providing a computer, computer equipment, computer supplies and/or software to a health services purveyor to facilitate the delivery of clinical laboratory services and health services to inpatients and outpatients of the general hospital, including, but not limited to, records access, patient admission, outpatient or inpatient service scheduling, and clinical laboratory service authorization, provided that the health services purveyor is a staff member or has professional privileges at the general hospital.

(d) Any computer, computer equipment, computer supplies and/or software provided to a health services purveyor in a manner prohibited by this Subpart, and which is in the possession of the health services purveyor at the time this Subpart becomes effective, shall be:

(1) returned to the clinical laboratory by the health services purveyor or reclaimed by the clinical laboratory within sixty (60) days of the effective date of this Subpart; or

(2) brought into compliance with this Subpart within sixty (60) days of the effective date of this Subpart.

Section 34-2.10 Waste disposal. The disposal or payment for disposal by a clinical laboratory for a health services purveyor of hazardous waste, radioactive waste and/or regulated medical waste shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

Section 34-2.11 Recall letters and reporting of test results.

(a) A clinical laboratory shall not communicate to a patient of a referring health services purveyor that a clinical laboratory test, including, but not limited to a Pap smear, is or will be due to be performed, or that a visit to the health services purveyor for diagnosis or treatment is or will be due. A clinical laboratory shall not prepare such communication for the health services purveyor to send, or otherwise facilitate the preparation or sending of such communication by the health services purveyor. Such communication or its facilitation shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(b) A clinical laboratory shall not communicate to a patient of a referring health services purveyor the results of a clinical laboratory test, including, but not limited to, a Pap smear. A clinical laboratory shall not prepare such communication for the health services purveyor to send, or otherwise facilitate the preparation or sending of such communication by the health services purveyor. Such communication or its facilitation shall be deemed consideration given for referral of specimens for performance of

clinical laboratory services and is prohibited, except that:

(1) a clinical laboratory may communicate to in writing to the patient (by mail or electronically) an accurate and complete account of the result of the laboratory test along with information required to be included in a report of test results pursuant to Subpart 58-1 of Title 10 under the following circumstances:

(i) the referring health services purveyor authorized by law to order and use the results of laboratory tests has provided affirmative written authorization (on paper or electronically), which specifically names the patient;

(ii) the laboratory test results have already been, or are simultaneously being communicated to the referring health services purveyor authorized by law to order and use the results of laboratory tests;

(iii) the clinical laboratory advises the patient that the referring health services purveyor authorized by law to order and use the results of laboratory tests has received or is receiving the test results;

(iv) the clinical laboratory shall include, in the communication to the patient, a clear statement, presented in a prominent manner, to the effect that the communication should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health service purveyor;

(v) the clinical laboratory directs the patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor; and

(vi) the communication to the patient does not include any information which would be consideration given for referral of specimens, including, but not limited to, medical advice specifically directed at the patient concerning the patient's condition, including diagnosis or treatment of the patient's condition.

Section 34-2.12 Waiver of co-payments, co-insurance, deductibles and fees.

(a) Routine waiver by a clinical laboratory of co-payments, co-insurance, or deductibles for clinical laboratory services performed for recipients of such services who are patients of a referring health services purveyor shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(b) Waiver of fees for clinical laboratory services for the patients of a referring health services purveyor who are enrolled in an HMO by a clinical laboratory which is not a participating laboratory of the HMO, where such waiver results in consideration being received by the referring health services purveyor, shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

(c) Nothing in Public Health Law section 587 or in this Subpart shall be construed to prohibit a clinical laboratory from:

(1) waiving a co-payment, co-insurance, deductible, or fee for a particular patient based on the patient's inability to pay, in which case the clinical laboratory shall maintain a record documenting the patient's inability to pay; or

(2) waiving a co-payment, co-insurance, deductible or fee, if the cost of collection is greater than the amount to be collected.

(d) Nothing in Public Health Law section 587 or in this Subpart shall be construed to prohibit a clinical laboratory from offering a discount to a referring health services purveyor provided that:

(1) the health services purveyor appropriately reflects the discount on any costs or charges reported and/or claimed by the health services purveyor under any third party reimbursement program; and

(2) the discounted price is consistent with fair market value; or

(3) the discounted price reflects a volume discount, whereby the amount of the discount is reasonably related to costs saved by the clinical laboratory.

Section 34-2.13 Direct billing. (a) Nothing contained in Public Health Law section 586 or this Subpart shall be construed to prohibit a clinical laboratory from sending a bill to or receiving payment for clinical laboratory services from the health services purveyor who ordered the clinical laboratory services, provided that:

(1) the clinical laboratory receives the name and/or other information relating to the test subject if the clinical laboratory is obligated to report such name and/or other information to the state or a local health department under state law or regulation;

(2) the bill for the clinical laboratory services shall be directed to the test subject or a payor expressly permitted by Public Health Law section 586 or this Subpart;

(3) the amount of the bill for clinical laboratory services shall be disclosed to the test subject or a payor expressly permitted by Public Health Law section 586 or this Subpart, and documentation of the disclosure shall be maintained by the health services purveyor who ordered the clinical laboratory services;

(4) if payment is made for the clinical laboratory services to the health services purveyor who ordered the clinical laboratory services, the payment amount must be equal to the amount stated in the clinical laboratory bill; and

(5) one of the following situations must apply:

(i) the cost of the clinical laboratory service is included in the usual and customary purchase price of a test kit that is approved by the federal Food and Drug Administration to be commercialized as a test kit that includes a collection device, specimen transport materials, and the clinical laboratory service; or

(ii) the clinical laboratory services are performed in relation to: a termination of pregnancy; testing for a sexually transmissible disease; HIV-related testing; drug abuse screening; or other tests specifically approved by the department where law or regulation recognizes the need for a heightened level of confidential protection of health information relating to the test subject.

Section 34-2.14 Financial relationship. A financial relationship between any entity and a referring health services purveyor, or any immediate family member of a referring health services purveyor, which relationship was secured or facilitated either directly or indirectly by or through the efforts of a clinical laboratory, shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

Section 34-2.15 Loans. Any loan for the benefit of a referring health services purveyor or for the benefit of any immediate family member of such purveyor, which was secured or facilitated either directly or indirectly by or through the efforts of a clinical laboratory shall be deemed consideration given for referral of specimens for performance of clinical laboratory services, and is prohibited.

Section 34-2.16 Compliance. It is the responsibility of the clinical laboratory and the health services purveyor to establish, including by appropriate documentation, that any practice between the two entities complies with this Subpart. Upon request from the department, the health services purveyor and/or the clinical laboratory shall make such documentation available for inspection and copying. If requested by the clinical laboratory, such documentation shall be eligible for exemption from disclosure under the Freedom of Information Law (article 6 of the Public Officers Law), pursuant to the authority in section 89(5) of the Public Officers Law.

Section 34-2.17 Exclusions. Any payment or billing transaction authorized by the direct billing law (see Public Health Law section 586) shall not be rendered illegal by any provisions of Public Health Law section 587 or this Subpart.