COMPLIANCE PROGRAM MANUAL

SEPTEMBER 2023

STANDARDS OF CONDUCT AND COMPLIANCE

COMPLIANCE PROGRAM MANUAL

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PREFACE

Huntington Health continues its commitment to conduct all business affairs with integrity and in compliance with federal and state laws, as well as private payer health plan requirements. Hospital policies on ethical and legal conduct are designed to prevent, detect, and correct any violations of the law. Standards of Conduct and other related policies have been implemented to reflect these commitments to the law.

Huntington Health has implemented a Compliance Program to conform its operations to the Federal Government's efforts to promote voluntarily developed and implemented programs to prevent fraud, waste, and abuse within the health care industry.

This *Compliance Program Manual* ("Manual") sets forth the means by which the Standards of Conduct and related policies are implemented and monitored. It defines the following areas related to the Compliance Program:

1. An introduction to compliance concepts
2. A description of the Compliance Program structure and function
3. A review of the Standards of Conduct
4. Department-specific Compliance Programs including the following:
    a. Laboratory (Appendix A)
    b. Patient Financial Services (Appendix B)

Huntington Health has entrusted its management personnel with the responsibility of achieving compliance with the Standards of Conduct and related policies. All management personnel are expected to set an example for their employees by conducting their duties in compliance with the Compliance Program. Further, management personnel are responsible for ensuring that their employees understand and follow the Standards of Conduct and related policies.

Although the term "employees" is used as the target audience throughout this manual, the general principles of compliance are applicable to all volunteers, members of the medical staff, and individuals or organizations contracted with Huntington Health.

For additional information on Huntington Health's Compliance Program or requests for educational presentations related to compliance issues, please contact Huntington Health's Compliance Officer at 626.397.5335.

Please submit all suggestions for modifications or updates of this Manual to the Compliance Officer.

THE COMPLIANCE PROGRAM RESOLUTION

Since 1997, Huntington Hospital's Compliance Program has operated under the auspice of Southern California Healthcare Systems' (SCHS) corporate compliance structure. With the formal dissolution of SCHS in December 2005, Huntington Hospital assumes complete oversight of its Compliance Program and, by this Resolution, reaffirms its commitment to the highest standards of ethical conduct, integrity and compliance with all applicable laws, rules and regulations of any federal, state or local governmental body with jurisdiction over the hospital.

RESOLVED, that the Board of Directors of Huntington Hospital is committed to the highest standards of ethical conduct and integrity in keeping with the hospital's Mission Statement and Core Values hereby reaffirms its commitment to absolute conformity to and compliance with all applicable laws, rules and regulations of any federal, state or local government body with jurisdiction over the hospital, including, without limitation, any provisions related to billing, payment and reimbursement; and further

RESOLVED, that the Board reaffirms Huntington Hospital's commitment to meet the recommendations outlined in the Department of Health and Human Services (DHHS) - Office of Inspector General's (OIG) Compliance Program Guidance for Hospitals (February 1998) and the Supplemental Compliance Program Guidance for Hospitals (January 2005) based on the United States Federal Sentencing Guidelines and all other compliance program guidance as applicable to the hospital's operations.

RESOLVED, that the Board authorizes and directs that the Hospital's Compliance Program continue to include, at a minimum, the following elements:

1. *The development and distribution of written standards of conduct, as well as written policies and procedures that promote the hospital's commitment to compliance;*
2. *The designation of a compliance officer and a compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;*
3. *The development and implementation of regular, effective education and training programs for all affected employees;*
4. *The maintenance of a process to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;*
5. *The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;*
6. *The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and*
7. *The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.*

PASSED AND ADOPTED at the meeting of the Board of Directors of Huntington Hospital held June 22, 2006.

I. INTRODUCTION

A. OBJECTIVE OF THE COMPLIANCE PROGRAM

1. Huntington Health's Compliance Program is designed to establish a culture within the organization that promotes prevention, detection, and resolution of instances of conduct that are not consistent with its Standards of Conduct or which do not conform to federal and state laws and regulations, and private payer health plan requirements.

B. MISSION STATEMENT AND CODE OF ETHICAL BEHAVIOR

1. Huntington Health's Mission Statement defines the organization's purpose and mission to excel at the delivery of health care to our community through the Core Values of respect, integrity, stewardship excellence and collaboration[1]. The Standards of Conduct define the approach Huntington Health will take in order to carry out its care-giving mission[2]. The Standards of Conduct encompass a wide-range of compliance issues and related policies as a means of providing health care with integrity, honesty and accuracy. The Standards of Conduct applies to all employees of Huntington Health. Each employee is personally responsible and accountable for his or her own conduct in complying with these Standards.

2. The Mission Statement and Core Values are the guiding philosophies which govern the conduct of all employees. In addition, the Standards of Conduct and other related policies referenced are statements of policy with which all personnel must comply.

3. Employees are often affiliated with professional organizations which adopt their own ethical standards. Employees are encouraged to abide by the ethical standards adopted by their individual professional associations also, as such organizations are able to address ethical challenges specific to an employee's specialty, expertise and industry that cannot be as comprehensively addressed by the Standards of Conduct or this Manual.

C. FOUNDATIONAL COMPLIANCE CONCEPTS

1. The concepts and issues described in this Manual assume an underlying commitment to foundational compliance principles. The following is a description of some of those principles:
   a. *The Spirit and the Letter of the Law*: The "letter" of the law refers to the actual written word on the legal page which describes, in detail, the application of certain laws. The "spirit" of the law, as the name implies, is the spirit in which the law was written, or the intent of the law. It is not possible to write a law in such a way that it can accommodate for every instance in which that law might be violated. As such, employees are required to abide by both the spirit of the law and the letter of the law.
   b. *Avoid the Appearance*: One's actions may not actually be in violation of the law, but it may "appear" that they are in violation of the law. Employees are strongly encouraged to avoid even the appearance of violating the law. No matter how innocent in fact a particular act

[1] See policy and procedure #001, "Mission, Vision and Core Value Statements"
[2] See policy and procedure #013, "Standards of Conduct"

may be, if it is one that can lead others to believe that a violation may have occurred, an investigation or other legal action may result. The Compliance Program is aimed at identifying processes or events throughout the organization that may even "appear" to be out of compliance with the law in order to resolve such instances and avoid unnecessary audits, investigations or other legal action from government enforcement agencies.

c. *Conscious Avoidance*: Conscious avoidance is defined as a deliberate "closing of the eyes" and pretending not to know when someone may be violating a law. The Compliance Program's objective is to seek out instances of conduct that do not comply with laws or regulations and resolve them, thereby having no ramifications from government or other law enforcement agencies. If employees identify instances of conduct that may be in violation of the law, they should report such instances to their manager or to the Compliance Officer.

d. *Collective Knowledge*: Collective knowledge represents the total sum of an organization's knowledge of a process or event. Even though individual components of a process may not be in violation of a law or regulation, the collective actions of an organization (or lack thereof) could equate to a violation. Corporations compartmentalize knowledge, subdividing the elements of specific duties and operations into smaller components. The aggregate of these components constitutes the organization's collective knowledge of a particular operation. It is irrelevant whether employees administering one component of an operation know the specific activities of employees administering another aspect of the operation. Management personnel are strongly encouraged to examine the collective processes throughout their departments, and between departments, to ensure compliance with the law. The key is to identify means of improving system processes in order to maintain legal compliance.

e. *Intent*: A key element in determining violations of the law is intent. Did the individual or organization *intend* to violate the law? This reveals whether or not an outward, conscious effort to violate the law exists.

f. *Reckless Disregard*: In an industry as complex as health care, it is conceivable that human error represents a factor that contributes to violations of the law, albeit unintentionally. However, if an organization is conducting its business practices in such a way that due diligence is not taken to ensure that its operations and practices are in compliance with the law, it could be construed that the company is acting with reckless disregard. Staff education, training, audits, monitoring and other proactive approaches to ensuring compliance with the law constitute appropriate efforts to conducting business with responsible due diligence. Without such programmatic functions in place, errors found could place a company in a difficult position to prove that it has otherwise acted with conscious integrity.

D. WHAT IS THE COMPLIANCE PROGRAM?

1. The Compliance Program is designed to keep the organization in compliance with applicable legal requirements by deterring and detecting actual or alleged violations of laws and regulations. The Compliance Program focuses on issues related to fraud and abuse, Medicare and Medi-Cal billing regulations, insurance and HMO laws, employment/personnel policies (e.g., discrimination, harassment, etc.), managed care regulations, antitrust laws, tax (and tax exemption) issues, confidentiality and privacy issues, ethics in the workplace, etc.

2. Office of Inspector General Compliance Program Guidance Manuals: To combat Medicare fraud, waste and abuse, the Department of Health and Human Services' (DHHS) Office of Inspector General (OIG) has issued several manuals on voluntary compliance programs including, among others, the *Compliance Program Guidance for Hospitals* (February 1998), the *Supplemental Compliance Program Guidance for Hospitals* (January 2005), *Compliance Program Guidance for Clinical Laboratories* (August 1998), and the *Compliance Program Guidance for Third-Party Billing Companies* (November 1998). These publications provide the foundation for the Compliance Program as presented in this Manual. It has been built upon the U.S. Sentencing Guidelines' seven elements of an effective compliance plan which include:
   a. Written Standards of Conduct
   b. Oversight Responsibilities including designation of a Compliance Officer and a Compliance Committee
   c. Conducting Effective Education and Training
   d. Developing Effective Lines of Communication
   e. Consistent Enforcement of Standards
   f. Auditing and Monitoring
   g. Responding to Detected Offenses and Developing Corrective Action Initiatives

E. WHY IMPLEMENT A COMPLIANCE PROGRAM?

1. Since the early 1990's, the government has highly scrutinized health care providers regarding compliance to the laws and regulations that govern the health care industry. Legislation is aimed at ensuring compliance with regard to health care funded by Medicare and Medi-Cal including the following:
   a. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191)
      i. The Health Insurance Portability and Accountability Act, more commonly referred to as HIPAA, Kassebaum-Kennedy Act, or Kennedy-Kassebaum Act , included what is widely considered the most comprehensive set of anti-fraud provisions to affect the health care field since the 1986 amendments to the Civil False Claims Act.
      ii. HIPAA's impact on the health care field is evidenced in the strengthening of existing civil and criminal penalties for fraud and abuse, and the expansion of the government's role in investigating and prosecuting health care fraud in the private sector. HIPAA's impact will be felt through its Fraud and Abuse Control Program through revisions to current sanctions for fraud and abuse violations and increased civil monetary penalties.
   b. Balanced Budget Act of 1997
      i. The Balanced Budget Act includes several anti-fraud provisions that include tougher enforcement rules for providers and stronger sanctions as well as the closing of loopholes that may have allowed fraud and abuse to occur. The Act also imposes civil monetary penalties for individuals who contract with an individual or entity previously excluded from participating in the Medicare program.
   c. Fraud Enforcement and Recovery Act of 2009
      i. The Fraud Enforcement and Recovery Act of 2009 places greater scrutiny on providers of health care services, broadens the definition of fraud in certain circumstances and delivers greater penalties against health care providers.

d. Health Information Technology for Economic and Clinical Health Act of 2009
    i. The Health Information Technology for Economic and Clinical Health Act, more commonly referred to as HITECH, encourages hospitals to adopt the electronic health record (EHR) system, tightens privacy and security requirements, and imposes higher penalties for HIPAA and HITECH violations.
e. The Patient Protection and Affordable Care Act (PPACA) of 2010
    i. This Act bolsters the government's funding and breadth of coverage to fight fraud, waste and abuse in the nation's health care system. This Act includes modifications to hospital-physician relations including changes to Stark laws, strengthens mandates around the timing of repayment of government funds inappropriately received, changes to application of civil monetary penalties, etc.

F. BENEFITS OF A COMPLIANCE PROGRAM

1. In addition to fulfilling Huntington Health's legal duty to ensure that false or inaccurate claims are not being submitted to the government and private payers, numerous additional benefits may be gained by implementing an effective compliance program. These programs make good business sense and will help the organization fulfill its fundamental care-giving mission to patients and the community and assist in identifying weaknesses in internal systems and management. Other important potential benefits include the ability to:
    a. concretely demonstrate to employees and the community Huntington Health's strong commitment to the honest and responsible provision of health care services and corporate conduct in harmony with its core values;
    b. provide a more accurate view of employee and contractor behavior relating to fraud and abuse;
    c. identify and prevent criminal and unethical conduct;
    d. improve the quality of patient care and the privacy and security of patient information;
    e. create a centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse and other legal compliance issues;
    f. develop a methodology that encourages employees to report potential problems;
    g. develop procedures that allow the prompt and thorough investigation of alleged misconduct by senior management, managers, employees, independent contractors, physicians, other health care professionals, volunteers and consultants;
    h. initiate immediate and appropriate corrective action; and
    i. minimize the loss to the government from false claims, through early detection and reporting, thereby reducing the hospital's exposure to civil damages, penalties, criminal sanctions, and other administrative remedies such as debarment or exclusion from government payer programs.

II. PROGRAM STRUCTURE & FUNCTION

A. WRITTEN STANDARDS OF CONDUCT

1. To be effective, the Compliance Program and Standards of Conduct must be communicated to all employees. The Compliance Officer and Compliance Committee are responsible for establishing procedures to ensure that every employee, medical staff member, volunteer and

contracted agency is familiar with and abides by the Program. The training and education program will be systematic and ongoing to enhance and maintain the awareness of program policies among existing and new personnel.

2. Written standards of conduct can be found in this *Compliance Program Manual* and in associated policies and procedures. An abbreviated explanation of the hospital's mission, values and Standards of Conduct, along with associated compliance areas, is available through a brochure titled *The Standards We Live By*.

B. OVERSIGHT RESPONSIBILITIES

1. Compliance Officer
   a. Huntington Health has designated a Compliance Officer to oversee the Compliance Program. The Compliance Officer, working with the Compliance Committee, will be responsible for monitoring compliance with all applicable laws, the Standards of Conduct and related policies and procedures.
   b. The Compliance Officer will make a report to the Governing Board's Audit and Compliance Committee at their regularly scheduled meetings or more frequently as deemed appropriate based on the nature and severity of current compliance-related issues.

2. Compliance Committee
   a. Members of the Compliance Committee will assist the Compliance Officer in monitoring, formulating and directing the Compliance Program. These individuals will serve to support the Compliance Officer in monitoring at the local or functional levels of operation to include training and education, disseminating regulatory updates, hotline follow-ups, coordinating audits, and most importantly, communicating to all employees.
   b. The Compliance Committee will hold regular meetings at least quarterly, or more frequently as required, to administer compliance matters, including the violation of hospital policies. The various functional areas represented in the Compliance Committee include, but are not limited to, patient financial services, patient care services, laboratory, medical records, quality improvement, utilization management, medical staff, HIPAA privacy and security, human resources, key operating departments and internal audit.

C. EDUCATION AND TRAINING

1. To be effective, the Compliance Program and Standards of Conduct must be communicated to all employees. The Compliance Officer and Compliance Committee are responsible for establishing procedures to ensure that every employee is familiar with and abides by the Program. The training and education program will be systematic and ongoing to enhance and maintain the awareness of program policies among existing and new staff.[3]

2. The Compliance Program will be explained to all employees. In addition, supplemental materials dealing with subjects such as compliance with fraud and abuse will be distributed to those employees with specific responsibilities in those areas that pose the greatest risk to the

[3] See policy and procedure #143, "Compliance Program Education and Training"

organization. Adherence to policies and procedures, including the Standards of Conduct, is a factor in the job performance guidelines of the employee evaluation process.

3. Every employee, medical staff member, volunteer and contracted agency will receive a copy of *The Standards We Live By*, a brief description of the Standards of Conduct and key issues of which all should be aware. All new employees to Huntington Health are introduced to the Compliance Program as part of the New Employee Orientation process. Furthermore, attendance and participation in ongoing training programs will be a condition of continued employment and failure to comply with training requirements will result in disciplinary action.

4. These standards are incorporated into this *Compliance Program Manual*, which is available to all departments of the organization through the hospital's Intranet web site through SharePoint and on the Compliance Hotline/WebLine Internet web site. An important component of the Compliance Program is ongoing training to keep employees abreast of changing laws and to serve as a reminder of the importance of compliance within the organization. In addition, monitoring compliance with periodic reviews and maintenance of an effective reporting system to keep management informed will be conducted.

5. The Compliance Officer and Compliance Committee are responsible for ensuring the proper documentation of attendance by all employees at training and education programs. Training and education programs are applicable to physicians, management, employees, volunteers and independent contractors who provide services to the hospital. Management will maintain sign-in sheets to ensure that all employees have completed the required training.

6. Training for all employees will be conducted on an annual basis. Departments with high risk for compliance related activities may be given special training in addition to the required annual in-service. The department manager of each department identified as high risk will work with the Compliance Officer to determine the most appropriate format and depth of training based on existing needs and risks identified by governmental enforcement agencies. Other departments may receive high-risk training depending upon the nature and risk of compliance issues being addressed throughout the organization or pursuant to changes in legal or regulatory requirements and governmental enforcement priorities.

7. This *Compliance Program Manual* is a document to be used as a reference to employees for specific details related to the Compliance Program. This document provides a description of the Program, how it is structured, educational training requirements, how occurrences of non-compliance are to be reported and an outline of the Standards of Conduct. This document is available on the hospital's Intranet web site through SharePoint and on the Compliance Hotline/WebLine Internet web site for reference by employees when necessary.

D. EFFECTIVE LINES OF COMMUNICATION

1. Huntington Health is committed to the policy that every employee is responsible to report to their manager any activity they believe is inconsistent with the Compliance Program or the Standards of Conduct. Any possible criminal activities will be reported to the employee's manager or the Compliance Officer. If the employee's manager does not resolve the issue, it

should be reported to the Compliance Officer. Employees who, in good faith, report possible compliance violations will not be subject to retaliation as a result of expressing their concerns. Hospital policies ensure anonymity of the individual when desired to the greatest extent allowable by law.

2. All employees are encouraged to report concerns to their manager or work through the appropriate chain of command to resolve issues. If issues cannot be resolved through the appropriate chain of command or if employees feel uncomfortable bringing issues forward to management, they are encouraged to report their concerns to the Compliance Officer who will treat all calls and reports of concerns as confidential to the greatest extent allowable by law.

3. Huntington Health recognizes that there are situations that warrant a confidential or anonymous method for asking questions or reporting concerns. As such, a national hotline service has been retained to receive reports from employees, medical staff members and volunteers regarding compliance concerns. Two services are available through this hotline service – the Compliance Hotline and the Compliance WebLine.
   a. The Compliance Hotline and WebLine are answered by a national hotline agency. The Compliance Hotline and WebLine are not staffed by Huntington Health employees.
   b. The Compliance Hotline and WebLine are available 24 hours a day, 7 days a week.
   c. The Compliance Hotline number is 866-311-4231. The Compliance WebLine web page is www.hhcompliancewebline.com.
   d. Adherence is given to Huntington Health's non-retaliation policy[4] when it comes to honoring information submitted to the Compliance Hotline and WebLine services.
   e. As a matter of practice, all submissions made to the Compliance Hotline or WebLine are kept confidential to the extent allowable by law. Callers may even leave an anonymous call, which means they can communicate a question or concern without leaving their name or identity.
   f. Each caller is given a callback reference number and informed it can be used to place a return call with the Compliance Hotline service to obtain an answer to their question or a status or resolution pertaining to their concern. Individuals submitting information to the Compliance WebLine may receive information via e-mail through the WebLine service.
   g. Posters providing information about how to access and use the Compliance Hotline and WebLine are posted in all employee commons areas throughout the hospital. Information about the Compliance Hotline and WebLine can also be found on the hospital's Intranet web site through SharePoint and on the Compliance Hotline/WebLine Internet web site. Additional copies of this public notice can be obtained from the Compliance Officer.

4. Communication of compliance questions or concerns can be made directly to the Compliance Officer through a number of avenues including the following:
   i. Written communication addressed to:
      Compliance Officer
      Huntington Memorial Hospital
      100 W. California Boulevard
      Pasadena, CA 91105

[4] See policy and procedure #145 "Non-Retaliation/Non-Retribution".

ii. The Compliance Officer's telephone number: 626.397.5335
iii. The Compliance Hotline: 866.311.4231
iv. The Compliance WebLine: www.hhcompliancewebline.com

5. Confidentiality and Anonymity
   a. Through the various reporting avenues available to employees, precautions will be taken to ensure the confidentiality and anonymity of caller identification. Employees are welcome to make an anonymous report to the Compliance Officer. In the process of making a report, it is possible that the reporter's identity may otherwise be made known through the course of communicating the issues. The Compliance Officer will make every effort to keep an individual's identity confidential when reporting any concern. However, should the federal government or other legal entity or agent become involved in the investigation, there does come a point, by law, where the reporting individual's identity may need to be revealed. It is anticipated that this would be a rare situation and employees are encouraged to report all instances of conduct that may be in question.
   b. Employees should be aware that questions or concerns made anonymously may limit the Compliance Officer's ability to research, investigate or resolve a particular concern if insufficient information is given to follow-up on the question or issue. Additional information may be requested if such anonymous calls are made through the Compliance Hotline or WebLine. Communication may be made by the Compliance Officer back to the original reporter through the Compliance Hotline or WebLine services requesting additional information in these cases. Those reporting concerns may always call the Compliance Hotline or WebLine to submit additional information on a previously reported concern at any time.
   c. All information collected from compliance reports are kept with the Compliance Officer to ensure confidentiality and are only shared with those who participate in the research and resolution of the issue. Reports received by the Compliance Officer by telephone are received in a secluded office out of listening range of others.

6. Nonretaliation[5]
   a. Huntington Health maintains a non-retaliation policy for individuals reporting compliance concerns. This means that if employees make a "good faith" report pertaining to a compliance concern, they will not be punished in any way relative to the reported concern. A "good faith" report is one in which an employee reports activities that he or she truly believes have occurred and that violate the Standards of Conduct or any law, statute, regulation, rule or other legal requirement. This non-retaliation policy, however, does not insulate a guilty individual from disciplinary action. If the employee is involved in the wrongdoing that he or she is reporting, they may still be subject to disciplinary action.

7. Investigation Process
   a. All reports of compliance concerns will be investigated by the Compliance Officer and others as appropriate to the nature of the concern. All investigations will be logged in a compliance database including information obtained in the research and the outcome or resolution of the concern. This information will also be held confidential by the Compliance Officer. There may be some instances where legal counsel is enlisted to

[5] See policy and procedure #145 "Non-Retaliation/Non-Retribution".

oversee the investigation depending on the nature and severity of the events or processes involved.

8. Reporting Process
    a. The Compliance Officer and the Compliance Committee are responsible for the following reporting procedures:
        i. Huntington Health is committed to establishing a work environment for employees to seek and receive prompt guidance regarding any possible violations of the Standards of Conduct or other law, statute, regulation, rule and related policies.
        ii. The Compliance Officer will maintain policies to ensure open communications with employees. The Compliance Officer will publish written and hotline methods of communicating violations. All of these communications will be handled on a timely basis with confidentiality to the extent feasible and legal. Furthermore, all management personnel will have an "open door" policy to receive any employee report on possible violations.
        iii. Employees should consult with their manager on possible violations of the Standards of Conduct and related policies. The manager should respond to questions and/or refer the possible violation to the appropriate personnel or the Compliance Officer.
        iv. Employees will cooperate with any reasonable demand made by government officials who are responsible for administering and enforcing those laws and for monitoring and regulating the hospital's activities[6].
        v. Any employee who receives an inquiry, subpoena[7] or other document regarding the hospital's business, including notice of an audit, review or more formal government investigation, whether at home or in the work place, from any government agency, should notify his or her manager or the Compliance Officer prior to acting on the demands of the legal document.
        vi. If an employee questions whether an action is legal or has difficulty interpreting a law, he or she should consult with his or her manager or the Compliance Officer as appropriate. Employees should report any actual or suspected violations of the Standards of Conduct to the Compliance Officer or their manager.
        vii. The Compliance Officer is responsible for the review, evaluation and investigation of any reported violation, whether actual or alleged.
    b. Employees will cooperate with any investigation undertaken by the Compliance Officer, outside legal counsel, contractors and all governmental agencies.
    c. The Compliance Officer will prepare an annual report identifying compliance work, accomplishments and identified proposed changes.
    d. For outside investigations by legal counsel or government agencies, it may be appropriate to advise employees of this possible contact. The manager, senior management or Compliance Officer will inform employees of their rights and obligations with respect to interviews with government investigators. Employees, managers, directors and senior management must refer any contact with government agents to the Compliance Officer[8].
    e. On discontinuance of employment at Huntington Health, an Employee Exit Survey will be distributed to all departing employees providing them with an avenue to communicate

[6] See policy and procedure #142, "Unannounced Visit by Government Investigators or Auditors"
[7] See policy and procedure #134, "Subpoenas"
[8] See policy and procedure #142, "Unannounced Visit by Government Investigators or Auditors"

any perceived issues, problems or concerns regarding operations or organizational activities which they believe may be out of compliance with legal statutes and directives.

E. ENFORCEMENT OF STANDARDS

1. Human Resources policies provide guidance for consistently applied and enforced discipline for non-compliant performance. Furthermore, the policies provide for a fair and equitable basis for discipline. Disciplinary action taken regarding issues related to legal compliance will follow the currently established disciplinary process through the Human Resources Department[9].

2. Huntington Health will document the reasons for employee disciplinary action taken for violations of the Standards of Conduct, applicable laws and regulations and related policies. Appropriate disciplinary action will be in accordance with Human Resources' policies. Adherence to hospital policies and procedures is a factor in the job performance guidelines of each employee's evaluation process.

3. In accordance with the Compliance Program, the Standards of Conduct, related Compliance and Human Resources' policies, the factors to be considered in disciplinary action will include:
   a. Nature and ramifications of the violation
   b. Disciplinary action imposed for similar acts of willful or unintentional violations
   c. Compliance Officer's investigation and reported conclusion of the violation
   d. Management's failure to guide and direct the employee conduct
   e. Retaliation against fellow employees for reporting the violation
   f. Degree of cooperation in the investigation of the incident

4. Any violation of the Compliance Program will subject a manager, employee, agent and/or contractor to disciplinary action which may include, without limitations, termination of employment, engagement or affiliation with Huntington Health.

5. Any person in a supervisory or management role found permitting, aiding, ignoring or covering up the actions of an employee engaged in behavior that is not consistent with the organization's Standards of Conduct and related legal and regulatory requirements may be subject to discipline up to, and including, termination.

F. AUDITING AND MONITORING

1. The Compliance & Internal Audit Services Department is responsible for overseeing both the Compliance Program and all internal audit functions of the organization[10]. On an annual basis, an audit plan is created and approved by the Board Audit & Compliance Committee. This audit plan outlines the areas, functions and processes that will be audited by the department.

2. Included in this plan are audits related specifically to legal and regulatory compliance risks that the organization may face. Auditing and monitoring functions may be conducted based on compliance issues prevalent in the organization, identified as part of a reported compliance

[9] See policy and procedure #144, "Compliance Program Enforcement and Discipline" and #850 "Human Resources – Discipline"
[10] See policy and procedure #170, "Function of Compliance & Internal Audit Services"

concern, part of a related audit finding, due to risks identified as being common in the industry, based on previous audits on the same topic, etc. Results of these auditing and monitoring efforts are reported to the Board Audit & Compliance Committee at their regularly scheduled meetings.

G. RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

1. The Compliance Program, the Standards of Conduct and related policies briefly describe the programs to follow to effectively implement and monitor compliance with the laws that impact the conduct of employees, members of the medical staff, volunteers and vendors/contractors.

2. For compliance violations, the Compliance Officer, with outside legal counsel (as necessary), will work with management in developing a corrective action plan to address and correct issues raised. Corrective action plans may include revisions to applicable policies and procedures and providing additional training and education to ensure compliance with the goals and objectives of the Compliance Program.

III. KEY COMPLIANCE RISK AREAS AND THE STANDARDS OF CONDUCT

A. STANDARDS OF CONDUCT

1. Huntington Health's Governing Board has established the Standards of Conduct policy of organizational ethics in recognition of the organization's responsibility to its patients, employees, physicians, volunteers, vendors and the communities it serves.

2. It is the responsibility of every member of the hospital – including governing board members, administration, medical staff members, employees and volunteers – to act in a manner that is consistent with this organizational statement and its supporting policies.

3. Huntington Health's behavior will be guided by its Core Values of respect, integrity, stewardship and excellence as evidenced in the following general principles:
   a. A dedication to the principle that all patients, employees, physicians, volunteers, vendors, and visitors deserve to be treated with dignity, respect, and courtesy. Huntington Health will constantly strive to adhere to these principles:
      i. Fairly and accurately represent ourselves and our capabilities.
      ii. Provide services to meet the identified needs of our patients, and consistently seek to avoid providing services that are unnecessary or inefficacious. If services are not available through Huntington Health facilities, patients will be assisted in obtaining services elsewhere.
      iii. Adhere to a uniform standard of care throughout the organization.
      iv. Conduct our business and patient care practices in an honest, decent, proper and lawful manner.
      v. Work collaboratively with other hospitals, staff members, health care providers, educational institutions and payers.

B. PATIENTS' RIGHTS

1. Patients must receive quality care delivered in a considerate, respectful and cost effective manner. Patients have the right to request care or make their own health care decisions after disclosure of all relevant information. The following are guidelines used for ensuring patients' rights:
    a. Employees must at all times treat patients with dignity, respect and courtesy. Patients are entitled to prompt and courteous responses to their requests and to their needs for treatment or service, consistent with the hospital's capacity, stated mission, and applicable laws and regulations. These patients will be involved in decisions regarding the care that is delivered to the extent that such is practical and possible. The hospital will continually seek to understand and respect patients' objectives for care.
    b. In all circumstances, the hospital will attempt to treat patients in a manner giving reasonable thought to their background, culture, religion and heritage.
    c. Care should be provided as economically as is consistent with maintaining quality. Patients are entitled to complete disclosure of all charges associated with their care.
    d. Patients must be informed of their right of self-determination. This right refers to the ability of competent adults to participate in and make their own health care decisions after receiving from their physicians' appropriate disclosure of their diagnosis, prognosis and treatment alternatives. A patient has the right to accept medical care or to refuse treatment to the extent permitted by law, and to be informed of the medical consequences of such refusal.
    e. Treatment of patients will be consistent with appropriate informed consent as determined by applicable consent law. Questions concerning a patient's competence or the right of another person to act on a patient's behalf should be handled in accordance with hospital policy.
    f. Employees must not discriminate against patients based on whether they exercise their right of self-determination, on the substance of their specific health care decisions, or on their ability to pay. In all of the various settings in which the organization provides patient services, we will consistently follow well-designed standards of care and protect the integrity of decision-making based upon the needs of the patient and without regard to their ability to pay. Even as we work to provide care in a more economical manner to patients and providers, we will strive to provide care that meets our own standards. Huntington Health will provide services only to those patients to whom it can safely care for within the organization, and will not turn patients away who are in need of services based on their ability to pay or based upon any other factor that is substantially unrelated to patient care. Allowances may need to be made for clinical epidemics, natural or man-made disasters, diversion, or other such unforeseeable events.
    g. Employees must at all times allow patients, without recrimination, to voice complaints regarding care received and submit such complaints to appropriate individuals for follow-up.
    h. Employees must protect a patient's personal privacy and preserve the confidentiality of a patient's medical treatment program, including the patient's medical records and other demographic and financial data collected, maintained or received by the hospital. Employees must observe the highest standards of ethical and legal conduct with respect to such information.

i. Employees are responsible for ensuring that patients' rights and responsibilities are upheld according to the Patient Rights and Responsibilities document provided to each patient at the time of admission.
j. Huntington Health will admit, discharge and transfer patients in a manner consistent with legal requirements for health care facilities.
k. If an employee questions any patient rights issues, he or she should consult with his or her manager to determine if consultation with the Compliance Officer is appropriate. Employees should report any actual or suspected violations of Patients' Rights to the Compliance Officer and/or their manager.

C. EMPLOYEES' RIGHTS AND OBLIGATIONS

1. Huntington Health will maintain a working environment free from harassment, illegal and/or mood altering drugs, alcohol and unlawful discrimination. Employees should report any actual or alleged violations of employees' rights and obligations to the Human Resources Department or the Compliance Officer. The following are guidelines used in ensuring employees' rights and obligations:
   a. Huntington Health is an equal opportunity employer. Employees will be recruited, hired, promoted, transferred, demoted and terminated on the basis of their skills, experience and performance without regard to race, color, religion, national origin, ancestry, mental or physical disability, medical condition, marital status, sexual orientation, age, gender or any other basis protected by law. Any employee who believes he or she has been unlawfully discriminated against should promptly report the facts of the incident to his or her manager, the Human Resources Department or the Compliance Officer as appropriate.
   b. Huntington Health strictly prohibits unlawful harassment, including sexual harassment. Sexual harassment includes sexual advances, requests for sexual favors, or any sexually offensive verbal, visual or physical conduct, and will not be tolerated. Any employee who believes he or she has been unlawfully harassed should promptly report the facts of the incident to his or her manager, the Human Resources Department or the Compliance Officer as appropriate.
   c. Huntington Health is committed to providing a work environment free from violence. Such behavior might include physical violence, verbal threats, intimidation, and other extreme interpersonal behavior. Huntington Health adheres to a "no tolerance" policy for violence in the workplace by any employee or other person working within the hospital. Even threats made in jest could result in disciplinary action.
   d. Huntington Health is committed to providing an efficient and productive working environment. Employees must perform their job duties safely, competently and efficiently in a manner that protects the hospital's interests and those of its co-workers. Employees are expected to conduct themselves in a manner that reflects integrity, brings credit to the hospital and meets its obligation to provide quality care to patients. Any involvement with illegal and/or mood altering drugs in the workplace by employees is prohibited and may result in disciplinary action, up to and including termination. In addition, possessing or consuming alcohol while on the job is strictly prohibited. For further information about the types of behaviors that are unacceptable, please refer to the Human Resources policies located on the hospital's Intranet web site through SharePoint.

e. Reports of criminal or illegal conduct by an employee may result in strict disciplinary action to include possible immediate termination as well as referral to authorized law enforcement agencies.
f. Huntington Health is committed to promoting a safe work environment. Employees who are involved in or witness an accident or occurrence that has caused or may lead to injury to a patient, co-worker or visitor, or that results in damage to property, must complete the appropriate reports, and report such to their manager.
g. If an employee questions any employee's rights issues, he or she should consult with his or her manager, the Human Resources Department or the Compliance Officer, as appropriate.

D. FINANCIAL ACCOUNTING RECORDS

1. Huntington Health will maintain honest and accurate financial accounting records. The following guidelines are used to ensure the appropriate accounting of financial information:
   a. Employees must record all entries in the hospital's books and records accurately, honestly and fairly so that such entries reflect the true nature and purpose of the transactions which are being recorded. Books and records must not contain any false or misleading information.
   b. Financial reports must fairly and consistently reflect performance and accurately disclose the results of operations. They must be prepared in accordance with the standards of the Governmental Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB) and comply with Generally Accepted Accounting Principles, rules and regulations of Office of Statewide Health Planning and Development (OSHPD), Centers for Medicare & Medicaid Services (CMS) and other applicable governmental or regulatory units.
   c. Employees must comply with all internal audit procedures of the hospital. All transactions must be conducted as directed by management.
   d. If an employee questions the integrity of any financial accounting record, he or she should consult with his or her manager, the Chief Financial Officer or the Compliance Officer as appropriate. Employees should report any actual or alleged violations to the Compliance Officer.
   e. Huntington Health will provide timely and accurate information to patients regarding their bill and will attempt to resolve related issues.

E. CONFLICTS OF INTEREST[11]

1. Employees of Huntington Health should avoid both conflicts of interest and the appearance of conflicts of interest between their job responsibilities as hospital employees and any outside interest. Employees should not engage in any activity which may conflict with the interests of the hospital. The following are guidelines used to ensure adherence to this principle:
   a. Employees must at all times seek to promote, enhance, and protect the interests of the hospital, and avoid taking any action which may be adverse to those interests. A conflict of interest arises when an employee's outside activities influence the performance of that employee's responsibilities in a manner that is contrary to the hospital's interests.

[11] See policies and procedures #029, "Conflict of Interest – Directors, Officers and Management Personnel" and #030, "Conflict of Interest – Hospital Employees"

b. Employees must be alert to any situation that may involve even the appearance of a conflict of interest and must disclose that situation promptly to their manager or the Compliance Officer.
c. The following rules address some situations that may occur:
    i. Relationships with Suppliers and Competitors
        01. Employees who deal with contractors, suppliers and competitors must not take advantage of their position to obtain personal benefits.
        02. Employees must not take personal advantage of a business opportunity that may be or appears to be of interest to the hospital without the approval of their manager.
        03. Employees must not conduct business on behalf of the hospital with any other company in which the employee has an interest without first disclosing that interest to their manager.
        04. Employees must not conduct business on behalf of the hospital with any individual or entity in which they have a personal relationship within the company in question, without first disclosing that relationship to their manager.
    ii. Charitable and Political Activities and Contributions
        01. Hospital employees will not use the hospital's time, funds, resources, facilities, employees or any other assets for non-hospital charitable or political activities, contributions or support of any kind, direct or indirect, without approval by a member of senior management or the Chief Executive Officer.
    iii. Gifts and Entertainment[12]
        01. Employees must not accept gifts or favors from any person or company that does business or seeks to do business with the hospital. Reasonable business activity, such as occasional meals, in accordance with good judgment and customary practice are acceptable.
        02. Employees are not to accept gifts or favors from patients or their families. Tokens of appreciation through the giving of nominal, perishable goods such as candy, flowers, etc. are acceptable as long as they are shared with the employee's department. Cash or cash equivalents (including gifts cards) of any value should never be accepted by employees. If patients or their family desire to donate money to the hospital, they should be referred to the Philanthropy Department.
        03. Employees will not accept gifts or favors from individuals, vendors or other entities conducting business with the hospital.
    iv. Employment of Relatives[13]

        Relatives may be employed EXCEPT under the following circumstances:
        01. Where relatives would be employed within the same work area and shift.
        02. Where one relative directly or indirectly supervises the other.
        03. Where employment would violate internal controls between departments (i.e. purchasing – accounts payable or human resources – payroll).
        04. Any other relationship that the hospital considers potentially harmful to the department and/or the hospital.

[12] See policy and procedure #028, "Gifts and Gratuities"
[13] See policy and procedure #818, "Employment of Relatives and Personal Relationships"

v. Outside Employment and Other Activities[14]
   01. Employees must not engage in outside activities during working hours and must not use hospital equipment, supplies or information in connection with their outside activities without prior approval from their manager.
   02. Self-employment or employment by others is permissible if it does not adversely affect the employee's job performance or create a conflict of interest.
   03. Employees must not spend time or company resources while on the job to promote personal business ventures or activities including the sale, marketing or solicitation of goods, products or services.

d. If an employee questions conflict of interest actions or issues, he or she should consult with his or her manager to determine if consultation with the Compliance Officer is appropriate. Employees should report any actual or suspected violations of the conflict of interest policy to the Compliance Officer or management personnel.

F. FRAUD AND ABUSE

1. Fraud generally involves misrepresentation of material facts. Fraud consists of an intentional deception or a misrepresentation which you know to be false, made with knowledge that the deception could result in some unauthorized benefit to you or some other person or entity (such as the hospital).
2. Examples in the context of Medicare and Medi-Cal include:
   a. billing for services not rendered
   b. misrepresentation of services rendered
   c. deliberate application for duplicate reimbursement
   d. false or misleading entries on cost reports
3. The term "abuse" in this case describes incidents or practices of providers, physicians, or suppliers of services and equipment which, although not usually considered fraudulent, are inconsistent with accepted sound medical, business or fiscal practices. These practices may, directly or indirectly, result in unnecessary costs, improper payment or payment for services which failed to meet professionally recognized standards of care or which are medically unnecessary.
4. Proof of criminal or civil wrongdoing, by a corporation or individual, depends on the facts and circumstances in each case. From the facts and circumstances, the prosecutor attempts to demonstrate the "intent" of the corporation or individual that allegedly committed fraud or abuse. Fraud is defined as knowingly and willfully disobeying a law. Abuse is attributable to instances where it is not as easy to succinctly define whether or not a provider acted knowingly and willfully.
5. The following are some guidelines related to violations of fraud and abuse:
   a. Employees must not engage in any of the following activities, all of which are prohibited by law:
      i. Billing for supplies or services not rendered
      ii. Upcoding or inappropriately unbundling of actual services rendered
      iii. Misrepresenting or duplicate billing of services actually rendered
      iv. Falsely certifying that services were medically necessary

[14] See policy and procedure #884, "Solicitation and Distribution"

v. Seeking to collect amounts exceeding the co-payment and deductible from a Medicare or Medi-Cal beneficiary who has assigned benefits
vi. Soliciting, offering or receiving a kickback, bribe or rebate in exchange for patient referrals or other organizational services

b. Employees must be especially vigilant in adhering to the highest ethical standards in conducting business that may implicate the fraud and abuse laws. Employees must not make false statements or misrepresentations at any time. This is especially important for employees having claims processing, coding and reimbursement responsibilities. Huntington Health is committed to fulfilling the terms of its agreements, including the assignment of patient benefits.
c. Employees faced with situations or actions that appear to be questionable under the fraud and abuse laws should consult with their manager or the Compliance Officer for guidance. Any questions about interpretations of the fraud and abuse laws should be discussed with the Compliance Officer. Employees who suspect that a violation of the fraud and abuse laws has occurred should disclose that situation to the Compliance Officer.

G. THE FALSE CLAIMS ACT

1. The Federal False Claims Act was signed into law by Abraham Lincoln in 1863 as a way to deter and punish unscrupulous profiteers who were providing substandard supplies to the Union Army. This Act has evolved over time and is used today to protect federal funds from being spent inappropriately due to false or fraudulent claims made to the government. The government spends trillions of dollars each year on health care expenditures for its beneficiaries and the False Claims Act is an effective tool for ensuring that such funds are used appropriately. The State of California has also enacted its own False Claims Act to protect the use of State funds including the Medi-Cal program.
2. The Federal False Claims Act imposes civil liability (including substantial monetary penalties and damages) on any person or corporation which does any of the following:
   a. knowingly presents or causes to be presented a false or fraudulent claim for payment to the United States government;
   b. knowingly makes, uses, or causes to be made or used a false record or statement to obtain payment;
   c. engages in a conspiracy to defraud the federal government by getting a false or fraudulent claim allowed or paid;
   d. falsely certifies the type or amount of property to be used by the government;
   e. certifies receipt of property used (or to be used) by the government on a document without completely knowing that the information is true;
   f. knowingly buys or receives government property from an unauthorized agent; or
   g. knowingly makes, uses or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government.
3. Violations of the Federal False Claims Act can result in civil monetary penalties and fines for each false claim, a repayment of up to triple the amount of damages to the government and possible exclusion from participation in federally-funded health care programs.
4. The statute defines knowing and knowingly as meaning that the person (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information.

5. In addition to the penalties described above, separate administrative remedies for false claims and statements also may be imposed by the government. Under the general federal Administrative Remedies for False Claims and Statements statute, each false claim may result in the imposition of administrative civil penalties, plus twice the amount claimed.
6. The False Claims Act allows a private individual, referred to as a whistleblower or *qui tam* relator, to bring a civil action in the name of the United States. The purpose of the *qui tam* provision is to give an incentive to whistleblowers to come forward to help the government discover and prosecute fraudulent claims by awarding them a percentage of the amount recovered. Generally, relators are entitled to up to 35 percent of the amount the government recovers as a result of the *qui tam* lawsuits. *Qui tam* cases filed under the False Claims Act have accounted for the majority of civil fraud cases pursued by the government.
7. There are specific protections afforded to employees of Huntington Health who come forward expressing concerns about possible legal and regulatory concerns including violations of the False Claims Act. Such protections are afforded to any employee who was discharged, demoted, suspended, harassed, threatened, denied a promotion or in any manner discriminated against by their employer because of their participation as a whistleblower.
8. California has passed laws expanding the prohibition against the submission of false claims in the context of the Medi-Cal program. California's civil False Claims Act is modeled on the federal law and provides for monetary penalties per claim, plus three times the amount of damages sustained by the state. *Qui tam* actions are also permitted under the California false claims statute. Additionally, employers are not permitted to interfere with employees' disclosure or initiation of false claims actions. California law prohibits employers, such as Huntington Health, from discharging, demoting, suspending, threatening, harassing, denying promotion to or otherwise retaliating against any employee based on his or her initiation of or participation in a false claims action.
9. Under the Deficit Reduction Act, employers receiving over $5 million in Medicaid payments must provide all employees with information pertaining to this section including the Federal and State False Claims Acts, the rights of employees to act as whistleblowers, protections to employees from retaliation for acting as a whistleblower, and the employer's policies and procedures for detecting and preventing fraud, waste and abuse. This *Compliance Program Manual* fulfills, in part, these requirements.

H. ANTI-KICKBACK STATUTE

1. The Anti-Kickback Statute provides both civil and criminal penalties for providers that knowingly and willfully offer, pay, solicit or receive, either directly or indirectly, any remuneration in order to induce the referral of any patient or business item for which payment may be made, in whole or in part, by a governmental payer.
2. There are four statutory exceptions to the statute's sweeping prohibitions for certain business arrangements from criminal prosecution or exclusion under the statute. These exceptions include:
    a. discounts obtained by a provider of services, if the discount was appropriately reflected in costs claimed or charges made to the government;
    b. amounts paid by an employer to an employee under a bona fide employment relationship;
    c. certain payments by vendors to group purchasing organizations; and
    d. waivers of coinsurance and deductibles with respect to an individual who qualifies for subsidized services under a Medicare supplemental, CHAMPUS or Medi-Cal program.

e. In addition to the statutory exceptions, the DHHS OIG has promulgated numerous regulatory safe harbor exceptions. The business arrangement must satisfy all of the criteria of the given safe harbor in order to be exempt.

3. The following are guidelines to be used when addressing anti-kickback statute concerns:
   a. Some areas of the anti-kickback laws include the prohibition against offering, paying, soliciting or receiving any money, gifts or services in return for the referral of patients or to induce the purchase of items or services. Situations that may arise include requests from physicians and other providers for special treatment or payments in return for referring patients or other business. Such requests might seek, for example, payment of an incentive each time a patient is referred, provision of free or significantly discounted billing, nursing or other staff services, or payment for services in excess of their fair market value.
4. Violation of the anti-kickback statute carries both civil and criminal penalties as well as possible exclusion from participation in Medicare or Medi-Cal programs. As previously stated, penalties for illegal remuneration and false statements include fines and/or imprisonment for each offense. The Secretary of Health and Human Services is required to exclude from participation in Medicare or Medi-Cal any individual or entity convicted of a criminal violation of the Anti-Kickback Statute.

I. SELF-REFERRAL ("STARK") LAWS

1. The "Stark" laws were enacted to address the perceived irreconcilable conflict of interest present when a physician has a financial relationship with an entity to which the physician makes referrals. Stark I prohibits referrals for clinical laboratory services payable under Medicare if the referring physician (or a member of the physician's immediate family) has a financial relationship either through ownership or compensation with the laboratory performing the service. Stark II extends these prohibitions on the physician self-referral to other designated health services, including physical therapy and home health services, and also extends the prohibitions to Medi-Cal services. Both Stark I and II were enacted to discourage inappropriate utilization of health care services by eliminating financial incentives to refer. If a claim for a referral is paid, the amounts paid by a beneficiary to the entity must be refunded on a timely basis which the government considers to be 60 days from the date of payment. The law provides civil monetary penalties for presentation of improper claims or failure to make required refunds; for entering into an arrangement with the principal purpose of circumventing the law (a "circumvention" scheme) and permitting otherwise prohibited referrals; or failing to make a report required by the "Stark" Laws.
2. Given the scope of the "Stark" Laws and the importance of understanding the definitional and interpretive issues, the *Compliance Program Manual* does not attempt to address the law or regulations in detail. If questions arise concerning the Stark Laws, please consult with the Compliance Officer.

J. PHYSICIAN RELATIONS

1. Employees of the hospital will maintain strong and positive working relationships with physicians. The following are guidelines for promoting positive physician relations:

a. All applications by physicians for affiliation with Huntington Health will be considered in a fair, prompt and reasonable manner, without discrimination in accordance with applicable medical staff bylaws, rules and regulations.
b. Employees must not offer or provide physicians with any items of value or other inducements in exchange for the referral of patients.
c. Huntington Health will not enter into financial relationships with physicians which could put the hospital in a position of possibly violating the prohibitions of the Federal Anti-Fraud and Abuse Statute, Stark I or II or state physicians self-referral prohibitions.
d. All physicians receive a booklet titled "A Relationship of Care and Accountability" upon appointment and re-appointment to the hospital's medical staff which gives instruction and guidance on key issues related hospital-physician relations.
e. If an employee has any questions regarding issues or actions about physician working relationships, he or she should consult with their manager to determine if consultation with the Compliance Officer is appropriate. Employees should report any actual or suspected violations related to physician relations to the Compliance Officer and/or management personnel.

K. CONFIDENTIAL CLINICAL AND BUSINESS INFORMATION

1. Employees of Huntington Health will not disclose confidential clinical or business information to unauthorized persons. The following are guidelines related to confidential clinical and business information:
    a. Huntington Health employees will maintain the confidentiality of protected health information (PHI) about patients who are treated at its facilities pursuant to the Administrative Simplification regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), California's Confidentiality of Medical Information Act (CMIA), California Health and Safety Code §1280.15 and §130203.
        i. Employees will disclose PHI only to individuals who have a specific need to know and will disclose only the minimum amount necessary to carry out the objective that initiated the request per federal and state guidelines.
        ii. Employees will access only those systems and files containing PHI for which they have a legitimate care-giving or administrative responsibility.
        iii. Employees may learn trade secrets, commercially sensitive information, and financial information about the hospital and its operations. Employees must not disclose such confidential information to unauthorized persons so long as it remains confidential. Examples of confidential business information include earnings estimates, expansion or curtailment of operations, an increase or decline in business, a merger or acquisition proposal or agreement, borrowing, litigation, unusual management developments, and purchases or sales of substantial assets.
        iv. Employees must not use confidential business information in a manner that is not related to business activities either during or after their employment with the hospital. Confidential information must not be given to competitors, suppliers, contractors or to other employees who do not have a specific need to know.
        v. If an employee has any questions regarding issues, actions or violations of handling confidential business information, he or she should consult with his or her manager to determine if consultation with the Compliance Officer is appropriate. Employees

should report any actual or suspected violations related to confidential/business information to the Compliance Officer or their manager.

vi. For a complete list of all policies related to the hospital's practices for achieving compliance with laws governing the protection of patient information, see policy and procedure #150, "Privacy and Security of Patient Information Program – Governing Principles".

L. ANTITRUST AND TRADE REGULATION

1. Antitrust laws preserve the competitive free enterprise system. There are several major federal antitrust statutes that apply to health care providers in a variety of activities, including mergers or acquisitions, expansion of existing facilities, participating in joint ventures, exclusive contracting with physician groups, and the credentialing and disciplining of physicians on a hospital medical staff. These antitrust provisions include the Sherman Act, the Federal Commission Act and the Clayton Act.
2. Employees of Huntington Health will avoid activities that reduce or eliminate competition, control prices, allocate markets or exclude competitors including the following:
   a. All employees must strictly comply with the letter and the spirit of all antitrust laws of the United States and the State of California. No officer, employee or agent of the hospital or any of its related entities has any authority to engage in conduct that does not comply with this policy or to authorize, direct, approve or condone such conduct by any other person.
   b. The purpose of the antitrust and trade regulation laws is to protect the hospital and other companies from unfair trade practices, promote competition, and preserve the free enterprise system. The antitrust and trade regulation laws are based on the belief that businesses and individuals should act independently in order to serve the economic good of all.
   c. Employees must not enter into understandings or agreements (whether written or oral) that reduce or eliminate competition, control prices, allocate markets or exclude competitors. Conduct to avoid includes activities, taken in conjunction with the hospital's competitors, that affect prices, charges, profits, services or supplier selection.
   d. Employees who negotiate and enter into contracts with competitors, potential competitors, contractors or suppliers must do so on a competitive basis based upon such factors as price, quality and service. This policy is especially important for employees having purchasing, planning or marketing responsibilities.
   e. Employees who attend trade association or professional association meetings or who otherwise come in contact with competitors must be especially cautious not to do or say anything that could be interpreted as collusion or cooperation between competitors.
   f. Employees faced with situations that appear to be questionable under the Antitrust and Trade Regulation laws should consult with their manager for guidance who should also consult with the Compliance Officer. Any questions about interpretations of the antitrust and trade regulation laws should be discussed with the Compliance Officer who may seek advice from legal counsel. An employee who suspects that a violation of these laws has occurred should disclose that situation to the Compliance Officer.

M. ENVIRONMENT[15]

1. Employees of Huntington Health will maintain a safe and healthy work environment abiding by the following guidelines:
    a. Huntington Health is dedicated to providing a work environment that is free from recognized health and safety hazards. Employees must conduct themselves in a manner that minimizes potential health and safety hazards and must notify their manager of any actual or potentially unsafe working conditions or practices.
    b. Employees must properly store and dispose of medical and chemical waste to protect human health, the environment and the surrounding community.
    c. Employees must operate sterilizers and underground storage tanks (containing fuels for emergency generators) pursuant to all permits and applicable procedures.
    d. Employees must comply with the hospital's environmental policies. Any questions concerning these policies should be directed to an employee's manager or the Safety Officer. An employee who suspects that a violation of environmental laws has occurred should disclose that situation to their manager who will then report to the Compliance Officer or the Safety Officer.

N. DOCUMENT RETENTION[16]

1. Hospital employees must ensure compliance with the California Hospital Association's document retention policy manual. Each department manager will monitor document compliance within his or her department. The Compliance Officer and department managers will be responsible for procedures to prevent the intentional or inadvertent destruction of documents that could lead to prosecution for obstruction of justice. Document retention is essential for subpoenas and/or investigations of violations. Departments should follow existing policies and procedures governing document storage, retrieval, destruction and management practices to avoid improper use or destruction of documents.

O. MARKETING

1. Internal and external marketing and communications efforts in relation to Huntington Health, its facilities, capabilities and services will adhere to the highest standards of integrity, truth and accuracy. Huntington Health will avoid marketing or advertising material that places competitors, patients, beneficiaries, or payers in a bad light. The hospital's marketing and communications efforts will protect the privacy of its patients, employees, physicians and volunteers.

P. CONTROLLED SUBSTANCES

1. There are both federal and state laws regulating controlled substances. Access to controlled substances should be limited to persons properly licensed and who have express authority to handle them. Federal and state laws may impose fines and imprisonment upon individuals for violation of these laws. Any federal or state conviction of manufacturing, distributing,

[15] See policy and procedure #543, " Safety Management Plan" for more information.
[16] See policy and procedure #415, "Information Technology Data Retention "

prescribing or dispensing of these controlled substances could exclude the hospital from the Medicare and Medi-Cal programs.

Q. DISCRIMINATION

1. There are both federal and state discrimination laws that prohibit discrimination or harassment on the basis of race, color, sex or other protected category. Some of these laws include:
   a. The Americans with Disabilities Act (ADA)
   b. The Employee Retirement Income Security Act (ERISA)
   c. The Occupational Safety and Health Act (OSHA)
   d. The Labor Management Relations Act
   e. The Age Discrimination in Employment Act
   f. The Fair Labor Standards Act (FLSA)
   g. The Immigration Reform and Control Act
   h. Federal and State Leave Laws, including but not limited to Family Medical Leave Act (FMLA), California Family Rights Act (CFRA) and Pregnancy Disability Leave (PDL).

R. ADDITIONAL STATE AND FEDERAL REGULATIONS

1. Huntington Health operates in a highly regulated industry and must comply with numerous regulatory agencies and provisions. These regulations usually do not carry criminal penalties. They control the licenses and certifications that allow health care facilities to deliver patient care. Some of these regulatory authorities include:
   a. State Hospital Licensure
   b. Accreditation through The Joint Commission (TJC)
   c. Medicare Certification
   d. Office of Statewide Health Planning and Development (OSHPD)
   e. Controlled Substance Registration
   f. Pharmacy Licensure and Registration
   g. Clinical Laboratory Licensure and Registration
   h. Occupational Safety and Health Administration (OSHA)
   i. The Deficit Reduction Act of 2005

IV. CONCLUSION

A. DISCLAIMERS

1. This *Compliance Program Manual* represents guidelines and expectations about proper job-related conduct. However, this Manual cannot anticipate every situation that an employee may encounter. Employees should consult with their manager or the Compliance Officer for guidance if this Manual does not provide adequate direction or if the employee is being pressured to compromise his or her behavior, whether by another employee, a physician, supplier, volunteer, vendor, competitor, supervisor or patient.

2. Each department has a unique set of laws and regulations to which it must abide. It is management's responsibility to ensure that employees are aware of such laws and regulations

and are adhered to within the department. The Compliance Officer is available to facilitate the implementation of such laws and regulations or consult with management at any time.

3. If employees are unable to resolve their concerns with their manager, employees should contact the Compliance Officer, Compliance Hotline or Compliance WebLine as described in this Manual. Any questions about interpretations of the law or the legality of a particular course of conduct should be discussed with the Compliance Officer who may in turn consult with legal counsel. No employee's concern is too small or unimportant if he or she thinks it implicates policies concerning proper conduct.

4. Huntington Health Administration reserves the right to add, delete, or modify policies and guidelines relative to the Compliance Program as laws and regulations change or as is necessary or required to carry out the hospital's mission and to meet the compliance needs of the organization.

APPENDIX A

LABORATORY COMPLIANCE PROGRAM

I. INTRODUCTION

As an extension of the existing Compliance Program, this Appendix represents Huntington Health's compliance program specific to issues related to its hospital-based clinical laboratory. The principles and concepts outlined in this section are adapted from the guidelines set forth in the Office of Inspector General's *Compliance Program Guidance for Clinical Laboratories* (August 1998). In those cases where program guidelines overlap with the overall Compliance Program, such programmatic parameters will rely on the main body of this Manual, except as otherwise indicated. This Appendix is meant to provide specific guidance on compliance issues as they relate to the hospital's laboratory.

II. PROGRAM STRUCTURE OF THE LABORATORY COMPLIANCE PROGRAM

According to the OIG's *Compliance Program Guidance for Clinical Laboratories*, there are seven essential elements necessary in order to have an effective compliance program for laboratory functions. The following seven sections outline each element necessary and a description of its application within the laboratory at Huntington Health.

A. WRITTEN PROCEDURES AND POLICIES

1. The Laboratory Compliance Program will rely on the Standards of Conduct as an approach to doing business in an ethical and legal manner. Guidelines relevant to the laboratory are outlined in this Appendix in order to address department-specific issues and to provide additional clarification.

2. Written policies and procedures are created to provide guidance to employees regarding compliance issues specific to operations within the laboratory. As an appendix to the Compliance Program, this document is available to all laboratory employees on the hospital's Intranet web site. As individuals begin employment with Huntington Health, they will receive instruction on the hospital's Compliance Program. New employees of the laboratory will also receive department-specific training related to compliance topics as appropriate to their roles and responsibilities.

B. DESIGNATION OF COMPLIANCE OFFICER AND A COMPLIANCE COMMITTEE

1. For purposes of compliance oversight and reporting, the Laboratory Compliance Program will rely on the hospital's Compliance Officer for definitive guidance on compliance issues. However, due to the technical and clinical nature of laboratory functions, wherever possible,

employees are encouraged to report concerns of compliance issues to the Laboratory Director first, in an effort to resolve any concerns that may arise. The Laboratory Director can address the issue or counsel with the Compliance Officer for further information on situations which may either require additional legal clarification or which may involve departments outside the laboratory. In such cases where an employee feels that their concern is left unresolved by the Laboratory Director, or if employees feel uncomfortable bringing an issue to the Laboratory Director's attention, they can still report such alleged violations directly to the Compliance Officer or through the hospital's Compliance Hotline or WebLine services.

2. A Compliance Committee has been established on a hospital-wide basis to address compliance with the laws and regulations governing the hospital. Included on this committee is a standing member who represents laboratory functions. An additional compliance committee exists within the laboratory to coordinate ongoing lab compliance training, audit high-risk areas and review external regulations and educational material.

C. CONDUCTING EFFECTIVE TRAINING AND EDUCATION

1. As a condition of employment, all employees are required to receive annual training and education on issues related to the Compliance Program. Employees and managers of laboratory departments will also receive training and education on compliance issues specific to laboratory compliance concerns, as necessary. This training will be in addition to the general employment requirement for compliance training. The scope and breadth of compliance training for laboratory employees will be determined by the Laboratory Director and the Compliance Officer to ensure coverage of essential topics of compliance. Topics covered in training sessions will be based on the latest compliance issues and will include written tests or exams, where appropriate, in order to ensure a sound understanding of compliance concepts by employees. Annual training is a condition of employment. Completion of training and adequate accomplishment of testing activities will be a factor in all employees' annual performance review. Elements of training may include, but not be limited to, the following:
   a. Compliance program parameters (both hospital and laboratory-specific programs)
   b. Legal compliance issues
   c. Reporting mechanisms
   d. Documentation principles
   e. Reimbursement issues
   f. Other issues as necessary and appropriate

2. Education and training efforts will be conducted by laboratory management in conjunction with the Compliance Officer. Attendance at education and training seminars will be logged by laboratory management. Education and training will be an ongoing function as needs arise. Such issues will be reviewed and addressed at staff meetings or by request depending on the nature and severity of the issue.

D. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

1. Laboratory managers are encouraged to keep an "open door" policy when it comes to receiving reports from employees regarding issues that may be related to legal compliance. Employees should report any instance of conduct they believe is not in compliance with legal statutes or regulations. Wherever possible, employees should report such instances to their manager. If employees have questions regarding procedures or policies or need clarification on how to handle questionable situations, they are strongly encouraged to counsel with their manager for further guidance.

2. In such cases where an employee is unable to resolve the issue with their manager, or if they feel uncomfortable bringing such issues to their manager's attention, for any reason, such reports should be made directly to the Compliance Officer or through the use of the Compliance Hotline or WebLine. Written communications are also accepted in the Compliance Office per the address or fax destination listed in the Compliance Program (see Section II.C.2.c.i). All communications will be held confidential to the degree allowable by law. Huntington Health maintains a non-retaliation policy[17] for employees who report instances of conduct that they believe are not in compliance with the law.

E. ENFORCING STANDARDS THROUGH WELL-PUBLICIZED DISCIPLINARY GUIDELINES

1. In such cases where employees are found to be in violation of Laboratory Compliance Program parameters, disciplinary action will take place per Human Resources policies[18]. Laboratory management will supervise the disciplinary process for violations of the Laboratory Compliance Program. For violations of the Compliance Program, the disciplinary process will be the same as those described in the *Compliance Program Manual*.

F. AUDITING AND MONITORING

1. Ongoing auditing and monitoring tasks will be performed routinely. All auditing functions will be properly documented and used as a tool for continual improvement with processes and events related to legal compliance in the laboratory. Specifically, audits may include a review of operations pertaining to compliance with anti-kickback statutes and coding and billing of laboratory services. Particular attention should be devoted to topics of focus with fiscal intermediaries and payers, the OIG Work Plan, *OIG Special Fraud Alerts*, OIG audits and evaluations, and publicly announced law enforcement initiatives along with other issues identified by the hospital through the course of routine auditing and monitoring activities. The laboratory will work in conjunction with the appropriate billing or accounting office when dealing with an identified overpayment issue from a payer.

2. Ongoing evaluation of the effectiveness of the Laboratory Compliance Program will be conducted routinely. Evaluation and measurement of the compliance program will include the following elements:
   a. Dissemination of the program's standards
   b. Training

[17] See policy and procedure #145, "Non-Retaliation/Non-Retribution"
[18] See policy and procedure #850, "Discipline"

c. Ongoing educational programs
d. Disciplinary actions
e. Accurate and appropriate reporting mechanisms

3. Once conducted, appropriate modifications will be made to the Laboratory Compliance Program for perceived deficiencies and identified opportunities for improvement.

G. RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

1. The Laboratory Compliance Program will rely on existing policies and procedures listed in the Compliance Program for resolving instances of detected offenses. Laboratory management, in conjunction with the Compliance Officer, will conduct a thorough investigation regarding the incident and maintain a report of all investigations, interviews, and other documentation or information specific to the case. Based on the findings of the investigation, appropriate corrective actions will be instituted including revisions in applicable policies and procedures, additional training and education sessions or courses to ensure compliance with the goals and objectives of the program. Prompt communication will be made with applicable payers and fiscal intermediaries for cases involving overpayments or significant programmatic deficiencies.

III. LABORATORY COMPLIANCE ISSUES AND RELATED TOPICS

The following list represents those areas of particular compliance risk within the laboratory. Included are a list of the issues, a description of why it is a risk topic and the manner in which Huntington Health's laboratory will approach the issue in question.

A. MEDICAL NECESSITY

1. Requisition Design
   a. The laboratory will standardize its non-customized test offerings and use common, uniform requisition forms that emphasize physician choice and ensure that physicians order only those tests that are appropriate for each patient. In addition, the requisition forms require physicians to document the need for all tests by inserting a diagnosis code for each test ordered. Requisition forms are designed to require physicians to order chemistry tests individually (i.e., separately) unless:
      i. the test is specifically part of a CPT or HCPCS defined automated multi-channel test series, or
      ii. the test is part of a CPT-defined "clinically relevant test grouping" such as an organ or disease panel or profile
   b. Physicians (or other individuals authorized by law to order tests) will order only those tests which are medically necessary for the diagnosis or treatment of the patient rather than for screening purposes.
2. Notices to Physicians
   a. The laboratory compliance committee will provide physician clients with annual written notices that set forth:
      i. the Medicare medical necessity policy

ii. the individual components of every laboratory profile that includes a multi-channel chemistry test or other automated multiple test result
iii. the CPT or HCPCS codes that the laboratory uses to bill for each profile
iv. the Medicare National Limitation Amount for each CPT or HCPCS code used to bill Medicare for each profile and its components, and
v. a description of how the laboratory bills for each profile.

b. The laboratory engages a physician clinical consultant and is available to discuss appropriate testing and test ordering.

3. Test Utilization Monitoring
   a. Huntington Health will conduct ongoing monitoring of test utilization each year to identify statistically significant fluctuations in test utilization. Such variability in test ordering will be analyzed for cause to identify potential compliance concerns.

B. BILLING

1. Selection of CPT or HCPCS Codes
   a. The hospital will ensure that the CPT or HCPCS codes used accurately describe the services ordered and performed. The hospital will choose only those codes which most accurately describe the ordered and performed tests. To ensure coding accuracy, laboratories will require that codes are reviewed by individuals with technical expertise in laboratory testing before such codes are approved for claim submission.
2. Selection of ICD-10-CM Codes
   a. Diagnostic coding or descriptions are required to determine medical necessity in order to verify whether tests are approved for payment. Such diagnostic information must be submitted either through the use of an ICD-10-CM code or a narrative description. Laboratories will ensure that only diagnostic information obtained from the physician ordering the test is submitted.
   b. Laboratories **will not**:
      i. use diagnostic information provided by the physician from earlier dates of service (other than standing orders, as discussed below)
      ii. use "cheat sheets" which provide diagnostic information that has triggered reimbursement in the past
      iii. use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the physician, or
      iv. make up diagnostic information for claim submission purposes.
   c. Laboratories **will**:
      i. contact the ordering physician to obtain diagnostic information in the event the physician has failed to provide such information
      ii. provide services and diagnostic information supplied pursuant to a standing order executed in connection with an extended course of treatment, and
      iii. accurately translate diagnoses obtained from the physician to ICD-10-CM codes.
   d. When diagnostic information is obtained from a physician or the physician's staff after receipt of the specimen and the requisition form, documentation of the receipt of such information will be captured and maintained.
3. Tests Covered by Claims for Reimbursement
   a. The laboratory will ensure that only claims for tests that were both ordered and performed are submitted for payment. If the laboratory receives a specimen without a test order or

with an ambiguous test order which is subject to multiple interpretations, the facility will verify with the physician to determine what tests he or she wanted performed before submitting a claim for reimbursement. Thus, if the laboratory performs a test that the physician did not order, a bill will not be erroneously submitted for that test. Verbal orders require written referral within 30 days. Similarly, if a laboratory cannot perform an ordered test (i.e., laboratory accident, insufficient quantities of specimen, etc.) the laboratory will not submit a claim for services which were not rendered. The OIG considers the submission of a claim for tests that were either not ordered or were not performed to be a false claim.

4. Billing of Automated Multi-channel Chemistry Tests
    a. The laboratory will ensure that it bills appropriately for automated multi-channel chemistry tests. All tests appearing on CMS's most recent list of automated multi-channel chemistry tests will be billed using the appropriate CPT or HCPCS codes. Tests appearing on this list will not be billed individually unless only one such analyte test is ordered and performed.
5. Billing of Calculations
    a. Since the OIG views compliance programs as a check and balance system to reduce error and improve quality, the Laboratory Compliance Program will ensure that the laboratory does not bill for calculations (e.g., calculated LDLs, T7s, indices, etc.).

C. ADVANCED BENEFICIARY NOTICES (ABNs)

1. Advanced Beneficiary Notices (ABNs) are used when there is a likelihood that an ordered service will not be paid. Before the service is furnished, the beneficiary should be notified, in writing, of the likelihood that the specific service will be denied.
2. After being so informed the beneficiary has the choice to either (1) decide to receive the service and sign the agreement to pay on the ABN or (2) decide not to receive the service and therefore does not sign the ABN. Beneficiaries should not be asked to sign blanket ABNs.

D. RELIANCE ON STANDING ORDERS

1. Standing Orders
    a. Although standing orders are not prohibited in connection with an extended course of treatment, they have often led to fraudulent and abusive practices. Huntington Health is committed to taking appropriate steps to prevent abuse. Consistent with state law requirements, laboratories will contact nursing homes from which the lab has received such standing orders and request confirmation, in writing, as to the validity of all standing orders. If end stage renal disease (ESRD) patients have such standing orders, the lab must request confirmation in writing, at least annually, as to the continued validity of all standing orders.

E. COMPLIANCE WITH APPLICABLE HHS/OIG FRAUD ALERTS

1. The DHHS OIG periodically issues *Special Fraud Alerts* setting forth activities believed to raise legal and enforcement issues. The Laboratory Compliance Program requires that any and all fraud alerts issued by the OIG are carefully considered by legal staff, the Compliance Officer, and other appropriate personnel. Moreover, the Laboratory Compliance Program will require that the laboratory cease and correct any conduct criticized in such fraud alerts, if applicable, and take reasonable action to prevent such conduct from continuing.

F. PRICES CHARGED TO PHYSICIANS

1. Charges
    a. Laboratories are paid for services by a variety of payers in addition to Medicare and other federally funded health care programs. Such payers include health insurers, other health care providers and physicians. The prices laboratories charge, particularly to physicians, raises potential compliance issues. The Laboratory Compliance Program ensures that as tests are included or added to profiles, the price for the enhanced profile increases and the overall price for the profile is never below cost. Laboratories will never charge below cost while billing other insurance entities the full third-party price for profile components. To do so would place the hospital at risk for false claims and kickback enforcement action.

G. REVIEW OF ANTI-KICKBACK STATUTES

1. As written in the Compliance Program, Huntington Health will strictly abide by all anti-kickback and Stark regulations, particularly as they are applicable to laboratory functions and services. Huntington Health will avoid even the appearance of violating such statutes.

IV. CONCLUSION

A. ADOPTION INTO HUNTINGTON HEALTH'S COMPLIANCE PROGRAM

1. Huntington Health's Laboratory Compliance Program serves as a guideline for laboratory personnel as a means of ensuring that laboratory operations are performed in compliance with legal and regulatory statute, as well as providing the structural means of reporting, auditing and resolving instances of conduct that may be in violation of such regulations. This Laboratory Compliance Program is formally adopted into Huntington Health's hospital-based laboratory operations. Updates and modifications to this Program will be made by laboratory management and the Compliance Officer.

B. DISCLAIMER

1. The Laboratory Compliance Program presents guidelines and expectations about proper job-related conduct. However, this documentation cannot anticipate every situation that an employee may encounter. Employees should consult with their manager or the Compliance Officer for guidance if this Manual does not provide adequate direction or if the employee is being pressured to compromise his or her behavior, whether by another employee, a physician, a supplier, a competitor, a manager or a patient.
2. Hospital Administration reserves the right to add, delete, or modify policies and guidelines relative to the Laboratory Compliance Program as laws and regulations change or as is necessary or required to carry out the hospital's mission and to meet the laboratory compliance needs of the organization.

For additional questions regarding the Laboratory Compliance Program, please contact the Laboratory Director at 626.397.5773. For questions regarding Huntington Health's Compliance Program, please contact the Compliance Officer at 626.397.5335.

APPENDIX B

PATIENT FINANCIAL SERVICES COMPLIANCE PROGRAM

I. INTRODUCTION

As an extension of the existing Compliance Program, this Appendix represents Huntington Health's compliance program specific to issues related to patient financial services, medical records coding and admitting. The principles and concepts outlined in this section are adapted from the guidelines set in the Office of Inspector General's *Compliance Program Guidance for Third-Party Medical Billing Companies* (November 1998). While the internal Patient Financial Services Department is not a stand-alone medical billing company, the concepts and guidelines recommended by the Office of Inspector General outlined in this compliance program guidance can be applied to the operations of an internal hospital billing department. As such, the Patient Financial Services Compliance Program will lean on those issues which are specific to its operations. In those cases where program guidelines overlap with the overall Compliance Program, such programmatic parameters will rely on the main body of this manual, except as otherwise indicated. This Appendix is meant to provide specific guidance on compliance issues as they relate to the hospital's patient billing, coding and admitting operations.

Throughout this Appendix, reference is made generally to the "Patient Financial Services Department". It should be understood that this reference includes all patient financial services, medical records and admitting functions for Huntington Health.

II. PROGRAM STRUCTURE OF THE PATIENT FINANCIAL SERVICES COMPLIANCE PROGRAM

According to the OIG's *Compliance Program Guidance for Third-Party Medical Billing Companies*, there are seven essential elements necessary in order to have an effective compliance program for patient financial services functions. The following seven sections outline each element necessary and a description of its application at Huntington Health.

A. WRITTEN POLICIES AND PROCEDURES

1. The Patient Financial Services Compliance Program will rely on the Standards of Conduct as an approach to doing business in an ethical and legal manner. Guidelines relevant to Patient Financial Services are outlined in this Appendix in order to address issues and to provide additional clarification.

2. Written policies and procedures are created to provide guidance to employees regarding compliance issues specific to the operations within the Patient Financial Services Department. As an appendix to the Compliance Program, this document is made available to all Patient Financial Services employees on the hospital's Intranet web site. As individuals begin

employment at Huntington Health, they will receive instruction on the Compliance Program. New employees of the Patient Financial Services and Medical Records Departments will also receive department-specific training related to compliance topics as appropriate to their roles and responsibilities.

B. DESIGNATION OF COMPLIANCE OFFICER AND A COMPLIANCE COMMITTEE

1. For purposes of compliance oversight and reporting, the Patient Financial Services Compliance Program will rely on the hospital's Compliance Officer for definitive guidance on compliance issues. However, due to the technical nature of billing functions, wherever possible, employees are encouraged to report concerns of compliance issues to their manager first, in an effort to resolve any concerns that may arise. The manager can address the issue or counsel with the Compliance Officer for further clarification on situations which may either require additional legal clarification or which may involve departments outside of the Patient Financial Services Department. In such cases where an employee feels that their concern is left unresolved by their manager, or if employees feel uncomfortable bringing the issue to their manager's attention, they can still report such alleged violations directly to the Compliance Officer or through the hospital's Compliance Hotline service.

2. A Compliance Committee has been established on a hospital-wide basis to address compliance with the laws and regulations governing the hospital. Included on this committee is a standing member who represents patient financial services functions. As such, a formal committee for patient financial services compliance will not be established. However, this does not preclude individual patient financial services departments from forming their own committees or sub-committees to address temporary or ongoing compliance concerns or other matters of business. The Compliance Committee is responsible for ensuring that employees receive training in their respective spheres of responsibility throughout the hospital.

C. CONDUCTING EFFECTIVE TRAINING AND EDUCATION

1. As a condition of employment, all employees are required to receive annual training and education on issues related to the Compliance Program. Employees and managers of patient financial services departments will also receive training and education on compliance issues specific to patient financial services compliance concerns, as necessary. This training will be in addition to the general employment requirement for compliance training. The scope and breadth of compliance training for Patient Financial Services employees will be determined by the Director of Patient Financial Services and the Compliance Officer to ensure coverage of essential topics of compliance. Topics covered in training sessions will be based on the latest compliance issues and will include written tests or exams, where appropriate, in order to ensure a sound understanding of compliance concepts by employees. Annual training is a condition of employment. Completion of training and adequate accomplishment of testing activities will be a factor in all employees' annual performance review. Elements of training may include, but not be limited to, the following:
   a. Compliance program parameters (both hospital and Patient Financial Services-specific programs)
   b. Legal compliance issues

c. Reporting mechanisms
d. Documentation principles
e. Reimbursement issues
f. Other issues as necessary and appropriate

2. Education and training efforts will be conducted by Patient Financial Services management in conjunction with the Compliance Officer. Attendance at education and training seminars will be logged by Patient Financial Services management. Education and training will be an ongoing function as needs arise. Such issues will be reviewed and addressed at staff meetings or by request depending on the nature and severity of the issue.

D. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

1. Patient Financial Services managers are encouraged to keep an "open door" policy when it comes to receiving reports from employees regarding issues that may be related to legal compliance. Employees should report any instance of conduct they believe is not in compliance with legal statutes or regulations. Wherever possible, employees should report such instances to their manager. If employees have questions regarding procedures or policies or need clarification on how to handle questionable situations, they are strongly encouraged to counsel with their manager for further guidance.

2. In such cases where an employee is unable to resolve the issue with their manager, or if they feel uncomfortable bringing such issues to their manager's attention, for any reason, such reports should be made directly to the Compliance Officer or through the use of the Compliance Hotline or WebLine. Written communications are also accepted in the Compliance Office per the address or fax destination listed in the Compliance Program (see Section II.C.2.c.i). All communications will be held confidential to the degree allowable by law. Huntington Health maintains a non-retaliation policy[19] for employees who report instances of conduct that they believe are not in compliance with the law.

E. ENFORCING STANDARDS THROUGH WELL-PUBLICIZED DISCIPLINARY GUIDELINES

1. In such cases where employees are found to be in violation of Patient Financial Services Compliance Program parameters, disciplinary action will take place per Human Resources policies[20]. Patient Financial Services management will supervise the disciplinary process for violations of the Patient Financial Services Compliance Program. For violations of the Compliance Program, the disciplinary process will be the same as those described in the *Compliance Program Manual*.

[19] See policy and procedure #145, "Non-Retaliation/Non-Retribution"
[20] See policy and procedure #850, "Discipline"

F. AUDITING AND MONITORING

1. Ongoing auditing and monitoring tasks will be performed routinely. All auditing functions will be properly documented and used as a tool for continual improvement with processes and events related to legal compliance in the patient financial services departments. Specifically, audits may include a review of operations pertaining to compliance with anti-kickback statutes and coding and billing of hospital services. Particular attention should be devoted to topics of focus with fiscal intermediaries and payers, the OIG Work Plan, *OIG Special Fraud Alerts*, OIG audits and evaluations, and publicly announced law enforcement initiatives along with other issues identified by the hospital through the course of routine auditing and monitoring activities.

3. The Patient Financial Services Department will manage verified overpayments in compliance with AB 1455 and any other regulatory requirements.

2. Ongoing evaluation of the effectiveness of the Patient Financial Services Compliance Program will be conducted routinely. Evaluation and measurement of the compliance program will include the following elements:
   a. Dissemination of the program's standards
   b. Training
   c. Ongoing educational programs
   d. Disciplinary actions
   e. Accurate and appropriate reporting mechanisms

3. Once conducted, appropriate modifications will be made to the Patient Financial Services Compliance Program for perceived deficiencies and identified opportunities for improvement.

G. RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

1. The Patient Financial Services Compliance Program will rely on existing policies and procedures listed in the Compliance Program for resolving instances of detected offenses. Patient Financial Services management, in conjunction with the Compliance Officer, will conduct a thorough investigation regarding the incident and maintain a report of all investigations, interviews, and other documentation or information specific to the case. Based on the findings of the investigation, appropriate corrective actions will be instituted including revisions in applicable policies and procedures, additional training and education sessions or courses to ensure compliance with the goals and objectives of the program. Prompt communication will be made with applicable payers and fiscal intermediaries for cases involving overpayments or significant programmatic deficiencies.

III. PATIENT FINANCIAL SERVICES COMPLIANCE ISSUES AND RELATED TOPICS

The following list represents those areas of particular compliance risk within the Patient Financial Services Department. Included are a list of the issues, a description of why it is a risk topic and the manner in which Huntington Health's Patient Financial Services Department will approach the issue in question.

A. BILLING FOR ITEMS OR SERVICES NOT ACTUALLY DOCUMENTED

1. Billing for items or services not actually documented involves submitting a claim that cannot be substantiated in the medical record documentation. Under no circumstance should products or services be billed when it is known that such services were not rendered. The Patient Financial Services Department will not bill for service or products which it knows were not rendered. If it is discovered that products or services were billed incorrectly by the department from which the services were rendered, such billings will be corrected in a timely manner.

B. UNBUNDLING

1. Unbundling occurs when a billing department uses separate billing codes for services that have an aggregate billing code. Such practices of inappropriate unbundling will be avoided by Patient Financial Services staff.

C. INAPPROPRIATE BALANCE BILLING

1. Inappropriate balance billing refers to the practice of billing Medicare beneficiaries for the difference between the total provider charges and the Medicare allowable payment. Patient Financial Services personnel will avoid billing Medicare beneficiaries for the balance of non-allowable payments.

D. INADEQUATE RESOLUTION OF OVERPAYMENTS

1. An overpayment is an improper or excessive payment made to a health care provider as a result of patient billing or claims processing errors for which a refund is owed by the provider. Examples of Medicare overpayments include instances where a provider is:
   a. paid twice for the same service either by Medicare and another insurer or beneficiary; or
   b. paid for services planned but not performed or for non-covered services.
2. The Patient Financial Services Department will manage overpayment and credit balances in accordance with AB 1455 and other regulatory requirements.

E. COMPUTER SOFTWARE PROGRAMS THAT ENCOURAGE BILLING PERSONNEL TO ENTER DATA IN FIELDS INDICATING SERVICES WERE RENDERED THOUGH NOT ACTUALLY PERFORMED OR DOCUMENTED

1. Huntington Health will ensure that no software is used that prompts or encourages billing personnel to modify or alter any data within the system in an effort to improperly bill claims.

F. FAILURE TO MAINTAIN THE CONFIDENTIALITY OF INFORMATION/RECORDS

1. Policies and procedures exist to protect and hold confidential all financial and medical information specific to a patient's course of care and financial obligations. Patient Financial Services employees will protect patient health information including demographic information or other information related to the billing process and pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and the California State Confidentiality of Medical Information Act (CMIA)[21].

G. OUTPATIENT SERVICES RENDERED IN CONNECTION WITH INPATIENT STAYS

1. Departments that submit claims for non-physician outpatient services that were already included in the hospital's inpatient payment under the Prospective Payment System (PPS) are in effect submitting duplicate claims. This concept is referred to as the DRG 3-Day Payment Window. If outpatient services are rendered to Medicare patients within 72 hours prior to their inpatient stay, such services are to be paid for as part of the inpatient DRG payment. The Patient Financial Services department will ensure that such outpatient activity is not billed when already covered under an inpatient payment as part of the PPS program.

H. DUPLICATE BILLING IN AN ATTEMPT TO GAIN DUPLICATE PAYMENT

1. Duplicate billing occurs when the hospital submits more than one claim for the same service or the bill is submitted to more than one primary payer at the same time. Although duplicate billing can occur due to simple error, knowing duplicate billing – which is sometimes evidenced by systematic or repeated double billing – can create liability under criminal, civil or administrative law, particularly if any overpayment is not properly refunded. Patient Financial Services will avoid any and all practices that appear to be an attempt to double bill. This excludes instances that due to a DOFR (Division of Financial Responsibility) document; it is unclear whom to bill between the medical group or the plan for a given service. In these cases, a bill may need to be sent to both entities for a final decision as to whom is responsible for payment.

I. ROUTINE WAIVER OF CO-PAYMENTS AND BILLING THIRD-PARTY INSURANCE ONLY

1. Billing departments should make a good faith effort to collect co-payments, deductibles and non-covered services from federally and privately insured patients. Billing "insurance only" may violate the False Claims Act, the anti-kickback statute, the Civil Monetary Penalties Law and State laws. The OIG has published a *Special Fraud Alert* on the routine waiver of co-payments or deductibles.[22] This does not include financial assistance eligibility whether by application or use of a third-party algorithm calculating presumptive charity eligibility.

J. CASH PAYING PATIENTS

1. Huntington Health has a practice in place for all patients who desire to pay cash for hospital services. To ensure appropriate payment from cash-paying patients, the hospital will follow its practices on this topic.

K. MEDICARE AS SECONDARY PAYER (MSP)

[21] See policy and procedure #150, "Privacy and Security of Patient Information Program – Governing Principles" for a complete list of HIPAA-related policies and procedures.

[22] See OIG *Special Fraud Alert*, December 19, 1994.

1. According to Medicare regulations, health care providers are required to ensure that the Medicare program not be the primary source of payment for services to its beneficiaries where another source of reimbursement is available (i.e., coverage under spouse's employment, third-party liability, coordination of benefits, specially-funded or excluded programs, etc.). The hospital will ensure that appropriate measures are taken using the Medicare as Secondary Payer process to assure that Medicare is not billed for services rendered to patients who have some alternate form of coverage.

IV. CONCLUSION

A. ADOPTION INTO HUNTINGTON HEALTH'S COMPLIANCE PROGRAM

1. Huntington Health's Patient Financial Services Compliance Program serves as a guideline for patient financial services personnel as a means of ensuring that billing, coding and admitting operations are performed in compliance with legal and regulatory statute, as well as providing the structural means of reporting, auditing and resolving instances of conduct that may be in violation of such regulations. This Patient Financial Services Compliance Program is formally adopted into Huntington Health's hospital-based Patient Financial Services operation. Updates and modifications to this Program will be made by patient financial services management and the Compliance Officer.

B. DISCLAIMER

1. The Patient Financial Services Compliance Program presents guidelines and expectations about proper job-related conduct. However, this documentation cannot anticipate every situation that an employee may encounter. Employees should consult with their manager or the Compliance Officer for guidance if this manual does not provide adequate direction or if the employee is being pressured to compromise his or her behavior, whether by another employee, a physician, a supplier, a competitor, a manager or a patient.

2. Hospital Administration reserves the right to add, delete, or modify policies and guidelines relative to the Patient Financial Services Compliance Program as laws and regulations change or as is necessary or required to carry out the hospital's mission and to meet the billing, coding and admitting compliance needs of the organization.

For additional questions regarding the Patient Financial Services Compliance Program, please contact the Vice President of Revenue Cycle Services at 626.397.3864. For questions regarding Huntington Health's Compliance Program, please contact the Compliance Officer at 626.397.5335.