

The Compliance Manual



Children's Hospital Boston

Document: CM 01.0.000

Compliance Reporting and "Whistleblower" Protections

It is Children's Hospital Boston (the "Hospital") policy to provide services and conduct its activities in compliance with all state and federal laws governing its operations and in accordance with established standards of business and professional ethics. To assist in this effort, the Hospital has established a Compliance Program (the "Program"). The Program is directed by a Compliance Committee and a Compliance Officer, who are charged by the Board of Trustees with reviewing Hospital compliance and specific compliance situations that may arise.

No compliance program can be successful, however, without the individual commitment and cooperation of each employee and professional staff member. The Hospital's continued ability to operate and fulfill its various missions depends upon each employee's and professional staff member's help in achieving compliance.

This manual describes several important legal principles applicable to the services and activities of the Hospital. It is designed to assist employees and professional staff members to understand some of the complex laws and regulations that affect the Hospital. Compliance with these principles and other Hospital policies, and adherence to commonly accepted professional standards and ethical principles, is expected of all employees and staff members. Conduct that does not comply with the statements in this Manual, other Hospital policies, and commonly accepted professional standards and ethics is not authorized by the Hospital and is considered outside the scope of Hospital employment and professional staff membership. Direct questions about the meaning or correct application of the principles mentioned in this Manual to one's supervisor or, if appropriate, to Hospital counsel, the Hospital's Compliance Officer, or to a member of the Compliance Committee.

Despite the best efforts of each individual associated with the Hospital to comply with Hospital policy and applicable law, inevitably there will be questions about the propriety of certain conduct or practices. Accordingly, employees or professional staff members who become aware of an actual, apparent, or potential violation of Hospital policy or law, are expected to report it to his or her supervisor, to Hospital counsel, to the Compliance Officer, or to some other appropriate Hospital official. Persons making such reports will be treated with appropriate confidentiality, and the information will be shared only on a bona fide need-to-know basis. Retaliation against any employee or staff member making such reports in good faith, or who cooperates in the investigation of such reports, is unlawful, violates hospital policy, and is prohibited.



02 Regulatory Compliance

Children's Hospital Boston operates in a highly regulated industry, and must monitor compliance with a wide variety of highly complex regulations. The Hospital needs the cooperation of employees and professional staff members in complying with these regulations and bringing lapses or violations to light. These regulatory frameworks control the licenses and certifications that allow the Hospital to deliver care to its patients and carry out its other missions in education, research and community service.

2.01 Registration, Licensure, and Accreditation

Some of the regulatory programs that employees and professional staff members may deal with in the course of their duties include:

- Massachusetts hospital licensure
- JCAHO accreditation
- Medicare and Medicaid certification and conditions of participation
- Determination of Need requirements
- Controlled substance registration
- Pharmacy licensure and registration
- Clinical Laboratory license and regulation
- Occupational Safety and Health regulation
- Building, safety, food service and fire codes

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

2.02 Tax-Exempt Status

The Hospital is a tax-exempt organization under Section 501(c)(3) of the Internal Revenue Code. That is, the Hospital is exempt from paying federal income tax on most of its revenue. The Hospital is also permitted to accept tax-deductible charitable contributions. Loss of the Hospital's exempt status would result in substantial penalties, interest, and the inability to receive tax-deductible charitable contributions.

To qualify for and maintain tax-exempt status, the Hospital must be organized and operated exclusively for charitable purposes and no part of its net earnings may inure to the benefit of private individuals. An exempt organization is not organized or operated exclusively for exempt purposes unless it serves a public rather than a

private interest. The IRS has taken the position that the fact that an activity undertaken to further a public purpose also results in benefit to a private person does not prevent the activity from qualifying as exempt, if the private benefit is "incidental" to the primary public benefit.

Because the Hospital is dedicated to its charitable purposes, all contracts and agreements must be negotiated at arm's length. Compensation provided to health professionals for recruitment, retention, employment, and personal services must be reasonable in the context of the services provided and the need for them. Reasonableness must be analyzed based on overall compensation and benefits. Areas of particular concern are below-market rents, compensation tied to Hospital or department revenues, income guarantees (especially where there is no obligation to repay), below-market loans, and loan guarantees. Any compensation arrangement involving one or more of these benefits should be reviewed with the General Counsel. If an employee or staff member is aware of payments by the Hospital to a private individual or organization that may be unrelated to the Hospital's mission or in excess of fair market value, these circumstances should be disclosed to the employee's supervisor and to the General Counsel.

Each of the professional foundations associated with the Hospital is also a tax-exempt entity under section 501(c)(3) of the Internal Revenue Code. Therefore, the provisions above apply to the foundations as well as to the Hospital.

2.03 Patient Referrals

Patient referrals are important to the delivery of appropriate health care services. Patients are admitted, or referred, to the Hospital by their physicians. Patients leaving the Hospital may be referred to other facilities, such as skilled nursing or rehabilitation facilities. Patients may also need durable medical equipment, home care, pharmaceuticals, oxygen, and may be referred to qualified suppliers of these items and services.

The Hospital's policy with respect to such referrals 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 diagnostic facility, or a supplier should be made by the patient, with guidance from the Hospital and his or her physician as to which providers are qualified and medically appropriate.

The Hospital recognizes, however, that physicians and other health care providers may have financial relationships with the Hospital or its 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.

These sorts of relationships raise issues under a federal law known as the "Stark law." The Stark law applies to any physician who has, or whose immediate family member has, a "financial relationship" with an entity such as the Hospital, and prohibits referrals by that physician to the Hospital for the provision of certain designated health services reimbursed by Medicare and Medicaid, unless the relationship falls within a specific exception to the referral prohibition.

The Stark law applies to the following "designated health services":

- Clinical laboratory
- Physical therapy and speech-language pathology services
- Occupational therapy
- Radiology and nuclear medicine (including MRI, CT, ultrasound, mammography, and PET scans)
- Durable medical equipment, parenteral and enteral nutrients
- Equipment and supplies
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Radiation therapy services and supplies.

The exceptions under the Stark law are complex, and several general rules must be followed. Leases for physician office space and personal services contracts with physicians must be in writing. Any premises leased must be specifically described and must not exceed the space reasonably needed for the physician's legitimate purposes. Rental charges must be set in advance and reflect the fair market value of the space, without regard to the volume or value of referrals by the physician. In other words, the lease must be commercially reasonable even if no referrals were made between the parties. Similarly, a personal service contract must specify the services to be provided by the physician to the Hospital. Those services must be reasonable and necessary for legitimate purposes. Compensation paid to the physician must be set in advance, must reflect the fair market value of the services provided and must be unrelated to the volume or value of referrals. Physician incentive plans, which may include volume-based compensation, are acceptable if certain specified requirements are met.

Other exceptions to the referral prohibition include: (a) purchasing clinical laboratory services or other items or services from the Hospital, so long as payment for those services reflects the fair market value of the services; (b) an arrangement whereby the Hospital bills for a group practice may be acceptable if it was in place prior to December 19, 1989 and meets certain other requirements; (c) a pathologist, radiologist, or radiation oncologist may provide Hospital laboratory, pathology, diagnostic radiology, or radiation oncology services on his/her own order or on a consultation request from another physician.

Penalties for violating the Stark law include

- no Medicare or Medicaid payment for the service referred illegally;
- a refund to the beneficiary of any amounts collected;
- fines of up to \$15,000 levied on both the physician and the entity for each service referred illegally, plus additional fines based on the amounts billed;
- civil monetary penalties of up to \$100,000 plus other assessments; and
- exclusion from the Medicare or Medicaid programs.

2.04 Hazardous Waste Disposal

The Hospital 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. The Hospital uses 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 Hospital and even criminal liability. Employees who come into contact with biological waste must be familiar with the Hospital's medical waste policy and procedures, and report any deviations from the policy to their supervisor, the Safety Officer, or the General Counsel.

The Hospital is also subject to a variety of federal and state laws and regulations governing the incineration, treatment, storage, disposal, and discharge of Hospital waste. If an employee or staff member suspects noncompliance or violation of any of these requirements, the circumstances should be reported to a supervisor, the Safety Officer, or the General Counsel.

Refer to the following policies and procedures for additional information about hazardous waste management.

- Safety Policy and Procedure [5.00 Hazardous Waste Management Plan](#)

2.05 Publicly Funded Grants

The Hospital from time to time receives various federal grants, such as funding from the National Institutes of Health. Federal regulations impose duties and obligations upon the federal grant recipients. As a recipient institution, the Hospital expects its personnel and staff members to abide by all applicable federal regulations, including but not limited to regulations relating to accurate reporting and appropriate expenditure of grant funds. Direct questions relating to matters concerning federal grants to the Vice President for Research Administration to ensure that all regulations are observed.

The Hospital may also receive state grants, some of which are funded by the federal government. Grants that are awarded by or through the state are subject to state regulations and may also be subject to related federal regulations. The Hospital expects personnel involved in administration of such grants to be familiar with and to comply with all applicable regulations. Direct questions relating to these regulations to the Compliance Officer.

2.06 Fund-Raising

To further its charitable purposes, the Hospital conducts fund-raising activities. The Hospital complies with applicable Massachusetts registration, record-keeping, and reporting requirements with respect to its fund-raising activities. Hospital policy requires that all solicitation of charitable contributions for the Hospital or its affiliates be done under the supervision of the Children's Hospital Trust. The Hospital does not authorize any employee or other individual to use the Hospital's name in any fund-raising activities not approved or supervised by the Children's Hospital Trust.

It is illegal for any employee or representative of the Hospital to make any false, deceptive, or misleading statement in connection with a solicitation of funds or a sale of goods or services to benefit the Hospital. It is against Hospital policy to use any sponsor or endorsement in connection with fund-raising activities unless the sponsor or endorsement has been approved by the Children's Hospital Trust.

2.07 Political Contributions

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

The Hospital'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, the Hospital may not contribute any money, or lend the use of vehicles, equipment, or facilities, to candidates for federal office. Nor may the Hospital make contributions to political action committees that make contributions to candidates for federal office. The Hospital may not require any employees or professional staff members to make any such contribution. Finally, the Hospital cannot reimburse its employees or professional staff members for any money they contribute to federal candidates or campaigns.

State law also limits the extent to which corporations may contribute to political candidates.

Consistent with its charitable purpose, the Hospital does not carry on "propaganda" or attempt to "influence legislation," as these acts are defined under the Internal Revenue Code. The Hospital and its representatives may not participate in or intervene in any political campaign for or against any candidate. Any questions regarding involvement by the Hospital, its employees or staff members in a political campaign should be directed to the Vice President for Child Advocacy or the General Counsel.

Related Content

- Safety Policy and Procedure [5.00 Hazardous Waste Management Plan](#)



03 Controlled Substances

Children's Hospital Boston, through its Pharmacy, is registered to compound and dispense narcotics and other controlled substances. Improper use of these substances is illegal and extremely dangerous. The Hospital requires that its employees and staff members comply with the terms of the Hospital's controlled substances registration and with 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 and staff members should carefully follow record keeping procedures established by their departments and the pharmacy. Unauthorized manufacture, distribution, use or possession of controlled substances by Hospital employees and staff members is strictly prohibited. Any employee or staff member who knows of unauthorized handling of controlled substances should provide the information immediately to his or her supervisor, the Compliance Officer, or the General Counsel.

Refer to the following policies and procedures for additional information about controlled substances.

- Personnel Policy [Substance Abuse Prevention](#)
- Nursing Policy and Procedure [12.1 Medication Policies](#)
- Pharmacy Policy and Procedure [02 Prescribing Medications](#)



04 Confidentiality of Patient Information

Children's Hospital Boston employees and health care professionals possess and have access to sensitive, privileged information about patients and their care. Patients properly expect that this information will be kept confidential. Federal and state laws and regulations impose a variety of obligations on the Hospital and its personnel to protect the privacy of patient information. The Hospital takes very seriously any violation of a patient's confidentiality. Discussing a patient's medical condition, or providing any information about patients to anyone other than Hospital personnel who need the information and other authorized persons, is prohibited. Employees and staff members should not discuss patients outside the Hospital or with their families.

The Hospital is the owner of the medical record, which documents a patient's condition, and the services received by the patient at the Hospital. Medical records are confidential, which means that they may not be released except with the consent of the patient or in other limited circumstances. Special protections apply to mental health records, records of drug and alcohol abuse treatment, and records relating to HIV infection. Medical records should not be physically removed from the Hospital, altered, or destroyed. Employees and staff should endeavor to preserve the confidentiality and integrity of medical records. No employee or staff member is permitted to access the medical record of any patient without a legitimate, Hospital-related reason for so doing. Any unauthorized release of or access to medical records should be reported to a supervisor.

Massachusetts' law prohibits unauthorized access to a computer system, either directly or by network or telephone. An individual who has a legitimate access code must only access information that is required for the performance of his or her Hospital duties. The Hospital has adopted the Information Security Manual: [Acceptable Use of Computer and Network Resources](#) policy and expects all Hospital employees and staff members to abide by this document.

Refer to the following policy and procedure documents and resources for additional information about Confidentiality.

- Personnel Policy [Confidentiality of Patient and Employee Information.](#)
- [Patient Health Information Policies](#)
- Children's Hospital Boston [HIPAA website](#)

The Compliance Manual



Children's Hospital Boston

Document: CM 05.0.000

05 Non-Discrimination

The Hospital is committed to a policy of nondiscrimination and equal opportunity for all qualified applicants, employees, and staff members without regard to race, color, sex, religion, age, national origin, ancestry, disability, or sexual orientation. Its policy of non-discrimination extends to the care of patients. The Hospital specifically prohibits sexual harassment, a form of discrimination covered under the Hospital's anti-discrimination policies.

An employee or staff member who believes he or she 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 the Human Resources Department. A patient who feels he or she has been the subject of unlawful discrimination or harassment should be encouraged to contact the Patient Relations Department. The Patient Relations Department will refer the matter to appropriate Hospital personnel for investigation.

Refer to the following Personnel policies and procedures for additional information about non-discrimination.

- [**Diversity, Equal Employment Opportunity, and Affirmative Action**](#)
- [**Sexual Harassment**](#)

The Compliance Manual



Children's Hospital Boston

Document: CM 09.0.000

06 Scientific Integrity

Regulations imposed upon the recipients of federal funds generally prohibit "misconduct in science." "Misconduct in science" includes intentional fabrication, falsification, or plagiarism in proposing, conducting, or reporting research. Honest errors or differences in interpretations of data are not considered misconduct.

The Hospital has adopted a Policy on Research Misconduct. Children's Hospital Boston is committed to complying with the regulations and avoiding any practice that may be interpreted as misconduct. Employees and staff are expected to follow the [Research Misconduct](#) policy and report violations as set forth in it.

Refer to the following policy and procedure for additional information about scientific misconduct:

- Research Policy and Procedure Manual: [Research Misconduct](#)



07 Conflicts of Interest

Children's Hospital Boston's (CHB) **Conflict of Interest Policy** is published in the Personnel Policies Manual. Hospital employees and staff members should endeavor to avoid conflicts of interest. Adherence to this policy ensures that the Hospital's employees and staff members act with objectivity in carrying out their duties. The Hospital encourages employees and staff members to consult with the General Counsel about activities or relationships that might constitute conflicts of interests.

7.01 Entertainment and Gifts

CHB recognizes that business dealings may include a shared meal or other similar social occasion. Many such activities and their associated expenses are not problematic.

However, Hospital Personnel Policy **Conflict of Interest** defines a conflict of interest as, among other things, acceptance of a gift (including excessive entertainment) from someone doing or seeking to do business with the Hospital, if acceptance of the gift could be reasonably interpreted as having been given to influence the Hospital to act favorably to the person. Generally speaking, gifts worth \$50.00 or more, or two or more gifts from the same person with an aggregate value of \$50.00 or more, should be disclosed to the General Counsel.

7.02 Purchasing

Purchasing decisions must be made in accordance with applicable Hospital policy. In addition, prohibitions discussed in the **Payments, Discounts, and Gifts** section of this Manual apply to purchasing decisions made on behalf of the Hospital. Purchasing decisions must in all instances be made free from any conflicts of interest that could affect the outcome. CHB is committed to a fair and objective procurement system that results in the acquisition of quality goods and services for the Hospital at a fair price.

7.03 Vendor Policy

Relationships with certain types of vendors, such as pharmaceutical and medical device manufacturers, who do business with the Hospital or who may seek to do business with the Hospital are governed by the Hospital's Vendor Policy. Among other things, this policy prohibits the acceptance of personal gifts from vendor representatives, and provides instructions and guidelines for handling other kinds of relationships with these vendors. Direct questions about the Vendor Policy and related matters to the General Counsel or the Compliance Officer. Refer to the following for additional information about vendors and conflicts of interest:

- **Vendor Policy**
- Personnel Policy **Conflict of Interest**



08 Financial Compliance

8.01 Billing and Claims

When claiming payment for Hospital or professional services, the Hospital has an obligation to its patients, third party payors, and the state and federal governments, to exercise diligence, care, and integrity. The Hospital is committed to maintaining the accuracy of every claim it processes and submits. Many people throughout the Hospital have responsibility for selecting and entering charges and procedure codes and other information necessary for accurate billing. Each of these individuals is expected to do his/her best to comply with applicable rules. Any false, inaccurate, or questionable claims should be reported immediately to a supervisor, the Compliance Officer, or the General Counsel.

False billing of the Medicare and Medicaid programs, other government payors, and third party payors is a serious offense. Examples of false claims include:

- Claiming reimbursement for services that have not been rendered
- Filing duplicate claims
- "Upcoding" to more complex procedures than were actually performed
- Including inappropriate or inaccurate costs on Hospital cost reports
- Falsely indicating that a particular health care professional attended a procedure or that services were otherwise rendered in a manner they were not
- 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
- Billing separately for services that should be billed as a single service
- Failing to report overpayments or credit balances
- Billing for services that were actually provided entirely by interns, residents or fellows

Hospital employees, professional staff, and agents who prepare or submit claims should be alert for these issues. It is also important to remember that outside consultants only advise the Hospital. The final decision on billing questions rests with the Hospital, its employees, and professional staff. If there is any question whether the Hospital may bill for a particular service, either on behalf of a physician or on its own behalf, the question should be directed to the Compliance Department for review.

The Hospital promotes full compliance with each of the relevant laws related to billing by maintaining a strict policy of ethics, integrity, and accuracy in all its financial dealings. Each employee and professional, including outside consultants, 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 and to raise any questions about the appropriateness or permissibility of a claim or any aspect of a claim to his or her supervisor, the Compliance Officer, the General Counsel, or the confidential Compliance Line hotline (888-801-2805).

False Claims Laws

A variety of federal and state laws applicable to Hospital operations (and physicians and other providers) are designed to prevent fraud, abuse and waste. These laws govern activities including documentation of services, coding, billing, and relationships between providers. Clinicians and managers need to be familiar with these laws and ensure compliance with them.

One of the most important tools the federal government uses in preventing fraud is the federal False Claims Act (31 USC §§3729 – 3733), which prohibits knowingly submitting a false claim or making a false statement to Medicare, Medicaid, or any other federal program. “Knowingly” under this law includes acting with deliberate ignorance or reckless disregard of the truth or falsity of the information in the claim. Neither actual knowledge that a claim is false nor specific intent to defraud the government is required to violate this law. Penalties for violating the False Claims Act include fines between \$5,500 and \$11,000 per claim, plus three times the amount of the claim, and potential exclusion from participation in Medicaid, Medicare and other health care programs.

The False Claims Act includes a “qui tam” or “whistleblower” provision that allows a private individual to bring a lawsuit in the name of the government if he or she has personal knowledge of a false claim. Such a person bringing a claim is called a “relator.” The claim must be presented to the government, which has 60 days to decide whether to intervene and pursue the action itself. A relator may not file a lawsuit under this provision based on public information, unless he or she was the source of the information. If the government decides not to pursue the case, the individual may bring the action directly. If the suit is successful, the relator may share in 15% to 30% of the total amount of the recovery, depending on the individual’s role and whether the government chooses to intervene. The False Claims Act contains protections for whistleblowers that allow them to recover employment reinstatement, back pay and other compensation that arise from retaliation by an employer against an employee for filing a lawsuit under the False Claims Act or for assisting in such an action.

Federal law also provides for administrative remedies for false claims and statements (31 USC §§ 3801-3812) in amounts up to \$5000 per claim or statement plus twice the amount of the claim, and potential exclusion from Medicare and Medicaid participation and “debarment” from eligibility for federal government contracts. These administrative penalty provisions apply to an individual (or organization) making any claim or any statement in connection with a claim (meaning any representation, certification, affirmation, document, record, or accounting or bookkeeping entry) that the individual knows or has reason to know (1) is false, fictitious or fraudulent, or (2) contains a material omission and the omission renders the claim or statement false, fictitious or fraudulent. As with the False Claims Act, no

proof of specific intent to defraud the government is required to find a violation under these provisions.

Massachusetts has a state False Claims Law (MGL ch. 12, §§ 5A-5O) that is similar to the federal False Claims Act and that applies to any claim submitted to the Commonwealth, to any political subdivision of the Commonwealth (such as a city, town or other public authority), or to any contractor if the claim would be paid with money from the Commonwealth. The False Claims Law provides for liability for, among other things, anyone who knowingly submits a false claim, makes a false statement in connection with a claim, conspires to defraud the Commonwealth by allowing the submission of a false claim, or who benefits from inadvertent submission of a false claim and who discovers the falsity of the claim and fails to disclose it to the Commonwealth within a reasonable period of time. As under the federal laws described above, "knowingly" under the Massachusetts False Claims Law includes acting with deliberate ignorance of the truth or falsity of the claim or statement or acting in reckless disregard of its truth or falsity; no specific intent to defraud or actual knowledge of falsity is required. The law provides for fines between \$5000 and \$10,000 per violation, plus three times the amount of damages, plus litigation costs. The law includes a "qui tam" or "whistleblower" provision similar to the federal False Claims Act allowing individuals to bring lawsuits on behalf of the Commonwealth and providing that a relator in such a case may be entitled to between 10% and 30% of any amounts recovered in a successful suit, depending on the circumstances and on whether or not the government decides to pursue the case. The law also prohibits employers from taking any retaliatory action against an employee for disclosing information to the government about a false claim, or for filing or assisting in a lawsuit under the False Claims Law, and allows any employee who is subjected to such retaliation to reinstatement of employment plus two times the amount of back pay lost on account of dismissal plus compensation for other damages.

8.02 Payments, Discounts, and Gifts

The Hospital participates in the Medicare and Medicaid programs. Federal law makes it illegal for the Hospital to provide or accept "remuneration" (including any kickback, bribe or rebate) to induce or in exchange for referrals of Medicare or Medicaid patients. The law also bars the payment or receipt of such remuneration in return for purchasing, leasing, ordering, arranging for, or recommending purchasing, leasing, or ordering of any goods, facilities, services, or items for which payment may be made under Medicare or Medicaid. In Massachusetts, state law prohibits the above-described activities with respect to all third party payors, not just Medicare and Medicaid.

These so-called "fraud and abuse" or "anti-kickback" laws are designed to assure that patient care and Hospital purchasing decisions are based on quality considerations and professional judgment rather than financial considerations. The Hospital is committed to observing carefully these laws and avoiding any practice that may be interpreted as abusive. Employees in the departments of Purchasing, Facilities, Laboratory, Pharmacy, Medical Staff Administration, and any department entering into personal service contracts are expected to be especially vigilant in identifying anti-kickback violations and bringing them to the attention of an appropriate Hospital official (e.g., Compliance Officer, General Counsel, supervisor, etc.).

Fraud and Abuse Laws

The federal and state fraud and abuse laws prohibit the Hospital, its employees, agents, professional staff and affiliates (collectively, Hospital "representatives") from knowingly and willfully soliciting or receiving or offering or paying, any remuneration (whether cash or in-kind benefit), directly or indirectly, in return for the referral of patients or other business that may be reimbursed by a third party payor. It should be noted that an actual referral of a patient or other business is not necessary to a finding of a violation under the fraud and abuse laws. The basic rule is that if just one purpose of an offer or payment of something of value is to influence referrals then the fraud and abuse laws have been violated. This is true whether or not the payment is also compensation for services actually rendered to the entity or person providing the payment.

Since the fraud and abuse laws are drafted broadly and since the courts' interpretation of the laws has called into question almost any payment or offer of anything of value from a vendor to a hospital or physician, it is often very difficult to distinguish between permitted and prohibited conduct. The federal fraud and abuse law itself provides some guidance in this area. For example, under the federal fraud and abuse law, certain vendor discounts are expressly permissible as long as they are properly disclosed and reflected in hospital cost reports. The law also excepts certain payments to employees, as well as certain payments by vendors to group purchasing organizations.

In addition to the exceptions contained in the federal law, the U.S. Department of Health and Human Services has promulgated regulations that describe certain types of activities that will be immune from prosecution under the fraud and abuse laws. These so-called "safe-harbor regulations" are intended to help providers avoid abusive payment practices, while protecting legitimate ones. If an arrangement fits within a safe harbor, it will not be subject to prosecution. If an arrangement fails to qualify under a safe harbor, it does not necessarily mean it is a violation of law. It simply means that if the arrangement were to be scrutinized, the government would apply the same standard of review to the arrangement as it would have prior to the promulgation of the safe harbors, i.e., it will take into account all of the facts and circumstances of the arrangement to come to a decision regarding its legality.

In view of the above, the fraud and abuse laws should be considered whenever something of value is given or received by the Hospital or Hospital representatives in connection with patient services or vendor arrangements. This is particularly true when the arrangement could, because of the incentives provided, lead the Hospital or Hospital representatives to select one vendor over another, over-utilize services or reduce patient choice. The Hospital's Vendor Policy is an important tool in safeguarding against circumstances that could lead to questions about possible violations of these fraud and abuse laws arising from vendor relationships.

There are many Hospital transactions that may violate the fraud and abuse laws if not properly structured. For example, Hospital representatives should not offer gifts, loans, rebates, services, or payments of any kind to a physician who refers patients to the Hospital, or to a patient, without first consulting the Compliance Officer or General Counsel. In addition, the Compliance Officer or his/her designee or the General Counsel should review all discounts offered to the Hospital by suppliers and vendors, as well as discounts offered by the Hospital to insurance companies or other third party payors. Patient deductibles and copayments should not be waived without the prior authorization of the Compliance Officer or General Counsel. Rentals of space and

equipment should be at fair market value, without regard to the volume or value of referrals that may be received by the Hospital in connection with the space or equipment. Agreements for professional services, management services, and consulting services should generally be in writing, have at least a one-year term, and specify the compensation in advance. Compensation should be based on the fair market value of services provided. Payments based on a percentage of revenue generally should be avoided. Joint ventures with physicians or other health care providers, or investment in other health care entities may also implicate the fraud and abuse laws.

Analysis of a payment practice under the fraud and abuse laws and the safe harbor regulations is complex. Employees and staff members should not make unilateral judgments on the availability of a safe harbor for a particular payment practice, investment, discount, or other arrangement. These situations should be directed to the Compliance Officer or reviewed by the General Counsel.

A violation of the federal fraud and abuse law is a felony, and can involve substantial civil and criminal penalties. Violation of the law can also result in the Hospital and/or a physician's exclusion from participation in the Medicare and Medicaid program. A violation of the Massachusetts fraud and abuse laws is also punishable by substantial fines and criminal penalties.

8.03 Market Competition

The Hospital 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 apply to health care services provided by hospitals and physicians.

While the antitrust laws clearly prohibit most agreements to fix prices, divide markets, and boycott competitors—which are addressed below—they also prohibit conduct that is found to restrain competition unreasonably. This type of conduct 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. Direct questions that might arise to the General Counsel.

Discussion with Competitors

Hospital policy requires that the rates it charges for Hospital services and related items, and the terms of its third party payor contracts, must be determined solely by the Hospital. In independently determining prices and terms, the Hospital may take into account all relevant factors, including costs, market conditions, widely used reimbursement schedules, and prevailing competitive prices (to the extent they 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, discounts, credit arrangements, or related terms of sale or service.

To avoid the possibility of misunderstanding or misinterpretation, Hospital policy prohibits any consultation or discussion with competitors relating to prices or terms which the Hospital or any competitor charges or intends to charge. Joint ventures and

affiliations that may require pricing discussions must be individually reviewed for antitrust compliance. Discussions with competitors concerning rationalization of markets, down-sizing, or elimination of duplication ordinarily implicate the antitrust laws and should be avoided.

Hospitals are often asked to share information concerning employee compensation. Hospital policy prohibits sharing with competing hospitals current information or future plans regarding individual salaries or salary levels. The Hospital may participate in and receive the results of general surveys, but those surveys must conform to certain guidelines.

Similarly, Hospital policy prohibits consultation or discussion with competitors with respect to the Hospital's 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.

Trade Associations

The Hospital and its health care providers are involved in a number of trade and professional associations. These organizations promote quality patient care by allowing the Hospital and providers 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 Hospital 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 hospitals. Any price, cost, or wage information released by the Hospital must be at least three months old. If an employee is asked to provide a trade association with information about the Hospital's charges, costs, salaries, or other business matters, he or she should consult the General Counsel. Joint purchasing through a trade association is generally acceptable, but joining any purchasing plan should be reviewed in advance by the General Counsel. If an employee or professional staff member has any question or concern about an activity of a trade association, he or she should consult with the General Counsel.

Boycotts

Hospital policy prohibits any agreement with competitors to boycott or refuse to deal with a particular person or persons, such as a vendor, payor, or other provider. These agreements need not be written to be illegal; any understanding reached with a competitor (directly or indirectly) on such matters is prohibited. Exclusive arrangements with payors, vendors, and providers should be reviewed by the General Counsel.

Physician Services

Hospital credentialing and peer review activities also may have 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 at the Hospital are conducted only through properly constituted committees and officers. Physicians participating in these activities are expected to use objective medical judgment.

If any Hospital employee is involved in negotiating a contract of employment or a personal services contract with a physician or other health care provider, it is important to review with care any non-competition provisions incorporated into the agreement. The appropriate geographic scope and duration of a non-competition agreement may vary from case to case. Direct questions about the appropriateness of a non-competition provision to the General Counsel

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 antitrust violations. If successful, private claimants are entitled to receive three times the amount of damages suffered, plus attorneys' fees.

Unfair or Deceptive Practices

In addition to the antitrust laws, the Hospital is committed to complying with other federal and state laws governing market competition. Federal and state law, prohibit the use of "unfair or deceptive acts and practices," including the distribution of labeling, advertising, and marketing materials that are false or misleading. Hospital employees responsible for preparing and distributing such materials should be familiar with these laws. Direct questions about specific materials to the General Counsel before distribution.

8.04 Physician Recruitment

The recruitment and retention of physicians requires special care to comply with Hospital policy and applicable law. Physician recruitment has implications under the fraud and abuse laws, the Stark law, and IRS rules governing the Hospital's tax-exempt status. Each recruitment package or commitment should be in writing and consistent with guidelines established by the Hospital. The physician cannot be required to refer patients to the Hospital, and the amount of compensation or support cannot be related to the volume or value of referrals. Physician recruitment presents special issues and should be reviewed in advance by the Compliance Officer or General Counsel on a case-by-case basis.

8.05 Independent Contractors and Vendors

The Hospital purchases goods and services from many consultants, independent contractors, and vendors. The Hospital's policy is that all contractors and vendors who provide items or services to the Hospital must comply with all applicable laws and Hospital policies. Each consultant, vendor, contractor, or other agent furnishing items or services should be given a copy of this Manual and should provide a written certification that it is aware of and will comply with the Hospital's Compliance Manual. Contractors should bring any questions or concerns about Hospital practice or their own operations to the Compliance Officer or General Counsel.

Hospital employees or staff members who work with consultants, contractors, and vendors or who process their invoices should be aware that the Hospital's compliance policies apply to those outside companies as well. Employees are encouraged to monitor carefully the activities of contractors in their areas. Direct any irregularities, questions, or concerns on those matters to the Compliance Officer or General Counsel.

8.06 Insider Trading & Confidential Information

The Hospital has relationships with many companies that have publicly traded securities. The Hospital's policy is that no trustee, officer, medical staff member, or employee who possesses material non-public information ("inside information") obtained in the course of that individual's relationship with the Hospital may

- (1) buy or sell securities of such a public company, or
- (2) in any other way take advantage of, or pass on to others, the inside information.
- (3) It is critical for the continued success of Children's Hospital Boston that you not take advantage of the inside information you possess, as even the appearance of an improper transaction can tarnish our reputation for high ethical standards.

Insider Trading

It is generally illegal for any person, either personally or on behalf of others, to buy or sell securities while in possession of material non-public information. It is also generally illegal to communicate (to "tip") material nonpublic information to another person who trades in publicly held securities on the basis of the information or who in turn passes the information on to someone who trades.

Penalties for violating these 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 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 the greater of \$1 million or three times the profit gained or loss avoided as a result of the employee's insider trading violation.

Any and 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, payor 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;
- important product developments;
- major personnel or medical staff changes;
- major litigation developments.

Additionally, information that is likely to affect the price of securities is almost always material.

Information is considered to be non-public 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. Simply because the information, such as budgets, is discussed widely within the hospital, does not mean that such information is public.

When you know material non-public information about the Hospital, you are automatically considered an "insider" and, therefore, you are prohibited from three activities:

- trading in the securities for your own account or for the account of another (including any trust of which you are a trustee or any other entity that buys or sells securities, such as a mutual fund);
- having anyone else trade for you; and
- disclosing the information to anyone else who then trades or in turn "tips" another person who trades

Neither you nor anyone acting on your behalf nor anyone who learns the information from you may trade for as long as the information continues to be material and non-public.

If you are considering buying or selling securities in companies with whom the Hospital does business, and have a question as to whether the transaction might involve the improper use of material non-public information, you should obtain specific prior approval from the President and CEO, the Chief Financial Officer, or the General Counsel. Consultation with your own attorney is also strongly encouraged.

Procedures for Protecting Confidential and Material Nonpublic Information

One basic rule for all of us to follow is to be aware, when appropriate, 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 Hospital's affairs in places where we can be overheard by others -- such as corridors, elevators, the cafeteria, restaurants, and on cellular phones -- and we should be careful about how we handle and dispose of sensitive papers.

Questions about this Policy

Compliance by all personnel with this policy is of the utmost importance to you and to the Hospital. If you have any questions about this Policy generally, or its application to any particular transaction, please contact the General Counsel's office at (617) 355-6108 for additional information. Please remember, however, that the ultimate responsibility for adhering to the Policy and avoiding improper transactions rests with you. In this regard, it is imperative that you use your best judgment.

Failure to observe this Policy could lead to significant legal problems for the Hospital and you, and may have other serious consequences including termination of any hospital affiliation, employment, or removal from the medical staff.

The Compliance Manual



Children's Hospital Boston

Document: CM 09.0.000

09 Response to Investigations

State and federal agencies have broad legal authority to investigate the Hospital and review its records. The Hospital will comply with subpoenas and cooperate with governmental investigations to the full extent required by law. The Compliance Officer and General Counsel are responsible for coordinating the Hospital's response to investigations and the release of any information.

If a department, employee, or professional staff member receives an investigative demand, subpoena, or search warrant involving the Hospital, it should be brought immediately to the General Counsel. Do not release or copy any documents without authorization from the General Counsel. If an investigator, agent, or Government auditor comes to the Hospital, contact the General Counsel immediately. In the General Counsel's absence, contact the Hospital's Chief Executive Officer or a member of the Compliance Committee. Ask the investigator to wait until the General Counsel or his designee arrives before reviewing any documents or conducting any interviews. The General Counsel is responsible for assisting with any interviews. If Hospital employees or staff members are approached by government investigators and agents, the employees and staff members have the right to insist on being interviewed only at the Hospital, during business hours and with counsel present.

If a professional staff member receives an investigative demand at his or her private office and the investigation may involve the Hospital, the staff member is asked to notify the General Counsel immediately.

Hospital employees and staff members are not permitted to alter, remove, or destroy documents or records of the Hospital. This includes paper, tape, or computer records.

Subcontractors of the Hospital who provide items or services in connection with the Medicare and/or Medicaid programs are required to comply with the Hospital's policies on responding to investigations. Subcontractors must immediately furnish the General Counsel, or authorized government officials with information required in an investigation.