



THE COMPLIANCE MANUAL

Boston Children's Hospital is committed to operating in a compliant and ethical manner in all that we do. Our mission is to provide the highest quality healthcare to children and families in our local community every day. The Compliance Department helps individuals understand their responsibilities in adhering to laws and regulations, and encourages continued ethical conduct in all of our daily activities so that we can succeed in realizing our mission. You must also read the Code of Conduct; it will help you be the best employee that you can be during your time here at Boston Children's.

***“At Boston
Children's, we're
committed to
thinking
differently,
finding answers,
and building a
better tomorrow
for children
everywhere.”***

***Kevin B. Churchwell, MD,
President and Chief
Executive Officer***

The Compliance Manual

Table of Contents

Table of Contents..... 1

Introduction 2

Scope 2

Reporting and Whistleblower Protections 2

Equity, Diversity and Inclusion..... 3

Fraud, Waste, & Abuse..... 4

Billing & Coding..... 5

Privacy & Security..... 5

Conflict of Interest..... 6

Gifts 7

Contracting & Vendors..... 8

Research Compliance 8

Physician Recruitment..... 8

Referrals..... 9

Non-profit Charitable Status 9

Investigations 10

Training & Education 10

Conclusion 11

Compliance Department Charter..... 11

Compliance Management Committee Charter..... 13

Committee Approvals 14

Related Policies 15

Document Attributes 15

End Notes 15

The Compliance Manual

Introduction

Boston Children’s Hospital (BCH) provides quality care in a compliant manner. Adhering to the highest standard of professional ethics is part of being a member of the Boston Children’s community. Healthcare is a highly regulated industry, and we must monitor compliance with a wide variety of complex rules that affect our day-to-day activities. We need everyone’s cooperation to comply with all regulations, and bring potential lapses or clear violations to light. This ensures that we deliver quality care to our patients and carry out our mission, values, and objectives outlined in the [Code of Conduct](#).

The Compliance Manual (and all policies and procedures) are tools that help us achieve our mission. The list below highlights important compliance concepts to support BCH department policies and procedures that govern your work here at Boston Children’s. All individuals who work for or provide services to Boston Children’s Hospital are responsible for ensuring that they understand the policies and procedures that apply to their role. An effective compliance program cannot be successful without everyone’s cooperation; and the first step is carefully reading the compliance concepts outlined in this Manual.

Scope

This Manual applies to the Children’s Hospital Corporation d/b/a Boston Children’s Hospital (“Hospital”), its parent corporation, Children’s Medical Center Corporation, and all of its corporate affiliates and satellite locations as well as the Hospital’s affiliated medical foundations (collectively, “Hospital affiliates”), together with all of their respective trustees, directors, officers, employees, independent contractors, medical and research staffs, faculty members, fellows, residents, interns students, visiting faculty or scientists, consultants, and volunteers (whether compensated or not). It also applies to individuals and entities engaged by the Hospital to provide services on its behalf, including but not limited to professional consultants, contractors and vendors. All individuals to whom this Manual applies are responsible for ensuring that they understand this Manual and policies and procedures that apply to their role. Conduct that does not conform to the requirements of this Manual or applicable policies will be subject to discipline.

Reporting and Whistleblower Protections

Being best in class in pediatrics, it’s important our culture/values reflect the world-class health care we provide. If you see something that doesn’t look quite right, or you believe is improper, speak up and report. We expect all who are involved with Boston Children’s Hospital, whether as an employee, a vendor, or students on a clinical rotation, to report compliance concerns. The Compliance Department may reach out with questions related to your inquiry or ask for additional information. We expect you to assist us in the investigation to thoroughly resolve compliance issues.

You may report through the following mechanisms:

- To your Department Leadership (supervisor or manager);
- To the Boston Children’s Hospital Senior Vice President and Chief Compliance Officer:
 - Timothy C. Hogan, JD, FHFMA, CHC (Timothy.Hogan@childrens.harvard.edu / 857-218-4681); or

The Compliance Manual

- To the Anonymous Compliance Hotline which is confidential and operated by an outside third party to protect anonymity.



Anonymous Compliance Hotline at (888) 801-2805

****Interpreter services are available for 237 different languages****

Boston Children's Hospital does not engage in intimidation, retaliation or retribution towards individuals who report compliance concerns in good faith.

We're all part of the same mission of providing world-class care for our patients, and we need your assistance to ensure that whether it's patient care, or business practices, all elements of a health care service are performed with careful attention to the laws, rules and regulations that govern these services. Should you be aware of a suspected compliance issue however fail to report or encourage, direct, facilitate or permit non-compliant behavior, you will undergo the appropriate disciplinary process. For employees, the BCH Human Resources Disciplinary Policy will be followed which outlines disciplinary processes ranging from verbal coaching, written warning, or termination. Individuals who serve in a non-employment capacity, such as a student, volunteer or vendor will have corrective action up to and including termination with their affiliation with BCH. It is the expectation that all compliance-related disciplinary policies are fairly and firmly enforced.

Compliance inquiries to BCH Department Leadership are to be communicated to the Compliance Department for appropriate follow-up.

Equity, Diversity and Inclusion

"Being a leader in equity for all is an attainable goal, and with your support and your dedication, it's a goal we will keep working toward until it's a reality." Kevin B. Churchwell, MD, President and Chief Executive Officer

Boston Children's Hospital is committed to fostering a culture that honors diversity, respect, inclusion, and excellence, both within our system and across our community.

This requires a system of care that treats all patients and our workforce effectively and compassionately regardless of socioeconomic status, race, ethnicity, language, nationality, sexual orientation, gender identity, religion, geography, abilities, age, and life experience.

BCH is united around objectives to enrich our community and reduce healthcare disparities in pediatric care. We aim to advance culturally effective pediatric care through education and scholarship; recruitment and retention of a diverse and inclusive workforce; and support for an environment of respect for different viewpoints. We measure our progress and hold ourselves accountable.

We renew this commitment because not only it is moral and ethical, but also for the fundamental reason it is the right thing to do. Should you have concerns related to equity, diversity or inclusion practices at BCH, you may contact your Department Leadership, Human Resources, or the Anonymous Compliance Hotline (888-801-2805).

The Compliance Manual

Fraud, Waste, & Abuse

Fraud, Waste, & Abuse laws assure that patient care decisions are made on professional judgment rather than by financial considerations. First, you may be asking, what is **Fraud**? In general, fraud is making false representations to obtain some benefit for which you are not entitled. Many different types of healthcare employees have been caught committing healthcare fraud. Examples of fraudulent behavior include knowingly billing for services that were not provided, billing for services rendered by an unlicensed provider, and altering claims to receive a higher reimbursement. Healthcare fraud is punishable by imprisonment for up to 10 years. In addition to civil penalties, you can face criminal fines of up to \$250,000.

Next, you may ask, what is **Waste**? Waste includes overusing services (or other practices) which result in unnecessary costs. Waste is generally not considered a criminally negligent action, but is characterized by the misuse of resources. Examples of waste include conducting excessive office visits; prescribing more medications than necessary for the treatment of a specific condition; and ordering excessive laboratory tests.

Finally, what is **Abuse**? Abuse involves receiving payment for services when there is no entitlement to payment. It differs from Fraud in that it does not require an intentional misrepresentation. Examples of Abuse include billing for unnecessary medical services; billing for brand name drugs when generics can be dispensed; charging excessively for services or supplies; and misusing codes on a claim (such as upcoding or unbundling codes).¹

To help us detect Fraud, Waste and Abuse, you need to be aware of some major governing laws and regulations like the Anti-Kickback Statute (AKS), Physician Self-Referral Law (also known as Stark Law), False Claims Act, and Exclusion Authority.



The **Anti-Kickback Statute** prohibits anyone from knowingly offering to pay or receive anything of value for the inducement of referrals. There are safe harbors that provide exceptions to this rule. Please see below for more specific information as to how the AKS may be implicated.

The **Physician Self-Referral Law (Stark Law)** prohibits a clinician from making a referral of certain services to an entity in which they (or a member of their family) have an ownership/investment interest or compensation arrangement. Like the AKS, there are additional safe harbors (like an employee agreement) that allow for exceptions to this rule.

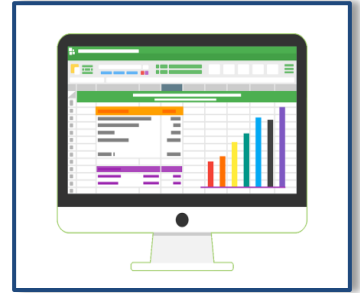
The **False Claims Act** prohibits knowingly making a false claim or statement to the government. Specific intent to defraud is not required for a violation, there just simply needs to be a reckless disregard of the truth.

A number of federal agencies have **Exclusion Authority** that disallows clinicians, institutions, and contractors from submitting claims to the government for reimbursement. Reasons for exclusion include fraud, patient abuse or neglect, felony convictions related to fraud or financial misconduct, or felony convictions for unlawful handling of controlled substances. The Compliance Department monitors published lists of excluded individuals to ensure that we abide by the law.

The Compliance Manual

Billing & Coding

We have an obligation to our patients, the government, and third party payers to exercise due diligence, care, and integrity in all that we do—and this includes submitting accurate claims for reimbursement. Our commitment to a strong Billing Compliance Program stems from our effort to ensure that we do all that we can to prevent Fraud, Waste and Abuse. Many laws cover activities like documentation, billing, coding, and relationships between providers. All employees need to be compliant with these laws.²



Submitting a false claim is a serious offense. Some examples that could lead to a violation are: claiming reimbursement for services that were not performed by the clinician indicated; filing duplicate claims; upcoding to more complex procedures than were actually performed; unbundling;³ billing for services or items that are not medically necessary; and billing excessive charges. Penalties for violating the False Claims Act include fines between \$10,000 and \$20,000 *per claim*, and can potentially include triple damages! It's important to know that the law provides protections for whistleblowers. Anyone may bring a lawsuit on behalf of the government if they have personal knowledge of Fraud, Waste, or Abuse.⁴

Our Billing Compliance team works hard to ensure that we remain compliant with every processed and submitted claim. A patient visit involves many people that have an effect on our billing process. We are all responsible to do what we can to ensure we clearly document services and submit accurate claims. This not only has a financial impact on both Boston Children's and the patient; but it actually has a direct impact on quality of care. Employees (including outside consultants) involved in documenting services and submitting claims must maintain personal responsibility; and must raise any questions about the appropriateness or permissibility of any aspect of a claim.

Privacy & Security

We are legally required to safeguard and protect the privacy of patient information. A violation of a patient's confidentiality is taken very seriously. Discussing or providing patients' confidential information to anyone other than authorized personnel is strictly prohibited. Please be aware of your environment when discussing confidential information, and remember that you should never discuss confidential patient information for an unrelated work purpose.

Always ask yourself . . .

- 1. Do I need this information to do my job?**
- 2. Does the person I am telling need it to do their job?**
- 3. Am I the right person to be using or disclosing the information?**

Employees and staff must always preserve the confidentiality and integrity of medical records. Medical records are confidential, which means that they may not be released except with the consent of the patient, or in other limited circumstances.⁵ They should not be physically removed from their clinical location, altered, or destroyed. No employee is permitted to access a patient's record without a legitimate work-related reason. Any unauthorized release of or access to medical records must be reported to a supervisor, the Compliance Department, or through the Anonymous Compliance Hotline.

Business Associate Agreements approved by the Privacy Officer are required for outside entities that are providing services to the organization that requires the transmission of protected health information. Data Use Agreements are also required in cases where limited data sets of

The Compliance Manual

information are sent to another entity. The Compliance Department maintains a comprehensive inventory of [Business Associate Agreements](#) on SharePoint.

Computer and network resources must also be used in a professional, ethical, and lawful manner. Your privacy rights do not extend to your use of the resources (including email, Internet, and any information stored on or transmitted over the network). Stored or transmitted information on computer and network resources is the sole and exclusive property of Boston Children's, and remains so even when stored on your personal laptop and/or mobile device. You are required to take all reasonable precautions to protect the integrity, access, and confidentiality of computer and network resources. Employees must only access information that is required for the performance of their job-related duties. Your access to the network may be monitored at any time and without prior notice and please note that employees must comply with the requirements outlined in the [Acceptable Use of Computer and Network Resources Policy](#). You must also be aware of other privacy and security policies in the [Information Security Manual](#) and [Compliance Department's Intranet Website](#).

Conflict of Interest

Many of the relationships discussed in this manual are subject to Boston Children's and Harvard Medical School's Conflict of Interest Policies. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders (like universities, companies, and the government). Some of those who are required to report include key personnel, executive management, trustees, researchers, research fellows and others. We maintain an online review system called Boston Children's Hospital eResearch Portal (CHERP) that helps us track all financial disclosures in an efficient manner.

Boston Children's recognizes that business activities and their associated expenses are not problematic. However, as a rule of thumb, employees should strive to avoid conflicts of interest. When a conflict is in fact unavoidable, you need to disclose it. There is an obligation to disclose financial relationships even if they are legal. The federal government requires collection of information about the payments drug and device companies make to physicians and teaching hospitals for things like travel, research, gifts, speaking fees, and meals. It also includes ownership interests that physicians or their immediate family members have in these companies. This data is made available to the public each year on the [Open Payments](#) website.



When evaluating your COI, consider the 'newspaper test' and ask yourself whether you would want the arrangement to appear on the front page of your local paper. The pharmaceutical industry (through PhRMA) and medical device industry (through AdvaMed) have adopted codes of ethics regarding relationships with healthcare professionals.⁶ Please contact the Conflict of Interest Officer in the Compliance Department with any questions.

The Compliance Manual

Gifts

The general topic of Gifts runs through many of the concepts outlined in this manual. Gifts can involve Conflicts of Interest, Contracting and Vendors, and implicate Fraud, Waste, and Abuse laws. As mentioned above, it is illegal for a clinician to give or receive a gift (or anything of value) to induce referrals. This means that we have to be acutely aware of some of the patient benefit programs that we operate. In the same regard, we need to be vigilant in ensuring that the benefits that our physicians receive are legal and ethical.



There are many examples of illegal gifts that make headlines almost on a weekly basis in the healthcare industry; some notable ones are: (1) A medical laser company agreed to pay \$126K to settle allegations of providing physicians an all-expense paid trip to the Masters Golf Tournament; (2) A drug company was alleged to have operated multi-million dollar incentive programs for doctors who steered patients toward its drugs. Incentives included payments for speaker programs that did not occur at all or that had few or no attendees; and were held where it would have been virtually impossible for any presentation to be made (like during fishing trips off the Florida coast); and (3) A blood lab bribed a doctor who took money, tickets and meals to refer his patients' samples to the lab. The deal only generated \$900K in business, but prosecutors sought \$50M from the physician.

Although some individuals believe that free lunches, subsidized trips, and gifts do not affect their judgment, research shows that these types of gifts can influence decision-making practices. Conversely, while we would like to offer some benefits to our patients to enhance their experience working with the Boston Children's community, the truth is that some of these practices may implicate the Anti-Kickback statute. Not only is the organization implicated, but also there can be individual repercussions involving illegal gift practices.

The **Foreign Corrupt Practices Act** is a law that all members of the workforce should be knowledgeable about. It prohibits paying or offering anything of value to a foreign official, directly or indirectly, with the intent to corrupt the official for obtaining an improper business advantage. This law requires institutions to maintain accurate internal controls, books and records so bribes cannot be hidden. "Anything of value" is broadly interpreted to include, among other prohibited items: cash, gifts, meals, entertainment, medical care, or offers of employment. Importantly, physicians and researchers outside the United States are often considered foreign officials for the purposes of this law.

As an international leader in clinical and scientific research, Children's interacts with foreign entities and people on a daily basis. Some of these activities include: importing/exporting healthcare products, medical devices, or research materials with a foreign country; enrolling foreign nationals in professional or continuing education courses; providing services to or receiving funds from foreign nationals; and conducting international research collaborations. The federal government enforces economic and trade sanctions based on foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, and others engaged in threats to the national security, foreign policy or the economy. Upon request, the Compliance Department can screen these individuals and entities to ensure that we are not interacting with any sanctioned individuals or entities.

The Compliance Manual

Contracting & Vendors

Fraud, Waste and Abuse laws also cover interactions with vendors, and it is often very difficult to distinguish between permitted and prohibited conduct. For example, certain vendor discounts are expressly permissible as long as they are properly disclosed and reflected in our cost reports. The OGC should be consulted whenever something of value is transferred in connection with patient services or vendor arrangements. This is particularly true when the arrangement could, because of the incentives provided, lead the organization to select one vendor over another. Employees in the departments of Purchasing, Facilities, Laboratory, Pharmacy, Medical Staff Administration, and any department entering into professional service contracts are expected to be especially vigilant in identifying potential violations. Our [Vendor Policy](#) helps us safeguard against possible violations.



When it comes to vendor interactions and contracting, employees should never make unilateral judgments. Vendor discounts offered to or from the organization must be reviewed by the OGC (this includes those involving insurance companies or other third party payers). The OGC drafted a [Contract Standard Operating Procedure](#) that provides a formal process

for the legal review of contracts; which includes authorization, preparation, execution, and document retention requirements. If you have a contract requiring review, you must send a request directly to OGC.ContractRequest@childrens.harvard.edu.

Research Compliance

The shared mission for clinical and basic research is to alleviate and prevent human suffering caused by illness, and it is our aim to assist researchers that work in this common effort. We strive to maintain the highest standards of honesty, integrity, and professionalism in our research. It is imperative to maintain our patients' confidence in our studies. They must be certain that our research is well justified, and that the risks are reasonable in relation to the potential benefits. Researchers owe their primary duty to the patient and research subject, and should never place vulnerable patients at risk.

Key processes for maintaining research integrity include independent peer review and oversight, replication, and accountability at each stage of research. Our [Research Misconduct Policy](#) addresses the instances in which some or all of these processes are alleged to have broken down.⁷ Our primary goal is to foster an ethically responsible environment so that evidence of potential misconduct is reported in a timely manner. Equally important is informing researchers about our policies and procedures, and our commitment to institutional and governmental compliance.



Physician Recruitment

Compensation paid to providers for recruitment, employment, professional services, and retention is **commercially reasonable**, and determined by **fair market value**. Fair market value partly determines compensation, and focuses on specialty and educational background as compared to other similar providers in the marketplace. Similarly, commercial reasonableness encompasses overall compensation and benefits. Employment, professional services, management services, and consulting services agreements should be in writing and negotiated at arm's length; have at least a one-year term; and specify both the compensation and services in advance. Provided services must be reasonable and necessary for legitimate purposes. Payments based on a percentage of revenue should be

The Compliance Manual

avoided, but some physician incentive plans are acceptable if specific requirements are met and they never take into account the volume or value of referrals.



Other particular areas of concern on this topic are below-market rents and loans, compensation tied to organizational or department revenues, joint ventures, income guarantees (especially where there is no obligation to repay), and loan guarantees. We also have a comprehensive [Housing and Education Loan policy](#) that provides guidance for terms and amounts that must be in alignment with current competitive market conditions.

Leases for physician office space must be in writing and be at least one year in length. A lease agreement must be specific and must not exceed the space reasonably needed for the provider's legitimate business 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. Any compensation arrangement involving one or more of these benefits must be reviewed by the OGC. Employees that suspect a violation of this policy (e.g., an agreement is not at fair market value or commercially reasonable) must report it to the Compliance Department or OGC.

Referrals

We are the global leader in referrals for pediatric care, and patient referrals are very important to the delivery of quality services. Patients are admitted or referred to us by their physicians, and we may then refer them to other facilities (such as skilled nursing or rehabilitation facilities). Patients may also need referrals to suppliers of various healthcare items and services. They are free to select their healthcare providers and suppliers. The choice must be made by the patient, with guidance from the organization and their physician as to which providers are qualified and medically appropriate.

Providers may have financial relationships with the Boston Children's and our affiliates. These relationships may include compensation for administrative or management services, income guarantees, loans of certain types, or free or subsidized administrative services. These sorts of relationships are governed by the Stark law (see above). This applies to physicians (including immediate family members) that have a financial relationship with an entity (such as the Hospital). It prohibits referrals by that physician to the Hospital for the provisions of certain healthcare services, unless the relationship falls within a specific exception to the prohibition. These exceptions are called safe harbors and the most common one is the exception for physicians that are employees of the organization. There are other exceptions to the laws that help providers avoid abusive payment practices and protect legitimate ones. Additionally, patient deductibles and copayments should only be waived according to Boston Children's policy. Situations involving referrals are complex, and several rules must be followed. Please contact the OGC to ensure that you are in a compensation arrangement that handles referrals in a compliant manner.



Non-profit Charitable Status

Boston Children's started as a hospital for poor urban children in 1869. We are a safety net hospital for the most critically ill children, most of who come from low-income families. We partner with surrounding neighborhoods to address the most pressing healthcare needs in the community. As a non-profit charitable organization, all of the hospital's resources go toward supporting these goals. Being a non-profit charitable organization means that we are

The Compliance Manual

a 501(c) (3) tax-exempt organization. This permits us to accept tax-deductible charitable contributions. In order to justify our tax-exempt status we must meet IRS requirements that include: operating a full-time emergency room; providing non-emergent services to Medicare and Medicaid recipients; maintaining an open medical staff; having oversight of a Board of Trustees that includes independent civic leaders; providing medical training, education and research programs; and, having a formal charity care policy.

It is imperative to meet these criteria because ninety-five percent of all major academic medical centers have a non-profit charitable status. It also allows us to focus on our mission rather than meeting quarterly demands of stockholders. Loss of exempt status would result in substantial penalties and the inability to receive these contributions. We must be organized and operate exclusively for charitable purposes to maintain a tax-exempt status; and net earnings may not benefit private individuals. Please note, an activity that benefits a private person, but also furthers a public purpose, may still qualify as exempt. A private benefit must be incidental to the primary public benefit.

Investigations

Government agencies have broad legal authority to investigate and review our records. We require you to comply with subpoenas and cooperate with governmental investigations to the fullest extent required by law. The Chief Compliance Officer and OGC are responsible for coordinating the response to investigations and for the release of any information. It is imperative to respect the legal rights of the institution, and the privacy of our employees and patients. Please immediately notify the Compliance Department and OGC if you receive an investigative demand, subpoena, or search warrant involving the organization. Do not copy or release documents without authorization. Please also notify Health Information Management for requests involving medical records and protected health information.



Contact the Compliance Department and OGC immediately if a government agent contacts you. Ask the investigator to wait until the OGC arrives before reviewing any documents or conducting any interviews. The OGC is responsible for assisting with interviews. Employees have the right to insist on interviewing only at a Boston Children's location, during business hours, and with counsel present. It is important to remember that the OGC represents the hospital's interests and acts on its behalf, even when it may conflict with your own personal interest. If a professional staff member receives an investigative demand at their private office, and the investigation may involve Boston Children's, the staff member must immediately notify the OGC. Subcontractors providing items or services are required to comply with our policy on responding to investigations. Subcontractors must immediately furnish the OGC or authorized government officials with information required in an investigation.

Records should never be destroyed if there is an ongoing or anticipated claim, audit, investigation (internal or external), appeal, or litigation. If you receive notice that your files are under a legal hold by the OGC, then you have a legal duty to preserve all evidence. This applies even if the records could be deleted in the normal course of operations. You must also preserve any newly generated electronic information after you receive a notice.

Training & Education

Boston Children's provides general and specialized training on the topics covered in this Manual. Each year, individuals are required to complete annual mandatory training modules on topics such as Compliance, Patient Privacy, and Information Security.

The Compliance Manual

Conclusion

Complying with these principles is of the utmost importance to ensure that we operate ethically as an organization. If you have any questions about their application, please contact the Compliance Department at 857-218-4681. Failure to observe these principles could lead to significant legal problems. Please remember, however, that the ultimate responsibility for adhering to compliance standards and ethical behavior ultimately rests with you. Please use your best judgment.

Compliance Department Charter

Purpose

To affirm the commitment of Boston Children's Hospital to abide by all federal and state laws, regulations, and rules governing its operation, and to conduct business at all times in a manner that is consistent with the highest professional standards for honesty and integrity. All individuals are required to carry out their duties in accordance not only with all applicable laws and regulations, but also in accordance with the Boston Children's policies.

Program Description

Boston Children's recognizes that conscientious adherence to the highest professional standards is essential to its mission. This commitment is important because a failure to comply with applicable laws and regulations could affect participation in government healthcare programs. We are committed to meeting the highest standards for honesty and integrity in all business practices.

For these reasons, Boston Children's established the Compliance Department to maintain and assist the Hospital with implementation of a Compliance Program. The Compliance Department is charged with helping individuals to understand their responsibilities in complying with federal and state legal requirements, as well as proper business conduct. This includes the statutes, regulations, and guidelines of federal and state healthcare programs, as well as the policies and procedures of private health plans.

Although the implementation and enforcement of the Compliance Program is centrally directed by the Chief Compliance Officer (CCO), the responsibility for compliance rests with each department and service. Boston Children's may assign responsibility for management and oversight of compliance-related activities to a specific individual, department, or committee as appropriate. Compliance is the responsibility of every individual. In accord with this policy, all individuals are responsible for familiarizing themselves with internal policies and procedures, which are available through SharePoint and the intranet website. The seven elements of Boston Children's Compliance Program include the following:

1. Chief Compliance Officer and Compliance Management Committee, whose combined roles include the responsibility and authority to direct efforts in maintaining compliance;
2. Written policies and procedures – including the Boston Children's Hospital Code of Conduct – to guide appropriate business and professional practices;
3. Several different methods for reporting potential noncompliance issues or other areas of concern without fear of retribution;
4. Effective training and education programs to promote an understanding of and adherence to applicable federal and state laws, regulations, and rules;
5. Internal monitoring and auditing to verify compliance, identify the need for corrective action, and/or improve training and education activities;

The Compliance Manual

6. Responding to detected noncompliance and developing corrective action initiatives, including disciplinary actions, policy changes, or other corrective measures; and
7. Enforcing standards through well-publicized disciplinary guidelines.

Investigation of potential compliance issues, whether reported to BCH Compliance or identified by audits or self-evaluations are led by the BCH Compliance Department. The assignment of the appropriate Compliance investigator is determined based on the Compliance team member's skill sets. Compliance fieldwork for investigation of issues consists of documentation reviews, interviews and/or root cause analyses. Findings from investigations are documented and compliance issues are corrected promptly and thoroughly. Policies and procedures to resolve the compliance issues are implemented, as applicable, so as to prevent recurrence. Follow up reporting, including corrective action, occurs to the BCH Compliance Management Committee (CMC).

New York Medicaid-Per the New York State Social Services Law Section 363-d and title 18 New York Code of Rules and Regulations Part 521, compliance issues pertaining to New York Medicaid services will be reported to the New York Office of Medicaid Inspector General or the New York State Department of Health.

For compliance matters involving intimidation or retaliation, reporting will occur to appropriate officials as identified in the New York State Labor Law sections 740 and 741.

Objectives

The objectives of the Boston Children's Compliance Program are to:

- Demonstrate the commitment of Boston Children's to honest and responsible corporate conduct;
- Increase the likelihood of preventing, detecting, and correcting unlawful or unethical behavior at an early stage;
- Encourage individuals to report potential problems to allow for appropriate internal inquiry and corrective action; and
- Minimize any financial loss, through early detection and reporting, to government healthcare programs, as well as any corresponding financial loss to the Hospital.

Chief Compliance Officer

The Boston Children's Compliance Department is directed by the Chief Compliance Officer (CCO). The Compliance Department is sited with the Office of the General Counsel. For administrative needs, the CCO reports to the General Counsel. In addition, the CCO shall have direct access to the Chief Executive Officer and to the Board of Trustees as deemed necessary by the CCO. The CCO will be provided with the necessary resources to effectively implement and operate the Program. The CCO may inquire into any matters within the purview of the Program including, but not limited to; matters involving unethical conduct; billing, claims, or payments; and regulatory compliance. Accounting, legal, and other personnel will be available to assist in these duties.

The CCO is empowered to investigate and report possible recommendations or initiatives to the CEO, OGC, or Compliance Management Committee (this may include disciplinary and other corrective measures). The CCO shall have access to all information relevant to compliance activities including, but not limited to: patient records, billing records, contracts and written arrangements or agreements with others. The CCO may seek advice of independent legal counsel and retain consultants. The CCO will design and implement an annual compliance work plan to prevent, detect, and correct potential violations of laws, regulations, rules, or Hospital policies. The work plan will include any scheduled auditing and monitoring activities for the upcoming year. If a non-scheduled compliance

The Compliance Manual

issue is identified through a routine audit, re-audit, or as the result of a reported violation, the Compliance Officer is responsible for prioritizing the matter as appropriate.

The Compliance Officer is responsible for developing, coordinating, and participating in educational and training efforts that focus on the elements of the Compliance Program, and that seek to ensure that individuals are knowledgeable of, and comply with, relevant federal and state laws and regulations. Education and training efforts may include, but are not necessarily limited to mandatory orientation programs, annual on-line training, informational bulletins, newsletter articles, staff meeting presentations, and individual educational sessions.

The CCO administratively reports to the General Counsel on inquiries conducted, recommendations for action, and all related matters. The CCO advises the Compliance Management Committee (CMC) at least quarterly on the status and activities of the Program. In addition, the CCO reports compliance matters to the Board of Trustees Audit and Compliance Committee. This Committee reports to the full Board of Trustees. As noted above, Boston Children's may also assign responsibility for management and oversight of certain compliance-related activities to a specific individual, department, or committee. The CCO will advise and collaborate with members of the workforce to develop and maintain effective compliance controls.

Compliance Management Committee Charter

Purpose

The Compliance Management Committee advises and assists the Chief Compliance Officer in the development and management of the Compliance Program. The Committee meets at least quarterly or more frequently as needed. It oversees primary compliance issues and objectives that are reported to the Board of Trustees Audit and Compliance Committee by the CCO. The Audit and Compliance Committee reports to the full Board of Trustees to ensure the highest level of organizational oversight.

Composition

The Committee is composed of the following positions below (listed alphabetically). The Committee may add other members and/or invited guests as deemed appropriate by the Committee or CCO.

- Chief Compliance Officer (Chair)
- Chief Financial Officer, Physician's Organization
- Chief Information Security Officer
- Chief Operating Officer, Physician's Organization
- Compliance Program Coordinator
- Compliance & Privacy Specialist
- Senior Director, Financial Reporting, Physician's Organization
- Director, Billing Compliance
- Internal Audit (PwC)
- Conflicts of Interest Officer
- President, Physician's Organization
- Privacy Officer
- Research Compliance Officer
- SVP, Chief Administrative Officer
- EVP, Finance/IT/Real Estate/Chief Financial Officer
- SVP of Information Services, Chief Information Officer

The Compliance Manual

- SVP, Chief Safety and Quality Officer
- SVP, General Counsel, Chief of Staff
- SVP, International Health Services
- SVP, Patient Care Operations and Chief Nursing Officer
- SVP, Chief Human Resources Officer
- SVP, Real Estate Planning and Development
- VP, Hospital Revenue Cycle
- VP, Clinical Services
- VP, Finance
- VP, Patient Safety, Quality and Clinical Regulatory Compliance
- VP, Research Administration.
- VP, Health Affairs
- Senior Director, Finance Operations
- Representative(s) from the Foundation Directors to be designated

Responsibilities

Members provide input in the following areas:

- Analysis of industry environment, legal requirements, and specific risk areas;
- Assessment of existing policies and procedures that address legal requirements and compliance risk areas to determine if they appropriately address the requirements and risks;
- Development of new policies and procedures that address legal requirements and compliance risk areas as needed.
- Annual review and updates are given as needed to the following:
 - Compliance Management Committee Charter; Compliance Program and Department Charter; Compliance Work Plan; Code of Conduct;
 - Internal systems, processes, and controls designed to implement compliance standards, policies, and procedures, as part of daily operations;
 - Protocols for compliance audits to monitor compliance standards, policies, and procedures as part of daily operations;
 - Training to educate board members, physicians, employees, and staff about the Compliance Program, standards, policies, and procedures;
 - Operations of an Anonymous Compliance Line and other methods of reporting compliance and privacy concerns; and processes to investigate and respond to reported concerns.

Committee Approvals

Adopted by the Compliance Management Committee on May 9, 2017, with revisions approved on October 6, 2020 and August 10, 2021.

Adopted by the Board of Trustees on July 18, 2017, with revisions approved on January 25, 2021 and November 30, 2021.

The Compliance Manual

Related Policies

Date	Policy	Reviewer
11/30/2021	Code of Conduct	Timothy C. Hogan, JD, FHFMA, CHC
06/2018	Vendor Policy	David Walsh, CMRP
01/24/2019	Research Misconduct Policy	Fariba Houman, PhD
01/27/2020	Conflict of Interest Policy	Timothy C. Hogan, JD, FHFMA, CHC
03/18/2021	Acceptable Use of Computer and Network Resources Policy	Paul Scheib / Dave Clark
09/01/2018	Housing and Education Loan Policy	Office of the General Counsel

Document Attributes

Title	The Compliance Manual		
Author	Mary Beckman, JD	Effective	06/20/2007
Reviewed by	Timothy C. Hogan, JD, FHFMA, CHC	Reviewed	10/12/2011, 08/01/2016, 07/18/2017, 01/25/21, 11/30/21
Copyright	© Boston Children's Hospital 2022	Revised	07/18/2017, 01/25/21, 11/30/21
Approved	Signature on file _____ Timothy C. Hogan, JD, FHFMA, CHC Senior Vice President and Chief Compliance Officer		

End Notes

¹ CENTERS FOR MEDICARE AND MEDICAID, *Medicare Fraud & Abuse: Prevention, Detection and Reporting*. MLN Network (Nov. 2012).

² 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.

³ Defined as billing separately for services that should be billed as a single service.

⁴ Massachusetts has a state False Claims Law (M.G.L. c. 12, §§ 5A-5O) that is similar to the federal False Claims Act and that applies to any claim submitted to the Commonwealth.

⁵ Special protections apply to mental health records, records of drug and alcohol abuse treatment, and records relating to HIV infection.

⁶ DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*, (accessed Feb. 2017).

⁷ Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. It does not include honest error or differences of opinion. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.