I. INTRODUCTION

The Johns Hopkins Health System Corporation and its affiliates (collectively referred to as “Health System”)\(^1\) are subject to a myriad of federal, state, and local laws and regulations as they carry out their mission as world leaders in the areas of patient care, teaching and research. These laws and regulations are voluminous and complex, and change periodically. The Health System is committed to compliance by both Health System personnel (such term shall include officers, all other employees, trustees, and agents or contractors) and by the Professional Staff who provide health care services at Health System hospitals and other health care delivery sites. In order to enhance our collective efforts to comply, the Health System, by action of the Board of Trustees, has adopted this Corporate Compliance Plan.

This plan supersedes the previously adopted Corporate Compliance Plan and acts to establish the overall framework for internal policies, procedures, and mechanisms which will give guidance to and assist each of us in complying with the laws and regulations that apply to our activities on behalf of the Health System. The plan is not designed to provide detailed guidance but rather a roadmap to the Health System’s compliance efforts coupled with the additional detailed policies and procedures that promote compliance and ethical conduct. Specifically, this plan, in providing overall compliance guidance for the Health System, is

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\(^1\) Included are the Health System entities that bill the various insurers: The Johns Hopkins Hospital, Inc.; The Johns Hopkins Bayview Medical Center, Inc.; The Howard County General Hospital, Inc.; Johns Hopkins Community Physicians, Inc.; Johns Hopkins HealthCare LLC; Suburban Hospital Healthcare System, Inc., The Lucy Webb National Training School for Deaconesses and Missionaries, dba, Sibley Memorial Hospital, Potomac Home Health Care, the Johns Hopkins HomeCare Group and All Children's Hospital, Inc. & All Children's Health System, Inc. (hereinafter “All Children’s”). The Plan also applies to those JHHS organizations that bill for professional services. Such organizations are governed by the JHSOM Billing Quality Assurance Plan hereby incorporated by reference at Addendum 1. Minority owned professional practices will be monitored on a case-by-case basis.
intended to supplement current compliance policies and procedures such as the Conflict of Interest Policy and Medicare Part D Compliance Supplement. The Medicare Part D Supplement addresses requirements related to drug plan sponsors such as the Hopkins ElderPlus Program of All-inclusive Care for the Elderly (“PACE”). Finally, the plan acts to bind affiliate Codes of Conduct for all personnel covered under this plan.

The plan is designed to incorporate recommendations enumerated in the Department of Health and Human Services Office of Inspector General’s (“OIG”) Compliance Program Guidance for Hospitals as well as reflect the elements of an effective compliance plan as described in the Federal Sentencing Guidelines. The Plan also explains fraud and abuse as it relates to the provision and billing of health care services and the applicable enforcement laws which may be utilized both by the government and our employees should such activities be determined. The Plan is to be a guide and resource to help all personnel ensure that their behavior is in compliance with all laws and regulations that affect their business dealings on behalf of the Health System. It is also intended to serve as a resource for Board Members and Health System Officers regarding their corporate responsibilities. The plan also describes the procedures that will be followed in enforcing these standards and ensuring that the Health System stays in compliance with all applicable laws.

**The Importance of the Compliance Plan**

The Health System is committed not only to providing patients with high quality and caring medical services, but also to providing those services pursuant to the highest ethical, business and legal standards. Our compliance efforts are designed to perpetuate a culture within the Health System that promotes prevention, detection and resolution of instances of conduct that do not conform to federal, state, and local laws and federal, state and private payor health care program requirements. This is not only the right thing to do, but it is also important for our continuing reputation for honesty and integrity in our business and medical dealings with others.

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2 The OIG Guidance for Hospitals was originally issued in 1998 and supplemented 2005.
The Compliance Plan is especially critical as an internal control in the reimbursement and payment areas. Throughout the health care industry, claims and billing operations often raise potential fraud and abuse concerns and, therefore, have been the focus of governmental reviews and sanctions.

Moreover, compliance with federal and state laws, rules and regulations is essential because of the potential for civil or even criminal liability if we were found to have violated the applicable legal standards. A governmental inquiry can lead to significant financial exposure and damage to our reputation for honesty and integrity. Prevention is certainly the wiser business plan, and that is what our Compliance Program is designed to accomplish.

**Purpose and Execution of the Compliance Plan**

The purpose of the Compliance Plan is to guide the Health System in its management and operation of compliance-related activities. The Health System intends to demonstrate that it is both committed to, and actually exercises, due diligence in seeking to prevent and detect systemic problems and violations of law by developing and sustaining a rigorous Compliance Plan. The Compliance Plan has at its foundation, seven elements that federal guidelines have deemed necessary for an effective, high-quality compliance program. This document provides the framework to meet the seven elements:

1. **Written standards of conduct** have been developed, centrally through the plan and reinforced through each system affiliate’s written policies to promote the Health System’s commitment to compliance. These standards establish the expectation of ethical behavior and compliant conduct and provide for disciplinary action for failure to adhere.

2. The Health System has a: **Chief Compliance Officer; Vice President for Compliance; Compliance Oversight Committee**, and a **Compliance Sub-Committee** of the **Audit, Compliance and Insurance Committee of the JHHS Board of Trustees** charged with the responsibility of operating and monitoring the Compliance Program.

3. There are currently regular **compliance education and training** programs for all affected personnel;
4. The Health System maintains a **hotline**, to receive complaints and to respond to questions, and has adopted procedures that emphasize nonretribution, nonretaliation policy and includes a mechanism for anonymous communications for which appropriate confidentiality is maintained.

5. There is a **system to respond to allegations of improper/illegal activities** and the enforcement of appropriate disciplinary action against personnel who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;

6. **Audits** and/or other evaluation techniques are utilized to monitor compliance and assist in the reduction of identified problem areas; and

7. **Identified systemic problems** are **investigated and remediated** and policies have been developed to address the non-employment or retention of sanctioned individuals.

The Health System is committed to upholding the highest standards of ethical conduct. The standards of conduct, however, cannot cover every situation that Health System personnel and Professional Staff might face. Accordingly, the Health System’s Compliance Department and the Compliance Hotline (1-877-WE COMPLY) are always available if there is ever any doubt as to what the proper course of conduct might be in a specific situation or if a violation of the standards of conduct set out in this plan is suspected.

The Health System will coordinate its compliance efforts with The Johns Hopkins University School of Medicine, the Office of Billing Quality Assurance, the Johns Hopkins Institutions Office of Hopkins Internal Audits and the Clinical Practices Association to ensure consistent application and to achieve efficiencies.

**A. STANDARDS OF CONDUCT AND GENERAL POLICIES**

The Health System is committed to following all applicable laws and regulations and in particular, those laws and regulations that address health care fraud, waste, and abuse such as the Federal False Claims Act and applicable State law and enforcement policies. To assist in this effort, this Compliance Plan and associated policies have been implemented throughout the Health System with a particular emphasis in the areas of financial billing,
accreditation, conflicts of interest, physician relationships, quality of care, research, gifts, confidentiality, non-discrimination and professional and/or organizational ethics. Compliance with the plan and associated policies and procedures is the responsibility of all Health System personnel and Professional staff.

The Health System expects that all personnel will take part attentively in education and training programs conducted by the Health System and that they will conduct their daily activities in conformance with the principles conveyed through such programs. Health System personnel and members of the Professional Staff also are expected to report actual or suspected violations of law or regulations of which they become aware and to cooperate in the investigation of any reported violations. Failure to comply with applicable laws and regulations or other provisions of this Corporate Compliance Plan will be viewed as a serious matter and can result in disciplinary action.

The Board of Trustees, the President of the Health System and senior management have made a commitment that it is the policy of the Health System, apart from applicable laws and regulations, to conduct its business with integrity and in accordance with the highest ethical standards. Honesty, integrity, dignity, respect and justice are expected in dealing with patients, physicians, fellow employees, visitors, vendors, students, auditors and other persons or entities with which the Health System has business relationships. Failure to act in accordance with these principles will be treated as a serious matter.

All Health System personnel must comply with the standards of conduct set forth in the Compliance Plan and in individual affiliate policies of the same. All personnel are expected to report potential issues and raise questions as set forth in the Compliance Plan. Strict compliance with the Plan’s legal and compliance standards is a condition of employment, and violation of any of these standards of conduct will result in discipline being imposed including, but not limited to, the following:

- Informing and discussing with the relevant personnel both the violation and how it should be avoided in the future;
- Providing remedial education (formal or informal) to ensure that the relevant personnel understand the applicable rules and regulations;
• Conducting a follow-up review to ensure that the problem is not recurring;
• Refunding any past payments that resulted from improper bills;
• Imposing discipline, as set forth below;
• Suspending all billing of the services provided, as set forth below; and
• When appropriate, voluntarily disclosing to an appropriate governmental agency
• Discipline in accordance with the applicable affiliate disciplinary policy, up to, and
  including, termination from employment.

The following represent areas of concern for both government and private payors, and the appropriate standards to deal with them:

**Billing Compliance:**

The Health System and certain affiliates are charitable organizations with a duty to provide healthcare services to members of their community and support medical training and research. In support of this charitable mission, Health System Personnel are required to administer medical services to patients in need of emergency care without regard to their ability to pay.

However, when billing for services provided, the Health System Compliance Program, through this Plan, its policies, procedures and affiliate Codes of Conduct, have taken into consideration the regulatory requirements we face in areas of concern that have been identified by the government. Accordingly, all billing must be accurate and truthful; and no personnel should ever misrepresent charges to, or on behalf of, a patient or third-party payors. The Health System bills only for those services that were actually and appropriately rendered and ordered by individuals licensed to do so. False statements or intentional omissions of material information by any personnel to a government agency or other payor will not be tolerated. All personnel, moreover, must avoid not only intentional misstatements, but reckless statements or omissions as well. It is, of course, illegal to intentionally falsify billing documents submitted to the government or private insurance companies or documents supporting such bills. It is also illegal to supply false information with either a deliberate ignorance or a reckless disregard of its falsity or truth. Thus, if personnel have any question as to the truth or accuracy of the documentation for billing purposes, or if there is material information that is missing, the bill for the services in
question should be held until the uncertainties are resolved. Anything less can result in over billing and is strictly prohibited.

The following represent areas of concern for both government and private payors, and the appropriate standards to deal with them:

1. Billing:

   a. **Medical Necessity for Services.** The Health System will submit claims to Medicare or Medicaid (or any other federally funded health care program or private insurers) only for services that were medically necessary or that otherwise constituted a covered service. Medical necessity will be determined individually for each service or test provided or ordered by the responsible physician or other individual licensed to do so. A medically necessary service or test is defined as one that is reasonable and necessary for the diagnosis or treatment of an illness, injury or to improve the functioning of a malformed body member. The government will generally only pay for services and tests that are medically necessary and will deny payments for those that are not medically necessary, such as routine physicals, many screening tests or tests conducted for research purposes. Every governmental claim form should be supported by a physician certification that the services were medically necessary for the health of the patient.

   b. **Billing for Items or Services Not Actually Rendered.** Submitting a claim representing that a provider performed a service all or part of which was simply not performed, is inappropriate, at a minimum, and possibly illegal. Only those medical services to patients that are consistent with acceptable standards of medical care may be billed. The Health System will only bill for the actual services rendered, and only when those services were consistent with accepted standards of medical care. The billing for such services must comply with all applicable rules and regulations governing correct documentation, coding and billing.

   c. **Billing without Adequate Documentation.** Billing should be based upon adequate documentation of the medical justification for the service provided and for the bill submitted, and this medical documentation must comport with all applicable regulations. A bill should not be submitted to a payor if the documentation of the nature or scope of the service is unclear or if it is otherwise unclear what the appropriate code is.

   d. **Correct Coding.** All federal and state regulations governing billing procedures are to be followed and all personnel responsible for billing will be trained in the appropriate rules.
governing billing, coding and documentation. If the documentation in the medical record is unclear, then billing personnel must request clarification or additional information from the physician or provider of services. This includes when the appropriate code or diagnosis is unclear. Billing personnel cannot create coding or diagnostic information based upon their own interaction with the patient, from information provided from an earlier date of service, or based on what they might conclude is the probable or most likely diagnosis.

e. **Upcoding.** This reflects the practice of using a billing code that provides a higher payment rate than the billing code that actually reflects the services provided to the patient. No Health System personnel shall knowingly engage in any form of upcoding. All federal and state regulations governing billing procedures will be followed.

f. **Duplicate Billing.** This occurs when a provider submits more than one claim for the same service or the bill is submitted to more than one primary payor at the same time. Although duplicate billings can occur due to simple billing error, systemic or repeated double billing may be viewed as a false claim, particularly if the overpayment is not properly refunded. It is the Health System’s policy to never intentionally submit duplicate billings and to correct any inadvertent duplicate billings.

g. **Cost Reports.** The Health System cost reports will be prepared in compliance with all applicable state and federal regulations. Costs will be claimed when based upon appropriate and accurate documentation; unallowable costs will not be claimed for reimbursement and all costs will be properly allocated to the appropriate cost centers based on verifiable information and data.

2. **Other Compliance Risk Areas:**
a. **Anti-Kickback.** The Health System is committed to complying with all laws that prohibit illegal remuneration, such as kickbacks, bribes, improper or excessive payments, free or below market rents or fees for administrative services, or interest-free loans. Health System personnel are prohibited from offering, providing, accepting, or asking for anything of value with the intent to influence or be influenced by patients, their families, suppliers, contractors, vendors, physicians, third-party payors, managed care organizations, or government officials. Health System personnel may not offer, provide, accept, or ask for anything of value for the referral of
individuals for services covered by Medicare, Medicaid, or other federal health care programs. Health System personnel are also prohibited from accepting or requesting payment for the purchase or lease of any good, item, or service covered under any federal health care program.

b. **Standards Relating to Referrals.** The federal Stark physician self-referral law generally prohibits a physician from referring a Medicare or Medicaid patient to an entity for certain “designated health services” if the physician (or an immediate family member) has a financial relationship with the entity providing the “designated health services” unless certain limited exceptions apply. A prohibited financial relationship includes both an ownership or investment interest and a compensation arrangement. In addition, many states, including Maryland, have similar, and at times broader, self-referral prohibitions. To ensure compliance with these self-referral prohibitions, all financial relationships between the Health System and any referring physician (or his or her immediate family members) must be reviewed and approved by the Health System Legal Department.

The Health System does not pay physicians, or anyone else, either directly or indirectly, for patient referrals. The decision to refer patients is a separate and independent clinical decision made by the referring physician.

**B. COMPLIANCE STRUCTURE AND OVERSIGHT**

The Health System formally designates Trustees, the Health System President, a Compliance Oversight Committee, a Vice President for Compliance, a Chief Compliance Officer, a Deputy Chief Compliance Officer and Director of Billing Compliance and other subject matter compliance officers, as applicable. The structure of and the reporting relationships for the Health System compliance function shall be as set forth below.

1. **AUDIT, COMPLIANCE AND INSURANCE COMMITTEE AND COMPLIANCE SUB-COMMITTEE**

   The Health System Audit, Compliance and Insurance Committee with the assistance of the Compliance Sub-Committee are charged with oversight of the Compliance Plan and all internal and independent auditing activity. The Committee is comprised of Trustees who
have an understanding of compliance issues delineated in this plan and those that affect the Health System so as to ensure compliance with legal and regulatory requirements.

2. COMPLIANCE OVERSIGHT COMMITTEE

The Compliance Oversight Committee will provide advice, counsel, and assistance to the Chief Compliance Officer in the performance of his/her duties. The members of the Corporate Compliance Oversight Committee, in addition to the Chief Compliance Officer, and the Deputy Chief Compliance Officer and Director of Billing Compliance, are the Johns Hopkins Bayview Medical Center Vice President, Finance, the Johns Hopkins Hospital Executive Vice President & Chief Operating Officer, the Johns Hopkins Hospital Vice President, Nursing & Patient Care Services, the Health System Controller, the Health System Vice President & General Counsel, the Johns Hopkins Hospital Vice President, Medical Affairs, the Health System Director of Internal Audit, the Health System Vice President for Corporate Compliance, the Health System Vice President, Finance & Treasurer, the Associate Dean of the Clinical Practices Association, the Howard County General Hospital Senior Vice President for Finance, the Johns Hopkins Medicine Vice President for Ambulatory Services, the Johns Hopkins Hospital Vice President for General Services, the Health System Senior Director for Patient Financial Services, the Suburban Hospital Senior Vice President for Finance and the Health System Vice President for Human Resources and senior management from Johns Hopkins Community Physicians; Johns Hopkins HealthCare LLC; and relevant staff from Sibley Memorial Hospital, Potomac, and All Children’s.

The Committee may be expanded to include representatives of the Health System Affiliates. The Committee shall meet on a quarterly basis, unless it decides that a different frequency is more appropriate. The Committee shall discuss the following agenda items: current Health System compliance issues, new laws or regulations or communications from regulatory authorities, problems with and suggested improvements to the Health System’s Corporate Compliance Plan, the status of any non-compliant activities being investigated or remediated by the Chief Compliance Officer and the Compliance Department, any matters for which the Chief Compliance Officer desires advice or counsel from the Committee, and any compliance related matters that any member of the Committee desires to raise.
3. VICE PRESIDENT FOR COMPLIANCE

The Vice President for Compliance has responsibility for assuring, as a senior member of the Health System executive team, that the Health System has an effective program to prevent and detect violations of any criminal or civil laws or regulations for which the Health System is potentially liable. The Vice President for Compliance also provides advice, counsel, and assistance to the Chief Compliance Officer in the performance of his/her duties. The Chief Compliance Officer has a reporting responsibility to the Vice President for Compliance. Additionally, the Vice President for Compliance with the Chief Compliance Officer has a reporting responsibility, when appropriate, to the President of the Health System and to the Audit, Compliance and Insurance Committee of the Health System Board of Trustees.

4. CHIEF COMPLIANCE OFFICER

The Health System Board has designated a Chief Compliance Officer to coordinate the development, implementation, communication and monitoring of the Corporate Compliance Plan. The Chief Compliance Officer reports directly to the Audit, Compliance and Insurance Committee of the Board of Trustees of the Health System and will have access to the Committee and to Committee members with respect to compliance issues at all times. In addition, the Chief Compliance Officer will have primary administrative reporting responsibility to the Vice President for Compliance and various reporting relationships with members of executive management and the Compliance Oversight Committee. The Chief Compliance Officer is also vested with the power to investigate instances of possible non-compliance with law or regulations or other provisions of the Corporate Compliance Plan and all Health System personnel are required to cooperate fully with the Chief Compliance Officer in connection with any such investigative activities. The Chief Compliance Officer will generally oversee and coordinate all compliance activities, including education and training and the compliance monitoring activities discussed below.
The Chief Compliance Officer will establish and maintain a record keeping system in connection with the Corporate Compliance Plan. These records shall include, but not be limited to, instances of possible non-compliance which come to the attention of the Chief Compliance Officer, a record of disposition of these matters, and all documents submitted to the Chief Compliance Officer in connection with the administration of the Corporate Compliance Plan. All records shall be kept in a secure location to protect their confidentiality and shall be retained for at least the period required by law or regulation and by sound business practice.

The Chief Compliance Officer shall maintain liaison with in-house and outside counsel and with regulatory authorities in connection with the administration of the Corporate Compliance Plan and when appropriate, shall consult with independent outside counsel through the Health System Legal Department when significant compliance issues arise (unless conduct of the Health System Legal Department is at issue, in which case such consultation with outside counsel will be direct).

The Chief Compliance Officer shall oversee the activities of the Deputy Chief Compliance Officer and the compliance liaisons that, in cooperation with the Chief Compliance Officer, are responsible for compliance in their own entities, departments or subject matter focus and for training of personnel within their scope with respect to compliance matters.

5. DEPUTY CHIEF COMPLIANCE OFFICER
The Health System has designated Deputy Chief Compliance Officer (“Deputy”) to provide guidance on the statutory and regulatory requirements to maintain the Health System’s compliance with third party payor billing and reimbursement rules. The Deputy reports directly to the Chief Compliance Officer.

The Deputy plays a key role in developing and implementing compliance-related education and training programs for the Health System. The Deputy will generally oversee and coordinate all billing compliance activities, including education and training of internal
Compliance audit staff. As such, the Deputy co-chairs the Billing Compliance Committee which is comprised of senior Health System personnel that represent all aspects of the billing process.

The Deputy is responsible for developing and implementing billing compliance policies and standards. The Deputy is vested with the power to investigate instances of possible non-compliance with law and regulations relating to health services billing and reimbursement and to coordinate corrective action in conjunction with the Chief Compliance Officer and Health System Legal Department, where appropriate. All Health System personnel are required to cooperate fully with the Deputy in connection with any investigative and corrective actions undertaken in this role. The primary focus of the Deputy is governmental payor billing and reimbursement related regulations and requirements and compliance education. The Deputy also has responsibility with respect to compliance with federal and state fraud and abuse statutes.

C. EDUCATION AND TRAINING

The Health System presently has various policies and education programs designed to teach personnel about the Compliance Department and their individual compliance responsibilities. One such policy establishes an initial, mandatory training program for new personnel. A part of the educational process involves the dissemination of regulatory advisements, changes in coverage policies and similar materials and is intended to update critical Health System personnel so that they can perform their jobs in a compliant framework. In addition, all Departments that undergo scheduled or investigative audits conducted by the Corporate Compliance Department shall receive specialized training to implement all recommendations from the final audit report which sets forth the laws and regulations which regularly apply to the performance of their duties. Building on these existing efforts, the Deputy Chief Compliance Officer and Director of Billing Compliance, in conjunction with the Chief Compliance Officer and the various subject matter compliance officers for the Health System have developed a standardized, comprehensive and continuing compliance training program applicable to all appropriate personnel.
All Health System personnel are responsible for incorporating into practice Compliance Department sponsored education and training sessions. Compliance training and education may be provided in a variety of ways, including educational programs conducted by knowledgeable Health System personnel and Compliance staff, programs conducted by knowledgeable outsiders, and/or attendance at outside seminars. Regardless of the presenter, the Deputy Chief Compliance Officer shall oversee, where appropriate, the program(s) to ensure attendance and active participation in training sessions. Participation in training may be a factor in each employee's performance appraisals. Advance notice of training programs will be given to ensure attendance. Participation in these programs shall be documented.

Additionally, the Billing Compliance Committee has been established as a forum for high-level personnel throughout the Health System to conduct educational sessions on all issues related to laws, rules, regulations and coverage decisions and the impact they have on billing. The Billing Compliance Committee meets bi-monthly and is co-chaired by the Deputy Chief Compliance Officer and Director of Billing Compliance and the Compliance Technical Advisor. Members include among others the: Director and Associate Director of Patient Financial Services; Regulatory Compliance Managers from The Johns Hopkins Bayview Medical Center and The Howard County General Hospital; Director of Internal Audits; The Johns Hopkins Hospital Health Information Supervisor; The Howard County General Hospital Director of Case Management; Health System Director of Case Mix; The Johns Hopkins Bayview Medical Center Director of Health Information Management; The Johns Hopkins Hospital Director of Admissions; Director of the Johns Hopkins Outpatient Center, relevant staff from the Suburban Hospital Health System, Sibley Hospital, All Children’s Hospital and the Johns Hopkins Director of Medical Records.

D. INDIVIDUAL INTEGRITY POLICY AND DISCIPLINARY STANDARDS FOR COMPLIANCE VIOLATIONS

All Health System personnel will deal with Health System organizations, Professional Staff and third parties with whom they have contact on behalf of the Health System
with honesty and integrity. They will provide sufficient information in any such dealings so as not to be misleading. In addition, all Health System personnel shall perform in the workplace in accordance with the Health System’s plan and related policies.

Personnel who are entitled to reimbursement for expenses by the Health System shall keep accurate records of such expenses, and shall not seek reimbursement except as permitted by applicable policies and procedures. Health System personnel involved in contracting with third parties and in the procurement of goods and services shall at all times act in a professional and ethical manner. Personnel involved in such activities will not solicit or accept any gift or gratuity other than customary business courtesies which are reasonable in frequency and minimal in value. All Health System personnel shall immediately disclose to the Vice President for Compliance or the Chief Compliance Officer any potential conflict of interest which could influence any decision or action which they may take on behalf of the Health System. Examples of situations which constitute conflicts of interest include transacting Health System business with family members or close friends or with entities in which the Health System personnel involved has a direct or indirect financial interest.

E. MONITORING COMPLIANCE

The most effective means to determine whether a compliance plan is successful is to monitor activities in relation to applicable laws and regulations to determine if those activities are being conducted in a compliant manner. To this end, the Corporate Compliance Department will conduct various monitoring activities to measure compliance. Such activities may include, for example, unannounced audits of certain patient records and periodic and systematic auditing of various areas by the Compliance Department or outside consultants. All personnel are expected to cooperate fully with any such monitoring activities. The purpose of monitoring is constructive as it provides an opportunity to identify and correct any systemic problems or misunderstandings about regulatory requirements so that the same incident of non-compliance does not recur.

On an annual basis, the Compliance Department prepares a work plan designed to assess and monitor compliance of the various Health System entities and departments by performing a series of scheduled proactive audits and related compliance activities. The work plan is
developed using a variety of sources and inputs such as Health System Department interviews, voluntary inquiries, and past investigations and audits. Additional information is obtained from outside sources – most notably, authoritative publications from the federal government such as the OIG, the Centers for Medicare and Medicaid Services and the Medicare Contractors. Additional sources for the annual Health System Compliance Work Plan involve Medicare and Medicaid coverage decisions, special projects, individual requests and the Compliance Hotline.

It is also important that there are regular evaluations of the effectiveness of the Compliance Program itself. This would include, but is not limited to, assessments made of the plans of correction instituted as a result of Compliance Department audits and investigations.

F. OPEN LINES OF COMMUNICATION

The reputation and integrity of both the organization and our employees are valued. The Health System recognizes its employees rights under the law, including the protections offered under the federal False Claims Act, as it relates to identifying compliance issues. We rely heavily on you, our employees, to help us comply with all of the legal and regulatory requirements applicable to us by identifying potential problems, reporting them and asking questions.

All Health System personnel have a responsibility, and are expected, to promptly report instances of actual or suspected non-compliance with laws, regulations, and policies of which they become aware. Such reports are critical to the effectiveness of the Compliance Plan. Personnel who fail to make such reports in a timely manner may be subject to disciplinary action. Instances of suspected non-compliance often are not intentional but rather result from a lack of knowledge or understanding on the part of the person involved or some systemic problem with the Health System's policies, procedures or systems which should be corrected.

The Health System encourages all personnel to utilize the chain of command whenever practical to obtain answers to questions or to report actual or suspected instances of non-compliance. Under this approach, the first option for asking questions or making reports is to discuss the situation with a supervisor. If someone is uncomfortable talking to his or her supervisor or does not receive a satisfactory response, then the next option, depending on the issue involved, is to contact the Human Resources Department at 410-955-6783, the Legal
Department at 410-955-7949, or the Compliance Department at 410-614-6693. A final option for asking questions or reporting actual or suspected instances of non-compliance is to call the Compliance Line at 1-877 WE COMPLY (1-877-932-6675). The Compliance Line or "hotline" permits reports to be made on an anonymous basis.

Health System personnel may report instances of actual or suspected non-compliance in confidence and without fear of retaliation or retribution. To allow for proper investigation of any reported non-compliance, as much information as possible should be provided to assist the Chief Compliance Officer. Procedures have been established so that reports and any accompanying information are handled and maintained in a manner to ensure confidentiality to the extent possible, consistent with the Health System's obligations of investigation and remediation.

G. ACTIONS IN THE EVENT OF NON-COMPLIANCE

The Chief Compliance Officer (or his or her designee) will investigate and retain outside counsel, as necessary, through the Health System Legal Department to investigate instances of possible non-compliance which come to the attention of the Chief Compliance Officer (unless the conduct of the Health System Legal Department is at issue, in which case the Chief Compliance Officer may retain outside counsel directly). In the event that investigation reveals that there has been noncompliance with laws, regulations, or other provisions of the Health System's Corporate Compliance Plan, the Chief Compliance Officer will take appropriate steps to remediate the violation. Appropriate steps may include, but are not be limited to, recommending changes in policies or procedures to prevent recurrence, recommendations for appropriate personnel action to be taken with respect to persons involved in non-compliant activity, reporting investigation results to the Vice President for Compliance, the affected area Vice President and, when appropriate, the Compliance Oversight Committee, the Compliance Sub-Committee and the Audit, Compliance and Insurance Committee. Verified overpayments will be repaid, as appropriate. There may be additional reporting to and cooperating with governmental authorities with respect to violations of law or regulation in appropriate circumstances after obtaining the advice of counsel.
H. INDIVIDUAL RESPONSIBILITY

The Health System is committed to maintaining the highest standard of legal, ethical, and business conduct. All prospective contracted and employed applicants are screened to identify any prior history of non-compliance with laws, regulations and applicable policies as well as exclusion or sanctions from Medicare, Medicaid, or other Federal health care programs. The employment application requires the applicant to notify the Health System about prior criminal convictions. Once employed through the Health System, personnel are required, by Health System Policy, to notify the Health System of any exclusion from the Medicare, Medicaid or other Federal health care programs. The Health System will not knowingly employ or retain persons or entities with such identified history. Intentional or repeated unintentional legal violations, dishonesty, non-disclosures and other acts and omissions (including compliance training sessions) of current employees which violate the letter or spirit of this Corporate Compliance Plan are considered equally significant. Adherence to this Corporate Compliance Plan will become an important element in the periodic evaluation of all personnel, supervisors, and managers. Serious violations of the Corporate Compliance Plan and/or related subject matter plans and policies may result in termination of employment.

In the event serious matters are identified, referrals may be made to the Investigation Resolution Committee to ensure consistent and appropriate disciplinary action. The Investigation Resolution Committee is a group, consisting of several executive management members of the Health System, who will convene to review results of investigations of potentially fraudulent or other criminal activity involving Health System personnel actions in the workplace. The Committee’s objective is to establish a logical, consistent and appropriate approach to these serious matters.

The Chief Compliance Officer will recommend to the Health System’s Vice President of Human Resources appropriate changes in personnel policies consistent with the obligations of personnel under the Corporate Compliance Plan and affiliate Codes of Conduct. This includes disciplinary policies for personnel who fail to cooperate or adhere to the Corporate
Compliance Plan and procedures for screening of prospective employees to prevent the hiring of persons with a history of non-compliant activities.

I. CONCLUSION

In conclusion, it is important to stress that the Health System has prided itself on its commitment to operating in an ethical and legal manner since its founding. The success of the Health System depends on the personal and professional integrity of all Health System personnel and Professional Staff members. This Corporate Compliance Plan has been developed as part of the Health System’s commitment to compliance. The Compliance Plan is designed to provide helpful guidance to Health System personnel in reaching legal and ethical solutions to the problems they face on a daily basis in their work on behalf of the Health System. The Compliance Plan also establishes a mechanism for reporting and resolving potential problems and concerns. All Health System personnel are expected to cooperate with, and abide by, the Compliance Plan.

THE JOHNS HOPKINS HEALTH SYSTEM CORPORATION
CORPORATE COMPLIANCE PLAN
MEDICARE PART D COMPLIANCE SUPPLEMENT

Medicare Part D prescription drug plan sponsors, such as Hopkins ElderPlus Program of All-inclusive Care for the Elderly (“PACE”), are required to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of their compliance plan. See 42 C.F.R. § 423.504(b)(4)(vi)(H). The Centers for Medicare and Medicaid Services (“CMS”) has issued interpretive rules and guidelines to assist Part D plan sponsors in implementing this regulatory requirement. See CMS Prescription Drug Benefit Manual, Ch. 9.

In light of the longstanding compliance program that has been established by The Johns Hopkins Health System Corporation on behalf of itself and its affiliates (collectively referred to as “Health System”), the decision has been made to continue to utilize the Health System’s compliance program for Hopkins ElderPlus/PACE program. This Medicare Part D Compliance Supplement has been developed to address the aspects of the Health System’s compliance program that are specific to Medicare Part D plan sponsors. The Part D Compliance Supplement does not replace the existing Health System compliance program, but rather operates in conjunction with the Health System’s existing compliance program.
First Tier Entities, Downstream Entities, and Related Entities

While it is common practice for Part D plan sponsors to enter into contracts with third parties to perform certain functions that would otherwise be the responsibility of the sponsor, the sponsor retains ultimate responsibility for fulfilling the terms and conditions of its contract with CMS. The third parties with which Part D plan sponsors may contract fall into 3 categories:

(1) First Tier Entities – any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor to provide administrative services or health care services for Medicare eligible individuals under Part D, such as pharmacy benefit managers (“PBMs”).

(2) Downstream Entities – any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between the Part D plan sponsor and the first tier entity down to the level of the ultimate provider of health and administrative services. For example, downstream entities would include pharmacies that enter into contracts with PBMs and the pharmacists who staff such pharmacies.

(3) Related Entities – any entity that is related to the Part D plan sponsor by common ownership or control and (i) performs some of the sponsor’s management functions under contract or delegation; (ii) furnishes services to Medicare enrollees under an oral or written agreement; or (iii) leases real property or sells materials to the sponsor at a cost of more than $2,500 during a contract period. An example of a related entity would be where the sponsor is the parent company of its own in-house PBM.

Given the ultimate responsibility of the Part D plan sponsor, any contracts with first tier entities, downstream entities, and related entities must include provisions permitting the sponsor to revoke the delegation activities or specify remedies in instances when CMS or the sponsor determine that the parties have not performed satisfactorily.

Written Policies and Procedures

The Health System will develop written policies, procedures and standards of conduct that articulate its commitment to comply with all applicable federal and state statutory, regulatory and other requirements related to Medicare Part D. The Health System’s Board of Directors and Senior Management are committed to ensuring that the organization operates in a compliant and ethical manner, particularly in relationship to Medicare Part D.

Compliance Officer, Liaison and Committees

The Health System will utilize the existing compliance oversight structure to satisfy the requirements under Medicare Part D that plan sponsors have a Part D Compliance Officer and a Compliance Committee. The existing compliance oversight structure is explained in the Health System’s Compliance Program. To the extent necessary to address issues under Medicare Part D, additional members may be appointed to the Compliance Committee on a permanent, temporary, or ex officio basis. In addition, the Johns Hopkins ElderPlus/Pace program will
designate a compliance liaison at the sponsor Pace program. The compliance liaison will chair a Pace Program Compliance Oversight Committee.

**Training and Education**

Consistent with the existing Health System compliance program, employees of the Part D plan sponsor will be provided with general compliance training. The training will be provided upon initial hiring and annually thereafter.

Employees of the Part D plan sponsor will also be provided with specialized compliance training, as necessary, based on the employee’s specific job responsibilities. The training will be provided upon initial hiring and annually thereafter. Examples of topics that may be covered under specialized training include, but are not limited to:

- Marketing the prescription drug benefit to Medicare beneficiaries.
- Managing or administering the exceptions and appeals process.
- Calculating true out of pocket costs (“TrOOP”).
- Making negotiated prices available to beneficiaries.
- Submitting the payment bid to CMS.
- Payment reconciliation.
- Submitting Part D data to CMS.
- Negotiating rebate agreements with Pharmaceutical Manufacturers, wholesalers, and other suppliers of Part D drugs.
- Negotiating pharmacy network agreements.
- Administering the compliance program and operations, i.e., the Part D Compliance Officer and his/her staff.
- Conducting administrative activities necessary for the operation of the Part D benefit.
- Managing employer group plans.
- Security and authentication instructions involved in Health Information Technology.

**Effective Lines of Communication**

The Health System will utilize the existing compliance procedures for receiving, recording, and responding to compliance questions and reports of potential or actual non-compliance related to Part D. Employees and contractors will be encouraged to contact the Health System’s Compliance Department at 410-614-6693 or the Compliance Line at 1-877 WE COMPLY (1-877-932-6675).

These same lines of communication will be open to first tier entities, downstream entities and related entities as well as Part D Plan enrollees. All compliance questions and reports of potential or actual non-compliance, regardless of the source, will be addressed in a timely and complete manner.
Enforcement of Standards

The Health System will utilize its existing, well-publicized disciplinary guidelines to enforce its standards related to Medicare Part D. In addition, Part D contracts with first tier entities, downstream entities and related entities will incorporate provisions that permit the Health System to terminate the contracts based on violations of Part D standards.

Monitoring and Auditing

The Health System will utilize the existing compliance monitoring and auditing structure to satisfy the requirements under Medicare Part D. In this regard, the Health System will develop a monitoring and auditing workplan that specifically addresses risks associated with Medicare Part D. In addition, the Health System will develop a strategy for monitoring and auditing first tier entities, downstream entities and related entities involved in the administration or delivery of Part D drug benefits.

Consistent with the existing compliance program, the Health System will develop a process for not paying for drugs prescribed or provided by providers who have been excluded from participating in governmental health care programs or debarred, suspended or otherwise prohibited from participating in federal procurement and non-procurement programs by checking the OIG’s List of Excluded Individuals/Entities (http://exclusions.oig.hhs.gov/search.html) and the General Service Administration’s list of debarred contractors (http://epls.arnet.gov).

Corrective Action

The Health System will utilize the existing compliance procedures for implementing timely corrective action in response to potential violations of applicable federal, state, or local laws and regulations or compliance policies.

Plan to Detect, Correct and Prevent Fraud, Waste and Abuse

Utilizing its existing compliance structures, the Health System will work to detect, correct and prevent fraud, waste and abuse in the operation of the Medicare Part D plan. Health System personnel involved in the operations of the Part D plan are expected not to engage in fraud, waste and abuse. Examples of potential fraud, waste and abuse include, but are not limited to:

- **Failure to provide medically necessary services**: Fails to provide, to a Part D plan enrollee, medically necessary items or services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to affect) the enrollee.

- **Marketing Schemes**: When a Part D plan sponsor, or its subcontractor, violates the Medicare marketing guidelines, or other federal or state laws, rules, and regulations to improperly enroll beneficiaries in a Part D Plan. Examples of such violations include, but are not limited to:
Offering beneficiaries a cash payment as an inducement to enroll in Part D;

Unsolicited door-to-door marketing;

Use of unlicensed agents;

Enrollment of beneficiary without their knowledge or consent;

Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS;

Misrepresents the product being marketed as an approved Part D Plan when it actually is a Medigap policy or non-Medicare drug plan;

Misrepresents the Medicare Advantage or Prescription Drug Plan being marketed (i.e., enrolling Medicare beneficiaries in a MA-PD when they wanted a PDP);

Requests financial beneficiary information or check numbers (i.e., potential identity theft by a Part D Plan’s marketing agents).

Requires beneficiaries to pay up front premiums.

- **Improper bid submissions:** The Sponsor inappropriately overestimates or underestimates the bid to manipulate risk corridors and/or payments, including miscalculations of administrative ratio costs within the bids (wrong service lines).

- **Payments for excluded drugs:** Sponsors must ensure that they only provide coverage for “covered Part D drugs,” as listed in their approved formularies.

- **Multiple billing:** Several payers billed for the same prescription, except as required for coordination of benefit transactions, such as the same prescription being covered and paid for under Medicare Part A or Part B, and then a second time under Part D, and/or possibly Medicaid.

- **Non-Compendium Payments:** Payments for Part D drugs that are not for a “medically accepted indication.”

- **Inappropriate formulary decisions:** Where Sponsors engage in formulary decision processes in which costs take priority over criteria such as clinical efficacy and appropriateness.

- **Inappropriate Enrollment/Disenrollment:** Improperly reporting enrollment and disenrollment data to CMS to inflate prospective payments. For example, Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary’s request.

- **Appeals process handled incorrectly:** Medicare beneficiary denied their right to appeal or denied a timely appeal.

- **Adverse selection:** Selecting or denying beneficiaries based on their illness profile or other discriminating factors. The Sponsor may anticipate costs being too high with certain beneficiaries with many or severe comorbid diseases, and improperly acts to expel or refuses to enroll a beneficiary in violation of the regulations or the contract.

- **False information:** Plan misrepresents or falsifies information it furnishes to CMS or to an individual under the Part D drug benefit program.
• Delinquent reimbursements: Beneficiary is not reimbursed by the plan following retroactive low income subsidy determination.

• Duplicative premiums: Receiving duplicative co-pays or premiums from beneficiaries.

• Excessive premiums: Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under the regulation.

• Inaccuracies in eligibility or coordination of benefits: Inaccurate or incomplete information on eligibility or benefits can lead to wasteful expenditure on drugs.

• Incorrect calculation of TrOOP: Miscalculation of a beneficiary’s TrOOP to manipulate beneficiary status in coverage (e.g., falsifying TrOOP calculations to keep beneficiaries in the coverage gap, or falsifying TrOOP calculations to push beneficiaries through the coverage gap into catastrophic coverage), or other incorrect calculation of TrOOP that may result in improper payments by CMS or beneficiaries.

• Inaccurate data submission: Sponsor submits inaccurate or incomplete prescription drug event (PDE) data or Part D plan quarterly data.

• Catastrophic coverage manipulation: Sponsors manipulate catastrophic coverage to increase payment by CMS.

• Failure to disclose or misrepresentation of rebates, discounts or price concessions: Sponsor fails to disclose or misrepresents rebates, discounts, price concessions, or other value added gifts, including concessions offered by pharmaceutical manufacturers.

• Bait and switch pricing: When a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount. This includes frequent formulary changes to induce beneficiaries to sign up for specific drugs that are later removed.

Conclusion

The Health System has a longstanding tradition of operating in an ethical and legal manner. The Board of Directors and Senior Management are committed to extending that tradition to its sponsorship of a Medicare Part D drug plan. This Medicare Part D Compliance Supplement is designed to operate in tandem with the Health System’s existing compliance program document. The Compliance Plan and this Supplement are designed to provide helpful guidance to Health System personnel in reaching legal and ethical solutions to the problems they face on a daily basis in their work on behalf of the Health System and its Part D plan. All Health System personnel are expected to cooperate with, and abide by, the Compliance Plan.
ADDENDUM #1

Billing Quality Assurances Plan for Professional Services

INTRODUCTION

The Johns Hopkins School of Medicine (SOM) and its Clinical Practice Association, known as the “CPA”, is committed to complying with regulatory, contractual and other guidelines or requirements regarding professional fee billing and reimbursement. To enhance its commitment and to better assist all employees and physicians in this area, the CPA is implementing a revised and expanded Billing Quality Assurance Program. The Program has the following key features:

A. Compliance Commitment and Oversight
B. Departmental Compliance Action Plans
C. Compliance Education
D. Internal Review
E. Communication
F. Accountability
The compliance program described in this document is intended to establish a framework for compliance by the CPA. It is not intended to set forth all of the substantive programs and practices of the SOM and CPA that are designed to achieve compliance or improve billing practices.

A. COMPLIANCE OVERSIGHT

1. Responsibility for Compliance Oversight - Responsibility for implementation of the CPA Billing Quality Assurance (Compliance) Program will be assigned to the Compliance Officer, who is appointed by the Dean of the School of Medicine. The Senior Director reports to the Compliance Officer and is responsible for all activities of the CPA’s Office of Billing Quality Assurance. Under the direction of the CPA Board of Governors, and in concert with any SOM or Johns Hopkins-wide compliance initiatives, the Compliance Officer and Senior Director will carry out the following responsibilities:

Oversee the CPA Billing Quality Assurance Program, coordinating educational initiatives, the internal review program, and compliance-related communication throughout the CPA and SOM.

Ensure that the Compliance Goals and Principles are incorporated into all activities (Attachment 1).

Develop a template for Departmental Compliance Action Plans, assist departments in the implementation of their plans, develop a self-reporting tool for quarterly updates to the Office of Billing Quality Assurance, and facilitate annual review and revision of the plans.

Coordinate activities as appropriate with the Johns Hopkins University Office of the General Counsel, Johns Hopkins Office of Internal Audit, Johns Hopkins Health System Compliance, the services of the CPA Office of Billing Quality Assurance, and any other Johns Hopkins compliance initiatives.

Work closely with the clinical departments, Physicians Billing Service, Managed Care Contracting, Ambulatory Services Administration, and the CPA physicians to ensure compliance with all applicable professional fee billing requirements.

Effect changes in the billing process to enhance compliance, or when current practices are deemed to be potentially non-compliant with applicable guidelines. Convene a Compliance Committee comprised of the physician and administrative compliance leaders from each Department, representatives from Johns Hopkins Internal Audit and JHU Office of the General Counsel, and other members as deemed appropriate, in accordance with the Bylaws of the Clinical Practice Association.

Coordinate all third party payer billing audits to ensure all relevant documentation has been located to support the services billed.

2. Review of Overall Compliance - The Senior Director is responsible for ongoing review and assessment of SOM / CPA billing compliance and identification of opportunities to capture missed revenue. Any potential areas of significant non-compliance or missed revenue will be immediately brought to the attention of the Compliance Officer who will report to the Dean and
Vice Dean for Clinical Practice, as necessary. The Chairman and the Administrator of any affected clinical departments will also be informed, and policies will be revised, as necessary, to ensure compliance. The Compliance Officer and Senior Director will meet with the Dean, Vice Dean for Clinical Practice, and JHU General Counsel at least quarterly to review billing compliance matters. The JHU Board of Trustees Committee on Audits and Insurance will receive reports as often as necessary from the Compliance Officer or Senior Director, including significant changes in regulatory requirements. The Senior Director will prepare an annual report that describes the general compliance efforts that have been undertaken during the preceding year and the recommended changes to improve and enhance the objectives of this program or to respond to regulatory changes. The annual report will be distributed to the JHU Board of Trustees Committee on Audits and Insurance, the Compliance Committee, the SOM clinical department Chairs and Administrators, and the CPA’s Board of Governors.

3. Response to Individual Compliance Issues - The Senior Director is responsible for reviewing and responding to potential compliance issues. The Senior Director may discuss with the JHU Office of General Counsel the scope of any review and follow-up, and will report all such discussions to the Compliance Officer and clinical department Director. A decision will be made at that time by the Compliance Officer and Senior Director, with the advice of General Counsel as needed, as to the appropriate type of follow-up and reporting to be done.

4. Access to Record and Business Documents - The Compliance Officer and Senior Director, and the staff of the Office of Billing Quality Assurance, will have access to all necessary records, reports and documents in order to fulfill their Compliance Oversight responsibilities.

B. DEPARTMENTAL COMPLIANCE ACTION PLANS

1. The Senior Director will work with the clinical department Chairs and Administrators to develop Departmental Compliance Action Plans specific to each department’s array of clinical programs. These plans will incorporate the Elements of a Gold Standard Compliance Plan which identify responsibilities of the individual provider, the clinical department, the Office of Billing Quality Assurance, and other offices of the University (Attachment 2). The Departmental Compliance Action Plans will be reviewed and approved annually by the CPA Board of Governors with plans revised for implementation at the start of the fiscal year (July 1). Each clinical department will appoint a physician and administrative compliance leader to work collaboratively with the Office of Billing Quality Assurance. Each department is responsible for ensuring proper controls and accountability for clinical practice and billing operations. (See Attachment 3 for the Departmental Compliance Action Plans.)

2. The clinical department Administrator and compliance leaders will coordinate department compliance activities with the Senior Director. This includes facilitating department-specific training programs as well as targeted pre- and post-billing audits to supplement the
Office of Billing Quality Assurance’s monitoring programs. The clinical department compliance leaders will assist with all reviews and follow-up performed either by the department or by the Office of Billing Quality Assurance.

3. Each clinical department will submit to the Office of Billing Quality Assurance a self-audit in the form of a Quarterly Compliance Report to monitor adherence to, and progress with, the Departmental Compliance Action Plan.

4. Oversight by the Office of Billing Quality Assurance will include the implementation of appropriate compliance initiatives based on a risk assessment, prior documentation review audit results, and/or areas targeted by payers or the OIG’s Annual Work Plan. If requested, the Office of Billing Quality Assurance will also assist departments in implementing specific elements of their compliance plans.

5. Hiring of external consultants to review clinical practice, billing operations, coding, documentation, or to provide training requires advanced approval of the Senior Director and may require approval of JHU General Counsel.

C. COMPLIANCE EDUCATION

Compliance education is mandatory and is presented to assure regulatory compliance and quality in the documentation, coding and billing of professional services. Course content addresses identified risk areas in physician billing practices and appropriate preventive policies. The Senior Director shall ensure that billing and reimbursement rules, guidelines, and policies are disseminated in a timely fashion to all staff involved in the billing process, and that any questions raised by staff regarding those materials are answered in a timely manner.

1. CPA Billing Quality Assurance Plan - The Plan will be available on the Office of Billing Quality Assurance’s web site and disseminated to department administrative and compliance leaders to inform them of the CPA’s commitment to compliance and familiarize them with the program.

2. CPA Billing Quality Assurance Program Manual - Resource materials will be compiled into a manual available on the Office of Billing Quality Assurance’s web site for all clinical faculty, fellows, residents, allied health staff, billing staff and administrative managers. The manual will incorporate standards and policies that guide SOM personnel and others involved with the professional fee billing process. These guidelines are reviewed annually with any interim changes or new guidelines communicated via memorandum or e-mail.

3. Mandatory Training - Training is mandatory for all clinical faculty, fellows, residents, allied health staff, billing personnel, administrative managers, department leaders, and outside vendors and contractors. The Senior Director will maintain a record of all scheduled training, topics reviewed and participants. The CPA will not bill for any clinical physician or allied health staff who fail to satisfy the mandatory training requirements. While some clinical faculty may
work in settings in which health care claims are not generated for their services, the understanding of federal guidelines regarding documentation to support correct coding and billing, and the ability to teach medical students, residents and fellows these skills are essential.

4. Educational Presentations and Materials - The Senior Director provides educational sessions and materials for all clinical faculty, clinical fellows, residents, allied health, billing and administrative staff, and contractors to ensure their understanding of coding, documentation and billing guidelines and regulations.

Core Curriculum
- Physician Provider Training (for attending physicians, clinical fellows and residents)
- Mid-Level Provider Training (for nurse practitioners, physician assistants, etc.)
- Billing Staff Training (for anyone involved in the billing process)
- Administrative responsibility for compliance (for department Chairs, Administrators, compliance leaders, division managers, clinic managers, etc.)

Types of educational sessions B Web-based training is offered for Physician Provider and Mid-Level Provider Training. In person training is delivered to new billing staff and others involved in the professional fee billing process. Annual refresher training on the above Core Curriculum is mandatory. Specialty-specific training classes are held as requested and individual training sessions are offered. The Office of Billing Quality Assurance maintains records of attendance for all training sessions.

Department Sponsored / Conducted Training B Clinical departments are encouraged to develop specialty-specific coding and documentation expertise, and to provide additional training to supplement the courses provided by the Office of Billing Quality Assurance. The training curriculum and credentials of the trainer(s) must be submitted to the Senior Director in advance for approval. Departments are responsible for orienting all providers and staff to departmental billing forms and office procedures.

D. INTERNAL REVIEWS AND MONITORING

The Senior Director is responsible for continuously assessing the compliance with all applicable professional billing regulations, and developing plans to ensure and enhance compliance as needed. The Senior Director will work closely with each clinical department and with the Physicians Billing Service to identify any potential areas of non-compliance or areas of missed revenue opportunity and ensure their resolution.

1. Random Reviews of Medical Records - Under the supervision of the Senior Director, a sample of medical records and corresponding bills for each department and division will be reviewed annually. The frequency of individual provider audits and number of services sampled will be determined, in part, by the results of prior reviews, volume of clinical activity, other risk
factors, and the OIG’s Annual Audit Work Plan. For those departments that delegate coding responsibility to billing staff, the Office of Billing Quality Assurance will sample the accuracy of the coding on at least a quarterly basis to ensure adherence to proficiency standards. Reviews may be conducted on a pre-billing or post-billing basis. The review process will involve comparing medical record documentation to the corresponding bills or other methods appropriate to the audit. Any information contained on the encounter form or billing system that is not supported by the clinical documentation will be reviewed with the provider and the clinical department and will be reprocessed as necessary. Likewise, services found to be documented but not billed will be reprocessed. Provider and administrative errors will be reported so that issues are appropriately corrected and monitored. A departmental or divisional report will be distributed to the Compliance Committee and CPA Board of Governors which describes the review results and any follow-up actions taken.

2. Plans of Resolution - If any reviews or discussions identify instances of possible non-compliance, the Senior Director shall create a timely plan of resolution, consulting with all necessary parties deemed appropriate. This may include placing a provider(s) on a mandatory pre-billing review plan until a satisfactory level of compliance is achieved. Plans of resolution will be designed to ensure not only that the specific issues are addressed, but also that similar problems do not occur in other areas or departments. The Senior Director or Compliance Officer will normally obtain advice and guidance from JHU Office of General Counsel in the development of any plan of resolution.

3. Effectiveness of Departmental Compliance Action Plans - The Senior Director will develop processes to continually monitor each clinical department’s plan, ensuring that the elements of the plan are being performed effectively. Areas needing improvement will be noted and a corrective action plan will be developed jointly by the Senior Director and the clinical department. Failure to work in good faith to meet the requirements of the departmental plan may result in sanctions from the Dean’s Office.

4. Quarterly Reports - The Senior Director will provide a quarterly report summarizing the previous quarter’s activities to the Compliance Officer, Dean, Vice President for Clinical Practice and JHU General Counsel and others as deemed appropriate.

5. Annual Report - The Senior Director and Compliance Officer will prepare an annual report that describes the general compliance efforts that have been undertaken during the preceding year and the recommended changes to improve and enhance the objectives of this program. The annual report will be distributed to the Dean, the CPA Board of Governors, the JHU Trustees Committee on Audits & Insurance, the Compliance Committee, the SOM clinical department Chairs and Administrators, and the JHU Office of the General Counsel.

E. COMMUNICATIONS

Effective communication of compliance standards and procedures and opportunities for employees to inquire about possible risk areas or report confidentially any concerns without fear of retaliation are essential elements of this program.
1. Dissemination of Standards, Policies and Updates - The Senior Director will ensure that compliance policies and procedures are reviewed regularly, updated as needed, and distributed to all appropriate departmental compliance leaders and CPA personnel. The Office of Billing Quality Assurance will monitor and communicate relevant CMS, Medicare or other major payer bulletins and transmittals.

2. Internal Helpline - Training materials and training session announcements will direct CPA personnel who have questions about compliance to submit e-mail or call the Office of Billing Quality Assurance at 410-955-1861. Employees will receive appropriate guidance concerning billing and reimbursement issues, including supporting documentation and/or educational presentations, as needed, in a timely fashion.

3. Reporting of Potential Compliance Issues - Training materials and announcements will direct CPA personnel to report any activity that they believe to be inconsistent with JHU or CPA policies or governmental and industry requirements to their immediate supervisor, to departmental compliance leaders, to the Senior Director of the Office of Billing Quality Assurance, or The Johns Hopkins Compliance Line at 1-877-WE COMPLY (1-877-932-6675). The Compliance Line is a toll free, 24-hour, 7-day-a week telephone resource administered through an independent company that allows employees to report workplace concerns. Callers may remain anonymous if they so choose.

4. Response Plans - In the event of contact by outside agents and/or payers requesting JHU, SOM or CPA business information, employees are required to immediately notify the Senior Director or Compliance Officer.

F. ACCOUNTABILITY

All SOM personnel including physicians and staff are responsible for cooperation with and participation in the CPA Billing Quality Assurance Plan. Individuals are responsible for knowing and following the rules and regulations governing professional fee billing and clinical practice. Any issue of non-compliance will be reviewed with the Compliance Officer and Dean for appropriate action.

1. Investigation - Any reports of potentially significant non-compliance will be reviewed expeditiously by the Senior Director in accordance with this Billing Quality Assurance Plan.

2. Consistent Enforcement - The Compliance Officer and Senior Director, in consultation as needed with the Dean and JHU General Counsel, will consistently enforce the Billing Quality Assurance Plan standards through appropriate sanctions with respect to the billing process and recommend disciplinary action when violations occur.

3. Prevention and Correction - If an offense is detected, the Compliance Officer and Senior Director will respond to prevent other similar offenses, including making corrective modifications to the Billing Quality Assurance Plan.
4. Termination, Background Screens, Non-Employment - Failure to meet the standards of the CPA Billing Quality Assurance Plan may result in cessation of billing of professional services, termination of employment and/or exclusion from federally funded programs. Any personnel actions will follow University faculty and staff policies and procedures. The Johns Hopkins University School of Medicine will screen the backgrounds of final applicants for all faculty and staff positions for previous criminal and health care fraud violations and will determine on a case-by-case basis whether to employ an individual with a history of such violations.

APPROVED BY: ____________________________________________ Date
Dean, School of Medicine

_________________________________________ Date
President,
Clinical Practice Association

_________________________________________ Date
Compliance Officer

_________________________________________ Date
Chair, University Trustees Committee
on Audits and Insurance