

UNIVERSITY OF ROCHESTER
MEDICAL CENTER

Compliance Program Policy Manual

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Compliance Program Policy Manual

General Policy

It is the Policy of Strong Health and its affiliates, Strong Partners Health System, Inc., The University of Rochester Medical Center (Strong Memorial Hospital, School of Medicine and Dentistry, School of Nursing, Eastman Dental Center and URMFG), Highland Hospital of Rochester, The Highlands Living Center, The Highlands at Pittsford, Laurelwood at The Highlands, The Highland at Brighton, and Visiting Nurse Service (collectively, "Strong Health" or the "System") to provide services in compliance with all state and federal laws governing its operations, and consistent with the highest standards of business and professional ethics. This Manual is a statement of that policy and sets forth the code of conduct and ethical behavior expected from all employees and staff. In order to ensure that the Strong Health compliance policies are consistently applied, the System has established a legal and regulatory Compliance Program. The program is directed by a Compliance Committee, a Compliance Program Medical Director and a Compliance Officer, who are charged with reviewing our compliance policies and specific compliance situations that may arise.

All Strong Health employees, as well as those professionals who enjoy professional staff membership or deliver care to its patients, must carry out their duties in accordance with this policy. Any violation of applicable law, or deviation from appropriate ethical standards, will subject an employee or independent professional to disciplinary action, which may include oral or written warning, disciplinary probation, suspension, reduction in salary, demotion, dismissal from employment, tenure revocation proceedings or revocation of medical staff privileges. These disciplinary actions also may apply to a supervisor (or a staff member's department chief) who directs or approves the person's improper actions, or is aware of those actions but does not act appropriately to correct them; or who otherwise fails to exercise appropriate supervision or detect non-compliance with this policy.

This Manual includes statements of Strong Health policy in a number of specific areas. All employees and professional staff members must comply with these policies, which define the scope of employment and professional staff membership. Conduct that does not comply with these statements is not authorized by the Strong Health entities, is outside the scope of employment and professional staff membership, and may subject employees and professional staff members to disciplinary action. If an employee or professional is unsure whether any action complies with the Strong Health policies or applicable law, he or she should present that question to that employee's supervisor, or, if appropriate, directly to the Compliance Officer. All employees or professionals should review this Manual from time to time to make sure that these policies guide their actions.

If, at any time, any employee or professional staff member becomes aware of any apparent violation of these policies, he or she **must** report it to his or her supervisor (in the case of an employee), Department Chair, Department Compliance Liaison or to the Compliance Officer. **All** persons making such reports are assured that such reports will be treated as confidential except as required by law; such reports will be shared only on a bona fide need-to-know basis. No adverse action will be taken against persons making such reports in good faith, whether or not the report ultimately proves to be well-founded. If an employee or professional staff member does not report conduct violating Strong Health policies, of which (s)he is or should be aware, that employee or professional staff member may be subject to disciplinary action, up to and including termination of employment or revocation of tenure or privileges.

The laws discussed in this Policy Manual are complex and many of the concepts are developed in case-by-case determinations. In addition, this Manual deals only generally with some of the more important legal principles. Their mention is not intended to minimize the importance of other applicable laws, professional standards, or ethical principles, which may be covered in other institutional policies. Where appropriate, reference is made to specific policies that have been in place at the various Strong Health entities and which are an integral part of the Strong Health Compliance Program. Any person who is in doubt as to the propriety of a course of action or concerned about whether a stated policy applies, must promptly communicate with his or her supervisor, Chair, or compliance liaison, or with the Compliance Officer, before taking action.

Finally, all employees and professionals with privileges should recognize that this Code of Conduct may be amended from time-to-time, to reflect changes in applicable laws and policies. All are expected to familiarize themselves with such changes and to abide by them.

Confidentiality

Strong Health employees and health care professionals possess sensitive, privileged information about patients and their care. Patients properly expect that this information will be kept confidential. The System takes very seriously any violation of a patient's confidentiality. Discussing a patient's medical condition, or providing any information to other unauthorized persons, will have serious consequences for the disclosing party. Personnel should not discuss patients in public or with their families.

Each provider is the owner of the medical record which documents a patient's condition and the services received by the patient. Medical records are strictly confidential, which means that they may not be released to outside parties except with the written consent of the patient or in other limited circumstances. Special protections apply to mental health records, records of drug and alcohol abuse treatment, and HIV related information. Medical records must not be physically removed from the provider's office or facility, altered, or destroyed. Personnel who have access to medical records must take pains to preserve their confidentiality and integrity, and nobody is permitted access to the medical record of any

patient without a legitimate, work-related reason for so doing. Any unauthorized release of or access to medical records should be reported to a supervisor or the Compliance Officer.

New York State has enacted a series of computer crime laws that are designed to punish and deter computer crime. In compliance with the law, Strong Health prohibits unauthorized access to its computer system, either directly or by network or telephone. An individual who does not have a legitimate password is unauthorized to gain access. The System also prohibits the destruction or corruption of electronically stored or processed data. Persons who violate these rules will be prosecuted to the full extent of the law.

Discrimination

Strong Health and its affiliates are committed to a policy of nondiscrimination and equal opportunity for all qualified applicants and employees, without regard to race, color, sex, religion, age, national origin, disability, or sexual orientation. Our policy of non-discrimination extends to the care of patients (who also may not be discriminated against based on source of payment). Discrimination may also violate state and/or federal anti-discrimination laws and trigger substantial civil penalties.

If an employee feels he or she or any patient has been discriminated against or harassed on the basis of his or her race, color, sex, or other protected category, he or she should contact Human Resources at his or her organization so that an investigation may be initiated.

Conflicts of Interest

Strong Health personnel should avoid all potential conflicts of interest. Adherence to this policy ensures that personnel act with total objectivity in carrying out their duties for the institution for which they work.

To this end, Strong Health personnel may not be employed by, act as a consultant to, or have an independent business relationship with any of an entity's service providers, competitors, or third party payers. Nor may personnel invest in any payer, provider, supplier, or competitor (other than through mutual funds or through holdings of less than 0.5 percent of the outstanding shares of publicly traded securities) unless they first obtain written permission from their Department Chair or other senior supervisor.

Personnel should not have other outside employment or business interests that place them in the position of (i) appearing to represent the system or one of its entities, (ii) providing goods or services substantially similar to those Strong Health provides or is considering making available, or (iii) lessening their efficiency, productivity, or dedication to their organization in performing their everyday duties.

Personnel may not use assets owned or leased by a Strong Health entity for personal benefit or personal business purposes. Employees may not have an interest in or speculate in products or real estate the value of which may be affected by the business of a Strong health entity. Employees may not divulge or use confidential information – such as financial data, payer information, computer programs, and patient information – for their own personal or business purposes.

Any personal or business activities by an employee that may raise concerns along these lines must be reviewed with, and approved in advance, by a Department Chair or supervisor.

In order for the Strong Health entities to comply with requirements of the Medicare program, every employee must notify a human resources supervisor and the Compliance Officer if he or she was at any time during the year preceding his or her employment with a Strong Health entity employed by the Medicare intermediary or carrier. An employee's failure to make this disclosure at the time of employment could cause the organization to lose its right to participate in Medicare.

Because the Medical Center participates in state programs such as Medicaid, employees must inform a human resources supervisor and the Compliance Officer if they have previously been employed by the State of New York.

Record Keeping and Retention

The Strong Health facilities are obligated under both state and federal law to maintain and retain numerous different types of records concerning nearly every aspect of their operation. Particularly important is the proper maintenance of hospital records concerning patient treatment. Proper record keeping is necessary not only to comply with state and federal law but also to ensure proper medical treatment for patients in the future. Patient records may also be important in the event there is litigation.

a) New York State Law

In order for a hospital to maintain and renew its hospital license under state law, it must comply with the following applicable record keeping requirements.

State law requires the hospital to maintain records of the diagnosis and treatment of patients, including medical history records and nursing notes, for 6 years after the discharge (or 3 years after a minor patient's 18th birthday, whichever is longer), or 6 years after death.

The Department of Health also requires the hospital to maintain various other records including: hospital surveys; contracts relating to the ownership of land, buildings and equipment; operating procedure manuals; patient complaints; and others enumerated in Department of Health Regulations.

Any questions about the hospital's duty to maintain specific records should be referred to the Compliance Officer or legal counsel.

b) Federal Law

Federal law also imposes strict record keeping requirements. Failure to comply with these laws and regulations may result in monetary penalties or suspension from participation in federal programs.

The Federal Controlled Substances Act requires certain personnel to prepare biennial inventories of all stocks of drugs and narcotics and maintain continuing current records of the amounts of drugs received and dispensed. 21 U.S.C. §§ 827 (a)(1), (a)(3). Federal regulations also require certain personnel to maintain records and inventories of each substance it dispenses. The retention period for these records is a minimum of two years. [21 CFR 1304.03, 1304.04.]

As a condition of continued participation in Medicare and Medicaid, federal law requires providers to maintain a variety of records, ranging from financial to medical. The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare and/or Medicaid programs. Providers must maintain such records as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due, including, but not limited to: hospital ownership, organization, and operation; fiscal, medical, and other record keeping systems; federal income tax status, asset acquisition, lease, sale or other action; franchise or management arrangements; patient cost service charge schedules; cost of operation; amounts of income received by source and purpose; and flow of funds and working capital. The required physician certification and re-certification statements must also be maintained.

A hospital must maintain medical records for every patient for a minimum of five years. The individual records must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications. All records must document the following, as appropriate: evidence of a physical examination; admitting diagnosis; results of all consultative evaluations; documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia; properly executed informed consent forms; all doctors' orders, nursing notes, and reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition; discharge summary with provisions for follow-up care; and final diagnosis with completion of medical records within 30 days following discharge. In addition, the hospital must maintain radiologic services records, surgical services records, anesthesia services records, and nuclear medicine records.

c) Confidentiality

The Medical Center is committed to properly maintaining the required records as well as preserving their confidentiality in accordance with applicable law and the Medical Center's policies. Please consult the Confidentiality section of this Manual for further details.

The Compliance Officer has established a records retention schedule that is available for review. If you have any questions, please contact the Compliance Officer.

Response to Investigations

State and federal agencies have broad legal authority to investigate health care providers and review their records. The Strong Health entities will comply with subpoenas and cooperate with governmental investigations to the full extent required by law. The Compliance Officer is responsible for coordinating the response to investigations and the release of any information.

If a department, an employee, or a professional staff member receives an investigative demand, subpoena, or search warrant involving the institution, it should be brought immediately to the Compliance Officer. Do not release or copy any documents without authorization from the Compliance Officer or legal counsel. If an investigator, agent, or government auditor comes to the institution, contact the Compliance Officer immediately. In the Compliance Officer's absence, contact the organization's CEO or a Vice President. Ask the investigator to wait until the Compliance Officer or his designee arrives before reviewing any documents or conducting any interviews. The Compliance Officer or his designee is responsible for assisting with any interviews, and the institution will provide counsel to employees, where appropriate. If personnel are approached by government investigators and agents, they have the right to insist on being interviewed only at the facility during business hours or with counsel present.

If a professional staff member receives an investigative demand at his or her private office and the investigation may involve one of the Strong Health entities, the staff member is asked to notify the Compliance Officer immediately.

Employees of the Strong Health entities are not permitted to alter, remove, or destroy documents or records of their employer. This includes paper, tape, and computer records.

Subject to coordination by the Compliance Officer, the System entities and their employees will disclose information required by government officials, supply payment information, provide information on subcontractors, and grant authorized federal and state authorities with immediate access to the facility and its personnel. Failure to comply with these requirements could mean that the organization will be excluded from participating in the Medicare and Medicaid programs.

Subcontractors who provide items or services in connection with the Medicare and/or Medicaid programs are required to comply with these policies on responding to investigations.

Subcontractors must immediately furnish the Compliance Officer, legal counsel, or authorized government officials with information required in an investigation.

Payments, Discounts, and Gifts

All of the Strong Health entities and most of their professional staff participate in the Medicare program, a federal program which provides health insurance to the aged and disabled, and the Medicaid program, a federal/state program which provides health care coverage to low income persons. Federal law makes it illegal for any person or entity to provide or accept "remuneration" (i.e. cash or anything else of value) in exchange for referrals of patients covered by Medicare, Medicaid or other Federal Health Care Programs (such as CHAMPUS, the Federal Employees Health Benefit Plan and the Railroad Retirement Board). The law also bars the payment or receipt of such remuneration in return for directly purchasing, leasing, ordering, or recommending the purchase, lease, or ordering of any goods, facilities, services, or items covered under the benefits of Medicare or Medicaid.

These so-called "fraud and abuse" or "anti-kickback" laws are designed to prevent fraud in health care programs and abuse of the public funds supporting the programs. Strong Health is committed to carefully observing the anti-kickback rules and avoiding any practice that may be interpreted as abusive. Employees in the finance departments, procurement services or purchasing, and facilities departments, laboratory, pharmacy, home health, medical staff administration, and any department entering into personal service contracts are expected to be vigilant in identifying potential anti-kickback violations and to bring them to the attention of their supervisor or the Compliance Officer.

(a) Anti-Kickback Laws

The federal anti-kickback laws are broadly written to prohibit Strong Health personnel and representatives from knowingly and willfully offering, paying, asking for, or receiving any money or other benefit, directly or indirectly from third parties in connection with items or services billed to federal programs. The anti-kickback laws must be considered whenever something of value is given or received by a Strong Health entity or its representatives or affiliates, that is in any way connected to patient services. This is particularly true when the arrangement could result in over-utilization of services or a reduction in patient choice. Even if only one purpose of a payment scheme is to influence referrals, the payment may be unlawful.

There are many transactions that may violate the anti-kickback rules. For example, no one acting on behalf of a Strong Health entity may offer gifts, loans, rebates, services, or payment of any kind to a physician who refers patients to that entity, or to a patient, without consulting his or her supervisor, legal counsel or the Compliance Officer. Such persons should review any discounts offered by suppliers and vendors, as well as discounts offered to third party payers. Patient deductibles and copayments must generally be collected and may not be waived without the prior authorization of the Department Chair or other senior supervisors. Rentals of space and equipment must be at fair market value, without regard to the volume or value of referrals

that may be received in connection with the space or equipment. Fair market value should be determined through an independent appraisal.

Agreements for professional services, management services, and consulting services must be in writing, have at least a one-year term, and specify the compensation in advance. Payment based on a percentage of revenue should be avoided in many circumstances. Any questions about these arrangements should be directed to legal counsel or the Compliance Officer. Joint ventures with physicians or other health care providers, or investment in other health care entities, must be reviewed by legal counsel.

The U.S. Department of Health and Human Services has described a number of payment practices that will not be subjected to criminal prosecution under the anti-kickback laws. These so-called “safe harbors” are intended to help providers protect against abusive payment practices while permitting legitimate ones. If an arrangement fits within a safe harbor it will not create a risk of criminal penalties and exclusion from the Medicare and Medicaid programs. However, the failure to satisfy every element of a safe harbor does not in itself make an arrangement illegal. Analysis of a payment practice under the anti-kickback laws and the safe harbors is complex, and depends upon the specific facts and circumstances of each case. Employees within the System should not make their own judgments on the availability of a safe harbor for a payment practice, investment, discount, or other arrangement. These situations must be reviewed with legal counsel.

Violation of the anti-kickback laws is a felony, punishable by a \$25,000 fine or imprisonment for up to five years, or both. Violation of the law could also mean that an entity (e.g. a facility) and/or a physician is excluded from participating in the Medicare and Medicaid programs for up to five years.

(b) Entertainment and Gifts

It is recognized that business dealings may include a shared meal or other similar social occasion, which may be proper business expenses and activities. More extensive entertainment provided by vendors or service providers, however, only rarely will be consistent with Strong Health policy and should be reviewed and approved in advance by the Department Chair or other senior supervisor. System employees may not receive any gift under circumstances that could be construed as an improper attempt to influence the provider’s decisions or actions. When an employee receives a gift that violates this policy, the gift should be returned to the donor and reported to the Compliance Officer. Gifts may be received when they are of such limited value that they could not reasonably be perceived by anyone as an attempt to affect the judgment of the recipient. For example, token promotional gratuities from suppliers, such as advertising novelties marked with the donor’s name (e.g. coffee mug) are not prohibited under this policy.

Whenever an employee or a professional is not sure whether a gift is prohibited by this policy, the gift must be reported to the Compliance officer upon its receipt.

Billing and Claims

When claiming payment for services, all providers in the System have an obligation to their patients, third party payers, and the state and federal governments to exercise diligence, care, and integrity. The right to bill the Medicare and Medicaid programs, conferred through the award of a provider or supplier number, carries a responsibility that may not be abused. Strong Health is committed to maintaining the accuracy of every claim. Many people, throughout the System have responsibility for entering charges, diagnoses and procedure codes. Each of these individuals is expected to monitor compliance with applicable billing rules and established coding guidelines. Any false, inaccurate, or questionable claims should be reported immediately to a supervisor or to the Compliance Officer.

False billing is a serious offense. Medicare and Medicaid rules prohibit knowingly and willfully making or causing to be made any false statement or representation of a material fact in an application for benefits or payment. Furthermore, federal law states that it is also unlawful to conceal or fail to disclose the occurrence of an event affecting a health care provider's right to payment with the intent to secure payment that is not due. Examples of false claims include, but are not limited to:

- Claiming reimbursement for services that have not been rendered
- Filing duplicate claims
- "Upcoding" to more complex procedures
- Including inappropriate or inaccurate costs on cost reports
- Falsely indicating that a particular health care professional attended a procedure
- Billing for a length of stay beyond what is medically necessary
- Billing for services for items that are not medically necessary
- Failing to provide medically necessary services or items
- Billing excessive charges.

Those who prepare or submit claims should be alerted for these and other errors. It is important to remember that outside consultants only advise the provider. The final decision on billing questions rests with the provider.

In compliance with federal law, the Strong Health entities do not permit charging for any Medicaid service at a rate higher than that approved by the state or accepting any payment as a precondition of admitting a Medicaid patient.

The Strong Health entities carefully follow the Medicare rules on assignment and reassignment of billing rights. If there is any question whether an entity or facility may bill for a particular service, either on behalf of a physician or on its own behalf, the question should be directed to a senior billing or finance supervisor, who may consult with the Compliance Officer. Special care should be taken in reviewing claims prepared by entities outside the System, and personnel should request documentation from outside entities if necessary to verify the accuracy of the claims.

A health care provider or supplier who violates the false claims rules is guilty of a felony, and may be subject to fines of up to \$25,000 per offense, imprisonment for up to ten years, or both. Legislation enacted in 1996 extends the reach of federal criminal penalties to false claims submitted not only to Medicare and Medicaid, but to any health care benefit program, including private third party payers. Other persons guilty of false claims may face fines of up to \$10,000 per offense, imprisonment for up to one year, or both. In addition to the criminal penalties, the Federal False Claims Act permits substantial civil monetary penalties against any person who submits false claims. The Act provides a penalty of triple damages as well as fines up to \$10,000 for each false claim submitted. The person (as well as the facility employer) may be excluded from participating in the Medicare and Medicaid programs. Violations of the assignment and reassignment rules are misdemeanors carrying fines of up to \$2,000 and imprisonment of up to six months, or both. State statutes impose similar criminal and civil penalties for false and deceitful conduct in connection with billing.

Numerous other federal and state laws prohibit false statements or inadequate disclosure to the government and mandate exclusion from the Medicare and Medicaid programs upon conviction. For instance, it is impermissible to make, or induce others to make, false statements in connection with a provider's Medicare certification. Persons doing so are guilty of a felony and may be subject to fines of up to \$25,000 and imprisonment for up to five years. A facility or individual health care providers will be excluded from the Medicare and Medicaid programs for at least five years if convicted of a Medicare- or Medicaid-related crime relating to patient abuse. Medicare and Medicaid exclusion may result if a facility or a provider is convicted of fraud, theft, embezzlement, or other financial misconduct in connection with any government-financed program.

It is illegal to make any false statement to the federal government, including statements on Medicare or Medicaid claim forms. It is illegal to use the U.S. mail in a scheme to defraud the government. Any agreement between two or more people to submit false claims may be prosecuted as a conspiracy to defraud the government.

Strong Health promotes full compliance with each of the relevant laws by maintaining a strict policy of ethics, integrity, and accuracy in all its financial dealings. Each employee and professional who is involved in submitting charges, preparing claims, billing, and documenting services is expected to maintain the highest standards of personal, professional, and institutional responsibility.

Patient Referrals

Patient referrals are important to the delivery of appropriate health care services. Patients are admitted, or referred, to hospitals by their physicians. Patients leaving a hospital may be referred to other facilities, such as skilled nursing or rehabilitation facilities. Patients may also need durable medical equipment, home care, pharmaceuticals, or oxygen, and may be referred to qualified suppliers of these items and services. Strong Health policy is that patients, or their legal representatives, are free to select their health care providers and suppliers subject to the

requirements of their health insurance plans. The choice of a hospital, a physician, a diagnostic facility, a supplier or any other healthcare provider should be made by the patient, with guidance from his or her physician as to which providers are qualified and medically appropriate.

Physicians and other health care providers may have financial relationships with the Strong Health affiliates. These relationships may include compensation for administrative or management services, income guarantees, loans of certain types, or free or subsidized administrative services. In some cases, a physician may have invested as a part owner in a piece of diagnostic equipment or a health care facility.

A federal law known as the “Stark law” applies to any physician who has, or whose immediate family member has, a “financial relationship” with an entity, and prohibits referrals by that physician to the entity for the provision of certain designated health services that are reimbursed by Medicare and Medicaid. If a financial relationship exists, referrals are prohibited unless one of the specific exceptions defined by the law is met. The System entities require that each financial relationship with a referring physician or his or her family member fit within one of the exceptions to the Stark law. All employees are expected to monitor financial relationships and report any irregularities to the Department Chair or other senior supervisors who shall report to the Compliance Officer.

The Stark law applies to the following types of services:

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology (including MRI, CT, ultrasound, and certain types of mammography)
- Durable medical equipment, parenteral and enteral nutrients
- Equipment and supplies
- Prosthetics and orthotics
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient services
- Radiation therapy services and supplies

The exceptions under the Stark law are complex, and several general rules must be followed. Both leases for physician office space and personal services contracts with physicians must be in writing, and signed by the parties. Any premises leases must be specified and must not exceed the space reasonably needed for the physician’s legitimate purposes. Rental charges must be set in advance, at fair market value, without regard to the volume or value of referrals by the physician. A lease must be commercially reasonable even if no referrals were made between parties. Similarly, a personal service contract must specify the services to be provided by the physician, which must be reasonable and necessary for legitimate purposes, and must be for at least one year. Compensation paid to physicians must also be set in advance at fair market value, be unrelated to the volume or value of referrals, and be commercially reasonable. Contract services may not involve the counseling or promotion of an illegal business arrangement.

Physician incentive plans, which may include volume-based compensation, will be acceptable if certain requirements are met.

Physicians purchasing clinical laboratory services or other items or services from a facility must pay fair market value. An arrangement whereby a facility bills for a group practice may be acceptable if it was in place prior to December 19, 1989 and meets certain other requirements. A pathologist, radiologist, or radiation oncologist may provide laboratory, pathology, diagnostic radiology, or radiation oncology services on his own order or on a consultation request from another physician.

Penalties for violating the Stark law include (1) no Medicare or Medicaid payment for the service referred illegally; (ii) a refund to the beneficiary of any amounts collected; (iii) fines of up to \$15,000 levied on both the physicians and the entity of each service referred illegally, plus additional fines based on the amounts billed; (iv) civil monetary penalties of up to \$100,000 plus other assessments; and (v) exclusions from the Medicare or Medicaid programs.

Physician Recruitment

The recruitment and retention of physicians requires special care to comply with applicable law. Physician recruitment has implications under the anti-kickback laws, the Stark law, and the IRS rules governing an entity's tax-exempt status. Each recruitment package or commitment should be in writing, consistent with guidelines established by the tax-exempt entity. New or unique recruitment arrangements should be reviewed by the Department Chair or other senior supervisor with the Compliance Officer. In general, support provided to a new physician is most likely to be acceptable if it is provided in order to persuade the physician to relocate to the recruiter's geographic service area in order to become a member of the professional staff, or if it is provided to a new physician completing his or her training. Support should be of limited duration. The physician cannot be required to refer patients to the recruiting entity, and the amount of compensation or support cannot be related to the volume or value of referrals. Income guarantees present special issues and should be reviewed by the Compliance Officer and counsel on a case by case basis.

Group Practice Acquisition

To improve the delivery of health care services, the Strong Health entities may, from time to time, acquire physician practices. These acquisitions require special care to comply with applicable law because they have implications under the anti-kickback laws, the Stark law, and the IRS rules governing organizations' tax-exempt status.

(a) Anti-Kickback Laws

As discussed above, federal law makes it illegal to provide or accept “remuneration” in exchange for referrals of patients covered by Medicare or Medicaid. Acquisitions of physician practices may implicate the anti-kickback laws because they may constitute illegal payments to induce the referral of Medicare or Medicaid patients.

Generally, acquisitions will comply with federal law when the amounts paid reflect the fair market value of the acquired practice. Fair market value should be determined through an independent appraisal. Payments in excess of fair market value may violate the anti-kickback laws, particularly when there is an ongoing relationship between the Medical Center and the acquired practice. Several specific types of payment are subject to scrutiny:

- Payment of goodwill
- Payment for value of ongoing business unit
- Payment for covenants not to compete
- Payment for exclusive dealing agreements
- Payment for patient lists
- Payment for patient records

The “safe harbor” protections discussed above may also apply to a particular acquisition. Employees should not, however, make unilateral judgments on the availability of a safe harbor. Any questions should be directed to legal counsel, and any proposed acquisition of a physician practice must be reported to the Compliance Officer.

Violation of the anti-kickback laws is a felony, punishable by a \$25,000 fine or imprisonment for up to five years, or both. Violation of the law could also mean that a System entity and/or physicians are excluded from participating in the Medicare and Medicaid programs for up to five years.

(b) Stark Law

Physician practice acquisitions also implicate the Stark law discussed earlier. Because the law is particularly complex, all transactions must be reviewed by the Compliance Officer and legal counsel to ensure compliance.

(c) IRS Scrutiny

The IRS retains authority to audit the activities of tax-exempt organizations. In particular, the IRS may revoke an organization’s tax-exempt status if payments for the acquisition of group practices are deemed “excessive.” The IRS can also impose monetary penalties, known as “intermediate sanctions,” for such conduct. While current, independent appraisals are important, equally important are the rationale and support for the reasonableness of the assumptions on which the valuation is based. Any questions should be directed to the Compliance Officer for review with legal counsel.

Patient Transfers

Operation of emergency departments is an integral part of the hospitals' service to the community under their charitable mission. The emergency department is known as a place where any sick or injured person may come for care regardless of his or her ability to pay. The federal government has enacted an "anti-dumping" law to ensure that patients are not transferred from a hospital emergency room to another facility unless it is medically appropriate.

Prompt and effective delivery of emergency care may not be delayed in order to determine a patient's insurance or financial status. Each patient who presents at the emergency department must receive an appropriate medical screening examination. Patients with emergency medical conditions, and patients in active labor, must be cared for in the hospital's emergency department until their condition has stabilized. An emergency may include psychiatric disturbances, symptoms of substance abuse, or contractions experienced by pregnant women.

If necessary, the stabilized patient may be transferred to another hospital that is qualified to care for the patient, has space available, and has agreed to accept the transfer. Before transfer, hospital staff shall provide the medical treatment which minimizes the risks to the patient's health and, in the case of a woman in labor, the health of the unborn child. A physician must sign a certification that the medical benefits reasonably expected from treatment at another medical facility outweigh the increased risks to the patient (and, if appropriate, the unborn child). No physician will be penalized for refusing to authorize the transfer of an individual with an emergency condition that has not been stabilized. The transfer must be performed by qualified personnel and transportation equipment, including life support measures during transfer if medically appropriate. A copy of the patient's record, including complete records of the emergency department encounter and any other records that are available, must be sent to the receiving hospital.

The "anti-dumping" law carries reporting obligations. If an employee or professional staff member believes that an emergency patient has been transferred to the hospital improperly, the suspected violation must be reported to his or her supervisor or the Chair of Emergency Medicine, and to proper authorities, within 72 hours of its occurrence. No employee will be penalized for reporting a suspected violation of the patient transfer law. The name and address of any on-call physician who refuses or fails to appear within a reasonable time to provide necessary stabilizing treatment of an emergency medical condition or active labor is to be reported immediately to the physician's Chair or the chair of Emergency Medicine.

In addition to medical records, the emergency department will maintain an on-call duty roster and a log documenting each individual who comes to the emergency department seeking assistance. The log must document whether the patient refused treatment or was refused treatment, transferred, was admitted and treated, stabilized and transferred, or discharged. When a patient or a patient's legal representative requests a transfer or refuses a transfer, the informed consent or refusal must be documented in writing. If there are questions about the records

required under the patient transfer law, the Compliance Officer will answer them or refer them to counsel.

The federal “anti-dumping” law is enforced through civil monetary penalties and through damages in private civil actions. If a facility violates the statute, it can be fined up to \$50,000 for each violation. A physician, including an on-call physician, who is responsible for the examination, treatment, or transfer of an emergency patient and who negligently violates the law may be fined up to \$50,000 for each violation. If the violation is gross and flagrant or repeated, the physician may be excluded from participation in the Medicare and Medicaid programs.

Discharge Planning and Ancillary Services Referrals

Federal regulations under the Medicare program and regulations administered by the New York State Department of Health govern the discharge planning process. In accordance with each entity’s long standing procedures, it is the policy of Strong Health to abide by these regulations in every respect. We all must recognize that the discharge of a patient to a residence or some other post-hospitalization setting is a critically important decision that must be made in the best interests of the patient and with the patient’s fully-informed consent. Improper discharge planning or referral to ancillary services providers not only might imperil the health of our patients, but might also place in jeopardy a facility’s or physician’s licensure and the continued ability to treat Medicare and Medicaid patients.

Market Competition

The Medical Center is committed to complying with all state and federal antitrust laws. The purpose of the antitrust laws is to preserve the competitive free enterprise system. The antitrust laws in the United States are founded on the belief that the public interest is best served by vigorous competition, free from collusive agreements among competitors on price or service terms. The antitrust laws help preserve the country’s economic, political, and social institutions; they apply fully to health care services provided by hospitals and physicians, and Strong Health is firmly committed to the philosophy underlying those laws.

While the antitrust laws clearly prohibit most agreements to fix prices, divide markets, and boycott competitors—which are addressed below—they also proscribe conduct that is found to restrain competition unreasonably. This can include, depending on the facts and circumstances involved, certain attempts to tie or bundle services together, certain exclusionary activities, and certain agreements that have the effect of harming a competitor or unlawfully raising prices.

(a) Discussion With Competitors

Strong Health policy requires that the rates its affiliates charge for care and related items and services, and the terms of its third-party payer contracts, must be determined solely by the individual entities. In independently determining prices and terms, a facility or provider may take into account all relevant factors, including costs, market conditions, widely used reimbursement schedules, and prevailing competitive prices, to the extent these can be determined in the marketplace. There can be, however, no oral or written understanding with any competitor concerning prices, pricing policies, pricing formulas, bids, or bid formulas, or concerning discounts, credit arrangements, or related terms of sale or service. To avoid the possibility of misunderstanding or misinterpretation, Strong Health policy prohibits any consultation or discussion with competitors relating to prices or terms which the particular entity, Strong Health affiliate or any competitor charges or intends to charge. Joint ventures and affiliations that may require pricing discussions must be individually reviewed by legal counsel for antitrust compliance. Discussions with competitors concerning rationalization of markets, down-sizing, or elimination of duplication ordinarily implicate market division and must be avoided.

Facilities within the System are often asked to share information concerning employee compensation. Strong Health policy prohibits the sharing with competing providers of current information or future plans regarding individual salaries or salary levels. System entities may participate in and receive the results of general surveys, but these must conform to the guidelines for participation in surveys provided under Trade Associations below.

Similarly, Strong Health policy prohibits consultation or discussion with competitors with respect to its services, selection of markets, territories, bids, or customers. Any agreement or understanding with a competitor to divide markets is prohibited. This includes an agreement allocating shares of a market among competitors, dividing territories, or dividing product lines or customers.

(b) Trade Associations

The Strong Health entities and individual professional staff are involved in a number of trade and professional associations. These organizations promote quality patient care by allowing professionals to learn new skills, develop policies and, where appropriate, speak with one voice on public issues. However, it is not always appropriate to share business information with trade associations and their members. Sharing information is appropriate if it is used to better inform consumers or to promote efficiency and competition.

The system entities may participate in surveys of price, cost, and wage information if the survey is conducted by a third party and involves at least five comparably sized facilities. Any price, cost, or wage information released must be at least three months old. If an employee is asked to provide a trade association with information about charges, costs, salaries, or other business matters, he or she should consult with his or her supervisor or department chair, who may review the issue with counsel or the Compliance Officer. Joint purchasing through a trade association is probably acceptable, but any joint purchasing plan should be reviewed in advance by legal counsel.

(c) Boycotts

Strong Health policy prohibits any agreement with competitors to boycott or refuse to deal with a particular person or persons, such as a vendor, payer, or other health care provider. These agreements need not be written to be illegal; any understanding reached with a competitor (directly or indirectly) on such matters is prohibited. All negotiations must be conducted in good faith. Exclusive arrangements with payers, vendors, and providers must be approved by legal counsel based on an analysis of the relevant market.

(d) Physician Services

Credentialing and peer review activities also may carry antitrust implications. Because of the special training and experience of physicians, their skills may best be evaluated by other physicians. It is appropriate for physicians to review the work of their peers. Because the physicians reviewing a particular physician may, by virtue of their medical specialties, be the physician's competitors, special care must be taken to ensure that free and open competition is maintained. As a result, credentialing, peer review and physician discipline within Strong Health are conducted only through properly constituted committees. Physicians participating in these activities are expected to use objective medical judgment.

If any Strong Health personnel are involved in negotiating a contract of employment or a personal service contract with a physician or other health care provider, it is important to review with care any non-competition provisions incorporated in the agreement. The appropriate geographic scope and duration of a non-competition agreement may vary from case to case. Questions about the appropriateness of a non-competition provision should be directed to legal counsel.

(e) Penalties

Penalties for antitrust violations are substantial. Individuals and corporations can be fined \$350,000 and \$10,000,000 respectively, for each antitrust violation, and individuals can be sentenced for up to three years in prison for each offense. In addition, actions giving rise to antitrust violations may violate other federal criminal statutes, such as mail fraud or wire fraud, under which substantial fines and even longer prison sentences can be imposed.

Antitrust violations also create civil liability. Private individuals or companies may bring actions to enjoin antitrust violations and to recover damages for injuries caused by violations. If successful, private claimants are entitled to receive three times the amount of damages suffered, plus attorneys' fees. Moreover, if the antitrust violation was a conspiracy, each member of that conspiracy may be liable for the entire damage caused by the conspiracy.

Tax-Exempt Organizations - Maintaining Tax-Exempt Status

a) General Principles

As non-profit providers serving charitable purposes, the Strong Health entities hold Federal tax-exempt status under section 501(c)(3) of the Internal Revenue Code. In order to qualify for that exemption, and to be eligible to receive tax-deductible contributions, an organization must be operated exclusively for charitable purposes – a standard which is generally met by operating an emergency department open to all, providing care to all who can pay, offering medical staff privileges to all qualified physicians, complying with anti-dumping and fraud and abuse laws, and maintaining a governing body comprised primarily of community members rather than organization insiders. The organization's exempt status may be revoked if it permits any private inurement of its assets to organization insiders or allows individuals to enjoy more than an insubstantial private benefit from the organization's activities. Even if exempt status is retained, the organization may be subject to "intermediate sanctions" penalty taxes if it enters into transactions that excessively benefit private individuals. In addition, the organization will be subject to tax (at corporate rates) on any income it receives from trade or business activities unrelated to its charitable purpose.

b) Private Inurement

A section (501)(c)(3) organization is prohibited from engaging in activities that result in "inurement" of its assets or earnings to insiders – that is, individuals whose special relationship offers them an opportunity to benefit economically from the exempt entity's income or assets. In the context of health care organizations, the IRS has broadly interpreted the term "insiders" to include not only founders, directors, and officers, but also physicians. If private inurement occurs, the IRS may revoke the organization's tax-exempt status.

Physician compensation often raises private inurement concerns, particularly in the context of revenue-sharing arrangements. An agreement to pay a specialist a fixed percentage of a department's gross income, for instance, may create private inurement. The entity's Chief Financial Officer, with the aid of counsel if desired, should review all such compensation arrangements to ensure that the total compensation paid is reasonable, that the recipient has no control over the organization, and that the arrangement is negotiated at arm's length. The CFO should also review other forms of incentive compensation for reasonableness, particularly if bonus payments are not capped and are based primarily on financial targets rather than patient satisfaction or the quality of care provided. Other potential sources of private inurement, which should be brought to the attention of the CFO and counsel if the arrangement is not negotiated at arm's length, include:

- Sales, exchanges, or leases of property between the entity and a private individual
- Loans or other extensions of credit between the entity and a private individual
- Contracts for goods, services, or facilities between entity and a private individual

- Payment or reimbursement of a private individual's expenses
- Partnerships or joint ventures between the entity and physician groups

c) Private Benefit

In contrast to the prohibition against private inurement, which only applies to organization insiders, the private benefit restriction applies to all individuals, regardless of their relationship to the organization. The private benefit limit requires the tax-exempt entity to serve public rather than private interests. Unlike the absolute prohibition on private inurement, however, incidental private benefit will not jeopardize an organization's exempt status. Senior Administrators and Directors should review contracts with commercial providers of goods or services, compensation packages of non-insiders, and joint ventures or partnerships with non-organization personnel or entities to ensure that the arrangements are reasonable and primarily benefit the entity's charitable functions rather than private interests.

d) Intermediate Sanctions

Many situations that raise concerns about private inurement or private benefit are also likely to create a tax liability under the "intermediate sanctions" rules. Intermediate sanctions allows the IRS to assess penalty taxes when certain individuals or entities, referred to as "disqualified persons," receive "excess benefits" from an exempt organization such as the University of Rochester. A "disqualified person" is defined as any person or entity that is in a position to exercise substantial influence over an organization. The organization's officers, directors, and trustees, as well as substantial donors and the five highest-paid employees, are likely to be considered disqualified persons. Physicians, although generally considered "insiders" for purposes of the private inurement prohibition, will only be "disqualified persons" subject to intermediate sanctions if they in fact possess substantial influence over the organization.

Intermediate sanctions will be imposed if a disqualified person receives an excess benefit from the tax-exempt entity -- in other words, if the organization provides an economic benefit whose value exceeds that of any consideration (including the performance of services) received in return. Likely sources of excess benefits are compensation packages (including fringe benefits and deferred compensation); sales, leases, or exchanges of organization property and assets; and joint ventures or partnerships with private individuals or entities. If an excess benefit transaction occurs, the disqualified person will be subject to an excise tax equal to 25% of the excess benefit received, and to an additional 200% tax if the benefit is not repaid or otherwise corrected within a given time after receiving notice from the IRS. In addition, any organization "manager" (officer, director, trustee, or person with similar responsibilities) who knowingly and willingly allowed the entity to provide the excess benefit will be subject to a 10% tax, capped at \$10,000.

To create a presumption that a given arrangement will not create an excess benefit, the compensation packages of disqualified persons, as well as any other potential excess benefit transactions, must be approved pursuant to the intermediate sanctions safe-harbor procedure. Specifically, the arrangement should be approved by the organization's Board (or a board committee); any board members with a conflict of interest regarding the transaction under consideration should excuse themselves. In evaluating the arrangement, the board (or

committee) should review specific data from comparable transactions. Relevant data for a compensation package, for example, would include compensation levels (including all fringe benefits and deferred compensation) paid by similar health care organizations (both for-profit and tax-exempt) for functionally comparable positions; the organization's location and the availability of similar specialties in the geographic area; independent compensation surveys by nationally recognized independent firms; and written offers from similar hospitals or facilities competing for the disqualified person's services. The board or committee must also document the basis for its decision to enter into the transaction; minutes should include a description of any conflicts of interest, the comparable data that was reviewed, and the basis for concluding that the disqualified person would not receive an excess benefit.

e) Physician Recruitment and Practice Acquisitions

The IRS closely scrutinizes incentives provided by tax-exempt providers to newly recruited physicians. Incentives such as a signing bonus, payment of malpractice premiums, below-market rental of office space, or income guarantee may be attacked by the IRS if those amounts, when added to the physician's actual salary and benefits package, result in a total compensation package that is unreasonable. Unreasonable compensation, if provided to a physician with substantial influence over an organization (e.g., the chief medical officer) may subject the physician and organization managers to intermediate sanctions penalties. In an extreme case, the IRS may revoke the entity's tax exemption on private inurement or private benefit grounds. To avoid incurring penalty taxes or risking the loss of the tax exemption, recruitment packages offered to physicians expected to possess substantial influence over the particular tax-exempt organization, or to physicians expected to be among the organization's highest paid employees, must be approved by a disinterested board or committee, with careful attention paid to data from comparable arrangements, and adequately documented to demonstrate the reasonableness of the total compensation package.

From a tax standpoint, physician practice acquisitions raise issues similar to those in physician recruitment. If the tax-exempt entity pays more than fair market value for the practice, the IRS may impose penalty taxes under intermediate sanctions on the physicians, if they possess substantial influence over the entity, and on managers who approve the transaction. Whether or not penalty taxes are imposed, the IRS may revoke the entity's tax exemption if the overpayment constitutes private inurement or private benefit. To guard against penalty taxes or loss of exemption, practice acquisitions should be reviewed by the entity's board (or a board committee) in accordance with the safe harbor procedure discussed above.

f) Unrelated Business Taxable Income ("UBTI")

A section 501(c)(3) organization will generally be exempt from federal income tax. The organization will be taxed at regular corporate rates, however, on income that it receives

from an unrelated trade or business (“UBTI”) that it regularly carries on. Investment income or gains generally will not constitute UBTI unless those proceeds are debt-financed or are received from a controlled corporation. UBTI may be offset by deductions for costs--such as rent or labor--that are connected with the UBTI.

A UTB in any activity that is performed by the tax-exempt organization and does not substantially relate to its exempt purpose. An activity will be substantially related if it contributes importantly or is causally related to the organization’s exempt purpose, but will not be so related if conducted on a scale larger than reasonably necessary to perform functions in furtherance of that purpose. A UTB does not include any trade or business in which substantially all the work is performed without compensation or which is carried on primarily for the convenience of the organization’s patients, employees, or officers. The following businesses, although often exempt from tax under that “convenience” exception, tend to attract IRS scrutiny and should be reviewed to determine whether UBTI is being generated.

- laboratory services
- pharmacy sales
- leasing of medical buildings
- parking facilities
- laundry services
- cafeterias, coffee shops, and gift shops

Income from medical research is also an occasional source of UBTI. Basic research--that is, research without an application-oriented testing component--generally will not give rise to UBTI, even if the research is privately sponsored. Likewise, research in which the drug or device being tested is used therapeutically is unlikely to create UBTI, as is research that serves to educate medical students or personnel. UBTI may result, however, from research incident to commercial operations, such as the ordinary testing or inspection of materials or products that benefit private rather than public interests. Thus, the more the entity’s activities resemble routine testing (in particular, testing that could be done commercially), the more likely UBTI will be generated. Sponsored research contracts should be reviewed to determine whether any of the arrangements give rise to UBTI.

g) Tax-Exempt Bonds

The Internal Revenue Code imposes strict limits on “private business use” of tax-exempt bond proceeds. Private business use, generally speaking, is the use of Bond proceeds or a Bond-financed facility by a person in a trade or business; the use of such proceeds or facilities by a section 501(c)(3) tax-exempt organization in furtherance of its exempt purposes does not constitute private business use. Examples of private business use include:

- leasing all or a part of a bond-financed facility to a for-profit endeavor, such as private physician offices, gift shops, or other concessions
- entering into contracts with service providers -- management organizations,

physicians, cafeterias, janitors, vending machine companies, and the like -- that do not satisfy management contract safe harbors or do not constitute incidental use under the private use regulations.

- operating parking garages that are not available to the general public on a first-come first-served basis or for patients or employees of the organization
- loaning Bond proceeds to for-profit person or endeavor
- constructing facilities to be used as private physician offices
- engaging in activities that give rise to UBTI
- entering into research agreements with private companies
- selling bond-financed property in violation of the change-in-use restrictions for each issuance of Bonds, private business use may be supported by up to 5% of the Bond proceeds, minus the percentage of issuance costs (usually 2%) financed with Bond proceeds. In effect, then, generally no more than 3% of Bond proceeds may support private business use. If Bond proceeds are spent directly on private business use, the percentage should be based on the actual dollars expended; if the private business use related to a Bond financed facility, the percentage should be measured in terms of square footage or output (e.g., number of hours). If the amount of private business use exceeds 3%, the Compliance Officer and counsel should determine whether that percentage can be reduced on account of payments received from the private user.

h) Political Campaigns and Lobbying Activities

The Internal Revenue Code prevents a tax-exempt organization, or any of its representatives acting in an official capacity, from participating or intervening in any political campaign on behalf of, or in opposition to, any candidate for public office. The organization is also prohibited from carrying on more than an insubstantial amount of lobbying, propaganda activities, or other attempts to influence legislation.

i) Charitable Solicitations

A tax-exempt entity is required to provide written disclosure to any donor who retains an interest in contributed property (e.g., a charitable gift annuity, lead trust, remainder trust, or pooled income fund) that may be commingled with other tax-exempt assets in a collective investment vehicle. Similarly, the organization must provide disclosures to donors who have made quid pro quo contributions--that is contributions for which the donor has received something of value in return. The IRS may impose penalties in the amount of \$10 for each quid pro quo contribution (up to \$5,000 per fund-raising event) for which adequate disclosure is not provided.

Securities Laws

When an organization's tax-exempt bonds (the "Bonds") are publicly traded securities, certain activities of the organization are subject to certain provisions of the federal securities laws. These laws govern the dissemination or use of information about the affairs of the organization or its affiliates. Federal securities laws also address the dissemination or use of information which might be of interest to persons considering the purchase or sale of the Bonds.

(a) Continuing Disclosure

The Securities and Exchange Commission ("SEC") requires continuing disclosure on municipal securities transactions by relevant parties. The Strong Health entities are committed to carrying out any continuing contractual disclosure obligations involving health care revenue bond transactions, and shall make appropriate annual disclosures and all necessary periodic or material disclosures in a timely manner. Employees and staff should be reminded each year of their obligation to refrain from insider trading and disclosure.

(b) Insider Trading

It is generally illegal for any person, either personally or on behalf of others, (i) to buy or sell securities such as the Bonds while in possession of material non-public information, or (ii) to communicate (to "tip") material nonpublic information to another person who trades in the Bonds on the basis of the information or who is person who trades in the Bonds on the basis of the information or who in turn passes the information on to someone who trades. All employees, trustees, and professional staff members must comply with these "insider trading" restrictions.

Penalties for violating the insider trading rules include civil fines of up to three times the profit gained or loss avoided by the trading, criminal fines of up to \$1 million, and imprisonment for up to 10 years. There can also be civil liability to those damaged by the trading. An employer whose employee violates the insider trading prohibitions may be liable for a civil fine of up to greater of \$1 million or three times the profit gained or loss avoided as a result of the employee's insider trading violation.

All information that an investor might consider important in deciding whether to buy, sell, or hold securities is considered "material." Examples of some types of material information are:

- financial and operating results for the month, quarter or year
- financial forecasts, including proposed or approved budgets
- utilization statistics such as occupancy rates, payer mix, number of discharges and ambulatory visits, etc.
- awarding or loss of major research funding

- possible mergers, acquisitions, joint ventures and other purchases and sales of companies and investments in companies
- obtaining or losing important contracts
- major personnel or medical staff changes
- major litigation developments

Information that is likely to affect the price of securities is almost always material.

Information is considered to be nonpublic unless it has been effectively disclosed to the public, for example by a press release. The information must not only be publicly disclosed, but there must also be adequate time for the market as a whole to digest the information. All information about an organization or its business plans is potentially “insider” information until publicly disclosed or made available by the organization. Thus, employees may not disclose it to others, such as relatives, friends, or business or social acquaintances, who do not need to know it for legitimate business reasons.

When an employee (or a member of the professional staff or trustee) knows material nonpublic information about the organization, he or she is prohibited from three activities:

- trading in the Bonds for his or her own account or for the account of another (including any trust of which the employee, member of the professional staff, or trustee is a trustee, or any other entity that buys or sells securities, such as a mutual fund);
- having anyone else trade for the employee;
- disclosing the information to anyone else who then trades or in turn “tips” another person who trades.

Neither the employee nor anyone acting on the employee’s behalf, nor anyone who learns the information from the employee, may trade for as long as the information continues to be material and nonpublic.

If an employee, member of the professional staff, or trustee is considering buying or selling the Bonds and has a question as to whether the transaction might involve the improper use of material nonpublic information, that individual should obtain specific prior approval from the Compliance Officer. Consultation with the individual’s own attorney is also strongly encouraged.

All of us should remember that outsiders may be listening to us or watching us and may be able to pick up information they should not have. We should not, for example, discuss the System’s affairs in places where we can be overheard by others – such as corridors, elevators, the cafeteria, other restaurants, and on cellular phones – and we should be careful about how we handle and dispose of sensitive papers.

Waste Disposal

Health care facilities produce waste of various types. Strong Health is committed to safe and responsible disposal of biomedical waste and other waste products. Compliance with applicable federal and state environmental regulations requires ongoing monitoring and care. Strong Health entities use a medical waste tracking system, biohazard labels, and biohazard containers for the disposal of infectious or physically dangerous medical or biological waste. Failure to follow the system could result in significant penalties to the entities in the System. Employees who come into contact with biological waste should be familiar with the employer's medical waste policy and procedures, and should report any deviations from the policy to the supervisor or the Compliance Officer.

The Strong Health entities comply with the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and other federal and state laws and regulations governing the incineration, treatment, storage, disposal, and discharge of waste. If an employee suspects noncompliance or violation of any of these requirements, the circumstances should be reported to a supervisor or to the Compliance Officer. Spills and releases of hazardous materials must be reported immediately, so that necessary reports can be made and cleanup can be initiated.

Strong Health supports ongoing legal and technical review to identify and correct environmental problems. The entities within the System will initiate environmental assessments and compliance audits as appropriate. Failure to prevent, report, or correct environmental problems can result in criminal and civil penalties as high as \$50,000 per day per violation or \$1 million total, imprisonment for up to five years, or both. Even merely negligent violations can result in imprisonment and substantial fines if they pose a serious threat to human health.

All employees and persons affiliated with the System are expected to follow their facilities' policies on waste disposal.

Controlled Substances

Any Strong Health entity having a pharmacy is registered to purchase, acquire, compound and dispense narcotics and other controlled substances. Improper use of these substances is illegal and extremely dangerous. Accordingly, the entities must comply with federal laws and regulations administered by the Drug Enforcement Administration (DEA) and New York State laws and regulations administered by the Department of Health.

All employees, as well as affiliated physicians who maintain DEA registration, must comply with all federal and state laws regulating controlled substances. Access to controlled substances is limited to persons who are properly licensed and who have express authority to handle them. No health care practitioner may dispense controlled substances except in conformity with state and federal laws and the terms of the practitioner's license. Employees

should carefully follow record keeping procedures established by their departments and the pharmacy. Unauthorized manufacture, distribution, use, or possession of controlled substances by staff employees working in the Strong Health System is strictly prohibited, and will be prosecuted to the full extent of the law. Any person who knows of unauthorized handling of controlled substances is to provide the information immediately to his or her supervisor or the Compliance Officer.

Federal law may impose sentences of up to twenty years in prison and fines of up to \$1,000,000. If an organization or its employee is convicted under federal or state law of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance, the organization or employee can be excluded from the Medicare or Medicaid programs.

Drug-Free Workplace

In addition to complying with the regulations governing the acquisition, storage, administration and distribution of controlled substances, Strong Health is committed to a workplace in which all professionals, caregivers and employees are free from impairment brought about by the ingestion of any drug or alcohol. The manufacture, distribution or unauthorized possession of controlled substances by individuals affiliated with Strong Health is strictly prohibited. Any person who knows of the unauthorized possession of, use or distribution of controlled substances by persons employed by or affiliated with Strong Health shall report the information immediately to his or her supervisor or the Compliance Officer. The Strong Health entities are committed to a “drug and alcohol free workplace.”

Federally Funded Grants

Certain Strong Health institutions and professional staff from time to time receive various federal grants such as grant funding from the National Institutes of Health. Federal regulations impose duties and obligations upon the recipients of federal grants. Any recipient institution within Strong Health expects its personnel to abide by all applicable federal regulations, including but not limited to regulations relating to accurate reporting and appropriate expenditure of grant funds. Questions relating to matters concerning federal grants should be directed to the Director of ORPA (if the recipient holds a faculty appointment at the University of Rochester) or the Compliance Officer to ensure that all regulations are observed.

Scientific Integrity

Anyone who receives federal funds and grants to conduct scientific research must comply with the federal regulations imposed upon the recipients of those funds. These regulations generally prohibit “misconduct in science,” which includes intentional fabrication, falsification, or plagiarism in proposing, conducting, or reporting research. Honest errors or differences in interpretations of data are not considered violations.

These so-called “misconduct regulations” are designed to prevent dishonesty and fraud in federally funded research programs. Strong Health is committed to complying with the regulations and avoiding any practice that may be interpreted as misconduct. Employees in the laboratory, medical staff and administration of any facility, and any department receiving federal funds to conduct research must be vigilant in identifying violations of these regulations and reporting them to the Compliance Officer.

The federal regulations provide procedures for a thorough and confidential internal inquiry and investigation of any allegation. Because evaluating these claims is complex and depends upon the specific facts and circumstances of each case, the Medical Center shall appoint an inquiry team consisting of legal counsel and at least two scientists experienced in the particular scientific field to determine whether a violation may have occurred. If further investigation is recommended, the Medical Center is required to notify the Office of Research Integrity of the Department of Health and Human Services, which monitors such investigations and is authorized by law to conduct its own review of the allegations.

Violations of these federal regulations could result in exclusion from eligibility for federal grants and contracts generally up to three years. Federal law also provides criminal sanctions for making false written or oral statements to the Office of Research Integrity during the course of an investigation.

Skilled Nursing Facilities

In 1987 the federal Nursing Home Reform Act imposed requirements for nursing facilities certified under the Medicaid program. As Medicaid participating facilities, the Strong Health skilled nursing facilities comply with these requirements. The law sets out standards for the quality of life for the residents of nursing facilities, the services that must be provided to them, the way their personal funds must be handled, and their rights in a variety of areas. The nursing facility must provide each resident with an assessment and plan of care. There is a civil penalty of up to \$1,000 for willfully and knowingly making a material false statement in a resident assessment and a civil penalty of up to \$5,000 for willfully and knowingly causing another person to make a false statement.

The Medicaid nursing facility requirements are enforced by the Medicaid agency as well as the federal government. Survey units provide information to state Medicaid fraud and abuse control units. The Medicaid agency conducts surveys of nursing facilities. If it finds that a nursing facility does not meet Medicaid standards, the available remedies range from monitoring and denial of certain payments, to termination of Medicaid participation, civil monetary penalties up to \$10,000 per day of noncompliance, or transfer of residents to other facilities. If a staff member is aware of a deficiency in a Strong Health nursing facility, he or she should promptly bring the deficiency to the attention of the facility’s administrator or the Compliance Officer so it may be corrected.

New York law also sets licensing standards for nursing homes. Strong Health is committed to conscientious adherence to state and federal licensing requirements and to the dignity of each nursing home resident.

Regulation

The Strong Health entities operate in a highly regulated industry, and must monitor compliance with a great variety of highly complex regulatory schemes. The cooperation is needed of employees and professional staff members in complying with these regulations and bringing lapses or violations to light. While the regulatory schemes may not carry criminal penalties, they control the licenses and certifications that allow the system to deliver care to its patients. The system's continued ability to operate and serve the community depends upon each employee's help in regulatory compliance.

Some of the regulatory programs which employees may deal with in the course of their duties include the following:

- New York State licensure
- JCAHO accreditation
- Medicare certification and conditions of participation
- Certificate of Need
- Controlled substance registration
- Pharmacy licensure and registration
- Clinical laboratory licensure and regulation
- Union rules and collective bargaining agreements
- Occupational Safety and Health regulation
- Building, safety, food service and fire codes
- Nurse Practice Act

The Compliance Officer can provide employees with information on these rules, and can direct questions or concerns to the proper person.

Political Contributions

Strong Health believes that our democratic form of government benefits from citizens who are politically active. For this reason, the System encourages each of its employees and staff to participate in civic and political activities in his or her own way.

An organization's direct political activities, however, are limited by law. Corporations may not make any contributions – whether direct or indirect – to candidates for federal office. Thus, a corporation may not contribute any money, or lend the use of vehicles, equipment, or facilities, to candidates for federal office. Nor may it make contributions to political action committees that make contributions to candidates for federal office. No Strong

Health entity may require any employees or professional staff members to make any such contribution. Finally, no organization may reimburse its employees or professional staff members for any money they contribute to federal candidates or campaigns.

Violation of federal election laws carries potential criminal penalties of up to one year in jail and a fine of \$25,000 or three times the amount of the illegal contribution, whichever is greater. Civil penalties also may be assessed.

New York law prohibits corporations from contributing more than \$5,000 annually to political candidates or organizations. The law prohibits not only cash contributions, but also contributions "in kind" such as office space, goods or services, in excess of \$5,000 annually.

Consistent with its charitable purpose, Strong Health entities should not carry on "propaganda" or attempt to "influence legislation," as these acts are defined under the Internal Revenue Code. The Strong Health entities and their representatives may not participate in or intervene in any political campaign for or against any candidate.

Purchasing

Purchasing decisions must be made in accordance with applicable policy. In addition, the prohibitions discussed in a preceding section of this Manual entitled "Payments, Discounts, and Gifts," apply to purchasing decisions made on behalf of the particular organization. Purchasing decisions must in all instances be made free from any conflicts of interest that could affect the outcome. Strong Health is committed to a fair and objective procurement system which results in the acquisition of quality goods and services at a fair price. Any concerns about the legality of the terms of a proposed transaction, including but not limited to, inducements offered by a vendor or supplier, should be discussed with legal counsel or the Compliance Officer.

Independent Contractors & Vendors

Goods and services are purchased from many consultants, independent contractors, and vendors. Strong Health policy is that all contractors and vendors who provide items or services to the Strong Health entities must comply with all applicable laws and Strong Health policies. Each consultant, vendor, contractor, or other agent furnishing items or services worth at least \$25,000 per year shall be given a copy of the Compliance Program Policy, or in the judgment of the person purchasing the goods or services, a relevant summary, and shall provide a written certification that it is aware of and will comply with Compliance Program Policy. Contractors should bring any questions or concerns about Strong Health practices or their own operations to the Compliance Officer.

Personnel who work with consultants, contractors, and vendors or who process their invoices should be aware that these compliance policies apply to those outside companies as

well. Employees are encouraged carefully to monitor the activities of contractors in their areas. Any irregularities, questions, or concerns on those matters should be directed to the Compliance Officer.

Fund-Raising

In furtherance of their charitable purposes, certain entities within Strong Health conduct fund-raising activities through various means. The organizations comply with New York State registration, record keeping, and reporting requirements with respect to its fund-raising activities. Strong Health policy requires that all solicitation of charitable contributions must be done under the supervision of the entity's development office. The Strong Health entities do not authorize any employee or other individual to use any entity's name in any fund-raising activities not approved or supervised by the organization's development office.

It is illegal for any person to make any false, deceptive, or misleading statement in connection with a solicitation of funds or a sale of goods or services to benefit an entity within the Strong Health system. It is against policy to use any sponsor or endorsement in connection with fund-raising activities unless the sponsor or endorsement has been verified by the entity's development office.

If an organization or its employees violate the law on charitable donations, the organization could lose its ability to raise funds. In addition, individuals could be subjected to criminal prosecution resulting in fines and imprisonment.

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Compliance Office