INTRODUCTION

The Compliance Department is responsible for implementing a program to establish and maintain a culture within the Johns Hopkins Health System Corporation ("JHHSS") that promotes prevention, detection and resolution of instances of conduct that do not comply with the numerous legal and regulatory requirements to which they are subject. The benefits of adopting a voluntary and robust corporate compliance program are numerous but not the least of which is a commitment to honest and responsible conduct. The Office of the Inspector General ("OIG") has made it clear, in its guidance to health care providers and suppliers, that while the implementation of a compliance program may not entirely eliminate improper or unethical conduct from occurring, evidence of an effective compliance program demonstrates a provider’s good faith effort to comply with applicable statutes, regulations, and other Federal health care program requirements. An effective compliance program may also reduce the risk of fines and penalties should a violation of the law ever occur. The Compliance Department embraced this guidance and implemented a successful compliance program.

The Compliance Department’s program includes, among other things, voluntarily and proactively identifying and auditing the risk areas identified both internally and by external sources such as the OIG. Indeed, a large part of JHHSS’s Compliance program is implemented through its annual Work Plan. On an annual basis, the Compliance Department schedules proactive audits of various departments or entities based on identified risks. Risks may be identified internally based on departmental interviews, inquiries and discussions. Risks may also be identified from outside sources including OIG audit reports, changes in national and local coverage determinations, and more recently, data mining reports from the Medicare and Medicaid claims error testing programs which identify aberrant trends or patterns in provider billing. The OIG’s annual Work Plan ("OIG Work Plan") has, however, always been an essential document used in drafting the Compliance Department’s annual Work Plan. Incorporating the areas of risk identified by the government, such as those in the OIG Work Plan, supports the goal of addressing potential compliance problems proactively.

In addition to this year’s OIG Work Plan, the ongoing implementation of Healthcare Reform via the Affordable Care Act ("ACA") will have a significant impact on the Compliance Department’s activities in the upcoming fiscal year. This law resulted in a number of sweeping changes in the areas of health care delivery, Medicare and Medicaid coverage, payment and program integrity, fraud and abuse reporting and civil and criminal enforcement authority. Within the next few years all providers and suppliers will be required to establish and maintain compliance programs as a condition of enrollment in Medicare, Medicaid and the Children’s Health Insurance Plan ("CHIP"). Specifically, all providers and suppliers will have to certify to Medicare and Medicaid that their compliance programs have certain "core elements" which will soon be established by CMS regulation. The compliance program mandate will further require that the providers and suppliers re-enroll in Medicare, Medicaid and CHIP which will, in itself,
impose a tremendous amount of time and resources. Changes in the enrollment process will also include the imposition of an enrollment/re-enrollment fee and the establishment of more rigorous screening procedures. This same provision also enables CMS to suspend payments to providers and suppliers pending credible allegations of fraud.

The ACA is also responsible for increasing the risk of more aggressive and expansive governmental audit initiatives. Overall the number and types of Medicare and Medicaid audits will increase as a result of the expansion and financial resources provided to the respective Integrity Programs. One provision in particular requires the expansion of the RAC Program to state Medicaid programs and Medicare Part C and D Plans. These large program expansions will add to the already high volume requests responded to as a result of the local contractor, Highmark Medicare Service’s multiple, pre and post payment focused review audits.

THE COMPLIANCE DEPARTMENT’S FY 2012 WORK PLAN:

The following sets forth both scheduled audits for the Compliance Department’s FY 2012 Work Plan and current, ongoing investigations and audits at Johns Hopkins Hospital (“JHH”), Johns Hopkins Bayview Medical Center (“JHBM”), Johns Hopkins Home Care Group (“JHHCG”), Howard County General Hospital (“HCGB”), Suburban Hospital (“SH”) and Sibley Memorial Hospital (“SMH”). Discussed below are the specific audits, investigations and other activities by entity as well as a general discussion of certain high risk elements which will be included in every Compliance Department review. As in the past, the JHHS Compliance Department will continue to maintain oversight of the Johns Hopkins Healthcare (“JHHC”) and Johns Hopkins Community Physicians (“JHCP”) audits in the 2012 Work Plan.

I. HEALTH SYSTEM-WIDE COMPLIANCE INITIATIVES

A. Practitioner Licensure and Credentialing

The Compliance Department continues to identify situations where certain non-physician practitioners and allied health professionals are providing services without the requisite hospital credentials and/or licensure. Therefore, as part of any scheduled audit or investigation, the Compliance Department will verify that employees providing services in a given department are working under an active State license, permit and/or certification as required as necessary for coverage of the Medicare and/or Medicaid service billed.

B. JHHS Compliance Department Education Initiatives

Since the time of its inception, the JHHS Compliance Department has been responsible for providing billing compliance education to the JHHS entities. This has been accomplished in various ways including through the Billing Compliance Committee (BCC), which provided education related to rules, regulations and coverage decisions and the impact they have on billing to all levels of staff that have some responsibility for billing and/or coding at a JHHS entity.

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2 Where appropriate, the Compliance Department will also coordinate work efforts with the JHHS Internal Audit Department for selected reviews.
Quarterly BCC meetings serve an informational update purpose and are focused on Medicare/Medicaid news and most important current healthcare industry issues that may impact our Health System. In addition to the BCC forums, targeted educational sessions are conducted across all of our entities ranging in topic from detailed coding and billing training, assistance in the creation of new forms and documentation standards coupled with formal written guidance when necessary.

In FY 2011, the Compliance Department’s educational efforts were focused heavily on Medicare One Day Stays, the documentation requirements for outpatient medical records, observation coverage rules and billing requirements, cardiac rehabilitation, sleep study services, emergency department visit level billing and documentation rules, and physician supervision for incident to and diagnostic testing services.

Several service areas continue to represent significant risk for improper billing at all the Johns Hopkins Health System entities and, as such, in FY 2012, the Compliance Department will provide additional entity wide educational sessions on Medicare and where applicable, HSCRC Observation Services coverage and billing rules, Medicare One Day Stay coverage and billing rules, and Hospital Emergency Department Services documentation and billing rules.

Finally, the Compliance Department continues to provide significant educational efforts in the areas of coding and billing rules for outpatient clinics and infusion services (including blood products). In addition, training for Advanced Beneficiary Notices (“ABN”) forms and Hospital Issued Notices of Noncoverage (“HINNs”) and associated documentation requirements are ongoing efforts. In FY 2012, we will continue providing to all JHHS entities training sessions on these subjects, adding any newly identified high risk issues to our educational menu and satisfying any other specific departmental or entity billing compliance training requests.

The Compliance Department will also ensure that designated JHHS employees take the annual updates to the web-based compliance training. To date, the web-based training has been required of 2,000 plus employees.

C. Medicare and Medicaid Documentation Requests and Reviews

In FY 2012, the Compliance Department will continue to face new challenges as a result of continued and increased external scrutiny and auditing of claims by the Medicare and Medicaid Programs. The Centers for Medicare and Medicaid Services (“CMS”) Recovery Audit Contractor (“RAC”) Program has now begun. The volume of claims anticipated to be requested and reviewed by the RACs could be as high as 500 every 45 days for Johns Hopkins Hospital alone. The Healthcare Reform Law mandated the expansion of the RAC program into Medicaid by requiring states to contract by December 31, 2010 with one or more RACs to identify underpayments and overpayments and recoup overpayments for Medicaid services. CMS expects States to fully implement their RAC programs by April 1, 2011. The law also requires the expansion of the RAC program to Medicare Parts C and D by requiring HHS Secretary to contract with RACs to, among other things, ensure that each Part C MA plan and each Part D prescription drug plan has an antifraud plan in effect and to review the effectiveness of such a plan. CMS has greatly also increased its Medicaid Integrity Contractors (“MICs”) audits of
Medicaid claims, cost reports and managed care plans. Unlike RAC, MIC requests have no record limit, a response period of 30 days and can go back for a period of 6 years.

The RAC and MIC reviews will add to the already demanding audit schedule of Highmark Medicare Services, the hospital’s MAC. In the last year, the numbers of pre and post pay audits have continued to increase at all JHHS facilities. Whereas these reviews have in the past been based on utilization trends or billing patterns outside the norm, the Healthcare Reform Law now permits Medicare contractors to perform prepayment reviews as a matter of course, rather than limiting them to instances where there is a suspicion of improper billing. This will more than likely greatly increase the volume of Medicare audits the JHHS entities are currently experiencing.

The Compliance Department will continue to work with each of the JHHS entity compliance liaisons or designees and Patient Financial Services to provide guidance and support to these initiatives. The Department will also continue to work with all JHHS entities in their response to any audit requests to provide guidance where necessary prior to medical record production or for any subsequent denial which may necessitate formal appeal. In addition, there is a proposed rule that would require select Medicare-certified providers and suppliers to provide Medicare outpatient beneficiaries written notice about their right to contact a Quality Improvement Organization (QIO) with quality concerns. Currently, only hospital inpatients receive QIO contact information, but the proposed rule would now extend the requirements to hospital outpatients.

II. ENTITY-SPECIFIC COMPLIANCE INITIATIVES

A. JOHNS HOPKINS BAYVIEW MEDICAL CENTER

JHBMc Pulmonary Rehabilitation Services Audit
A pulmonary rehabilitation (PR) program is typically a physician-supervised, multidisciplinary program individually tailored and designed to optimize physical and social performance and autonomy of care for patients with chronic respiratory impairment. The main goal is to empower the individuals’ ability to exercise independently. Exercise is combined with other training and support mechanisms such as education/instruction, activities of daily living, bronchial hygiene, and psychological services to encourage long-term adherence to the treatment plan.

As of January 1, 2010, Medicare part B pays for PR programs and related items and services, if specific criteria are met by the Medicare beneficiary with moderate to very severe Chronic Obstructive Pulmonary Disease (“COPD”). In addition, the PR program itself must comply with the Medicare criteria associated with specific requirements for the setting in which it is administered, and the physician administering the program as outlined in Highmark Medicare Services Local Coverage Determination (“LCD”) L31483. PR services are now reported using a new Health Care Common Procedure Coding System (“HCPCS”) code that can be used to report up to a maximum of 2 one hour sessions of PR per day. Based on these new guidelines, the Compliance Department will conduct an initial audit in FY2012 of Pulmonary Rehabilitation services at JHBMc in accordance with the revised coverage and billing requirements of the LCD.
JHBM Community Psychiatry IOP Programs Audit
An Intensive Outpatient ("IOP") mental health program offers services to individuals experiencing emotional and behavioral difficulties. The IOP program at Johns Hopkins Bayview Medical Center ("JHBM") offers mental health services to children and adolescents who have attention difficulties, learning problems, impulsive or aggressive behavior, depression, substance abuse problems, school difficulties, poor social adjustment, and behavioral problems. Each child and adolescent receives an individualized treatment plan ("ITP") provided by a multidisciplinary treatment team consisting of a licensed psychiatrist, and licensed mental health professional staff, including social workers, nurses, and clinical professional counselors. The JHBM IOP program provides a minimum of three hours of psychiatric therapeutic activities per day, which includes a variety of group therapies including occupational therapy, problem solving, behavioral psychotherapy, socialization, and recreation therapies.

IOP services may only be provided and reimbursed by programs approved under Maryland Law. COMAR regulations (COMAR 10.21.20) sets forth the licensing requirements of the professionals engaged in delivering mental health services to patients covered by Medicaid ("MA"), the components of the treatment plan, the level of intensity of the program (hourly requirements), and the coverage requirements needed for reimbursement. In FY2012, the Compliance Department will conduct an initial audit of IOP services at JHBM in accordance with COMAR and Medicare coverage and billing requirements.

JHBM Cardiology Diuresis Clinic Audit
Diuresis is an increase in the production of urine by the kidneys, which typically results in a corresponding increase in urine expelled by the body; diuresis without an accompanying increase of urination can cause severe medical problems. There are a wide range of causes for diuresis, and an assortment of treatment approaches, when treatment is required. As of April 2011, The Johns Hopkins Bayview Medical Center ("JHBM") will operate a Diuresis Clinic which provides outpatients with infusion of diuretics and a cardiologist will directly monitor these services. Patients including those with congestive heart failure presenting to the ED in need of diuresis will be transferred to the Clinic for continuation of the service.
In July 2006, the Health Services Cost Review Commission ("HSCRC") established a new billing methodology for clinic evaluation and management ("E/M") services. The HSCRC also provided guidance on when it is appropriate to bill E/M and a procedure together. Medicare also has specific requirements related to billing E/M and procedures together. Additionally, in early CY08, both the Centers for Medicare and Medicaid Services ("CMS") and Highmark Medicare Services announced their concern about the correct billing of infusion services by providers. These services are subject to a set of CPT coding rules, which are very complex and not well understood by providers. Thus, this could pose a significant risk for overpayment. In FY2012, The Compliance Department will conduct an initial audit of diuresis infusion services at JHBM to ensure the appropriateness of documentation, billing of infusion services and clinic visits for the same day and that the evaluation and management levels are appropriately assigned.
**JHBMC PET Scan Services Audit**

Positron Emission Tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET Scan procedures are performed using a positron camera (tomograph) to measure the decay of the radiopharmaceutical and the rate of decay provides biochemical information on the metabolism of the tissue being studied.

Effective for PET Scan services performed on or after April 3, 2009, CMS adopted a coverage framework that replaced the 4 part diagnosis, staging, restaging, and monitoring response to treatment categories with a 2 part framework that differentiates, FDG (Fludeoxyglucose or Fluorodeoxyglucose radiopharmaceutical used in PET imaging commonly abbreviated as FDG) PET imaging under the initial treatment strategy from other uses related to guiding subsequent treatment strategies after the completion of initial treatment. The Medicare Program made changes to the National Coverage Determination for PET services in April 2009. These changes included additional coverage for PET services as an initial treatment strategy and for subsequent treatment strategy. In addition, new PET modifiers were established for reporting on claims associated with PET initial treatment strategy and subsequent treatment strategy billing.

As a result of the significant changes that occurred with the Medicare coverage and billing requirements for PET services in April 2009, the Compliance Department will be conducting an initial audit of PET services in FY2012 to determine if JHBMC PET services are being billed in accordance with Medicare coverage and billing requirements.

**JHBMC Wound Care Follow-Up Audit**

Wound care involves evaluation and treatment of a wound, including identifying potential causes of delayed wound healing and modification of treatment when indicated by a certifying physician. Determining the underlying reasons of delayed wound healing such as vascular disease, infection, diabetes or other metabolic disorders, immunosuppression, unrelieved pressure, radiation injury and malnutrition will help determine the course of treatment. Evaluations may require a comprehensive medical evaluation, vascular evaluation, orthopedic evaluation, functional evaluation, metabolic/nutritional evaluation, and a plan of care.

An initial audit of wound care services was conducted in FY2006 and a follow-up was conducted in FY2009. The findings from the FY2009 audit indicated that 11 out of 30 claims did not contain sufficient documentation to support that an E/M service that was significant, separately identifiable and unrelated to the procedure was performed. In addition, 9 out of 30 claims did not have sufficient documentation to support the level of excisional debridement billed.

Medicare coverage for wound care on a continuing basis for a given wound in a given patient is contingent upon evidence documented in the patient’s record that the wound is improving in response to the wound care being provided. These coverage requirements including specific wound care CPT coding changes are set forth in Highmark Medicare Services Local Coverage Determination L27547 which was revised in February 2011. In FY2012, the Compliance
Department will conduct an initial audit of wound care services at JHBMC in accordance with the revised coverage and billing requirements of the LCD.

**JHBMC ATS Program Audit**
The Addiction Treatment Services ("ATS") is a comprehensive treatment center for individuals suffering from substance use disorder and other psychiatric illnesses. ATS provides a range of services from standard outpatient care (1 – 3 hours per week) to intensive outpatient care (10 hours per week). ATS uses a multidisciplinary treatment approach which is managed by full-time psychiatrists, clinical psychologists and a team of certified nurse practitioners and physician assistants, nurses, social workers, and professional counselors. An individualized treatment plan is developed for each patient by the treatment team and is reviewed and revised as needed. The treatment plan includes clinical interventions such as routine and specialized individual and group therapies, behavioral interventions to motivate therapy attendance, and a broad range of medications that reduce the use of alcohol and other drugs. The combination of these clinical interventions into an integrated stepped-care treatment plan is widely recognized as the best approach to treating substance use disorder.

COMAR regulations (COMAR 10.09.80) sets forth the licensing requirements of the professionals engaged in delivering substance abuse treatment services to patients who are covered by Medicaid ("MA"), the components of the treatment plan, the level of intensity of the program (hourly requirements), and the coverage requirements needed for reimbursement. In FY2012, the Compliance Department will conduct an initial audit of ATS services at JHBMC in accordance with COMAR regulations.

**B. THE JOHNS HOPKINS HOSPITAL**

**JHH Interventional Radiology Services Audit**
Interventional radiologists use imaging to perform procedures, such as angioplasty and stent placement, without having to do invasive surgery. The coding of interventional radiology procedures is very complex. With the steady stream of technology advances and the recent 2011 Current Procedural Coding (CPT) changes that combine the procedure and guidance for needle placement or radiological supervision and interpretation into one code, there is a greater potential for billing errors with interventional radiology services.

Also, as Medicare Recovery Audit Contractors (RAC) and Medicare Contractors intensify their reviews of high risk services, the potential risk for improper coding and billing of interventional radiology services will make this service an area that will most likely become a focus of Medicare RACs.

In FY2012, the Compliance Department will conduct an initial audit of interventional radiology procedures at JHH to determine if these services are being billed in accordance with CPT coding rules, HSCRC charging requirements, and, wherever applicable, Medicare billing requirements.
Wilmer Eye Low Vision Clinic Conversion Audit
As of April 18, 2011, The Johns Hopkins Hospital ("JHH") will convert the Wilmer Eye Low Vision clinic from an unregulated physician's office to a regulated hospital outpatient clinic under the Health Services Cost Review Commission ("HSCRC"). Under a regulated clinic environment, the billing methodology and documentation requirements associated with the charging of hospital outpatient services is based on the resources utilized by the hospital and represents a significant change from an unregulated physician office as it relates to both the billing and documentation of services.

In July 2006, the HSCRC established a new billing methodology for clinic evaluation and management ("E/M") services. HSCRC also provided guidance on when it is appropriate to bill an E/M service and a procedure together. Medicare also has specific requirements related to billing E/M and procedures together.

In light of past issues identified in other Johns Hopkins Hospital regulated clinics with billing the appropriate outpatient clinic visit levels and/or procedures when provided on the same day, the Compliance Department scheduled an audit in FY2012 to review a sample of these services post conversion.

Radiology Oncology, (Intensity Modulated Radiation Therapy ("IMRT") and Brachytherapy Audit
Radiation oncology is a form of medical treatment that utilizes high energy ionizing radiation in the treatment of malignant neoplasms and certain non-malignant conditions. It uses several distinct therapeutic modalities; teletherapy, brachytherapy, hyperthermic, and stereotactic radiation. Brachytherapy is a type of radiation therapy that utilizes natural or manufactured radioactive isotopes or radionuclides that are temporarily or permanently implanted to treat malignancies or certain benign conditions and derives a physical advantage based upon the inverse law of physics. Brachytherapy may be used independently as the sole treatment or as an adjunctive treatment in combination with external beam therapy and other modalities such as surgery or chemotherapy. Intensity Modulated Radiation Therapy (IMRT) is a technology for delivering highly conformal external beam radiation to solid tumors. Due to the complex nature of these services and the Medicare specific indications and limitation of coverage for brachytherapy and IMRT, the OIG has identified these services as an area of risk for improper billing. In addition, the Maryland Medicare Contractor, Highmark Medicare Services has published a Local Coverage Determination (LCD), LCD L27515 that outlines the Medicare documentation and billing requirements for Radiation Therapy Services.

In FY2012, the Compliance Department will be conducting an initial audit of Brachytherapy and IMRT radiation oncology services to determine if these services are being billed in accordance with Medicare coverage and billing requirements.

JHH Infusion Services Follow-Up Audit
In 2008, both CMS and Highmark Medicare Services announced their concern about the correct billing of infusion services to providers. These services are subject to a set of CPT coding rules, which are complex and not well understood by providers. In addition, the difference in monetary
value of the codes is significant. Thus, incorrect coding creates a significant risk for overpayment. The Compliance Department conducted an initial audit of infusion services in FY 2009 which found areas for improvement in the reporting and billing of infusion services at JHH. Training and education was provided by the Compliance department on the correct reporting and coding of infusion services at JHH. As a result of these findings and the Medicare Recovery Audit Contractor identification of infusion services as an area of risk for improper billing, a follow up audit of infusion services will be performed at JHH in FY2012. The scope of the audit will include verification of proper documentation of time (infusion codes are time based), correct charging of RVUs/CPT codes, and the correct usage of the hierarchy of CPT codes.

**JHH Outpatient Psychiatric Therapeutic Services Audit**

Psychiatric care includes the therapeutic services provided to patients in the treatment of mental, psychosis, and personality disorders which are directed toward identifying specific behavior patterns, factors determining such behavior, and effective goal oriented therapies.

The training requirements and state licensure of individuals who perform psychological services are intended to ensure an adequate level of expertise in the cognitive skills required for the performance of diagnostic and therapeutic psychological services. For psychotherapy services rendered under the incident to provision, the billing provider must evaluate the patient personally and must initiate a course of psychotherapy. The documentation must also show the continued active participation of the billing provider in the course of the therapy.

A Partial Hospitalization Program ("PHP") is an intensive outpatient program of psychiatric services that hospitals may provide to individuals in lieu of inpatient psychiatric care. The program is to provide individuals who have mental health conditions with individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. Johns Hopkins Hospital provides PHP to patients who would otherwise need to be treated in an inpatient setting without the intensive psychiatric services rendered in the PHP setting. An Intensive Outpatient Program (IOP) provides a minimum of 3 hours of psychiatric therapeutic activities by a disciplinary team on multiple days per week as referenced in the Code of Maryland Regulations ("COMAR" 10.21.25). This is considered a short term intensive treatment intervention. An IOP may only be provided and reimbursed by programs approved under Maryland Law and the IOP designation is not recognized by the Medicare program.

In February 2011, Highmark Medicare Services published a revised Local Coverage Determination (LCD), LCD L27514 which outlines the Medicare documentation, coverage, and billing requirements for Psychiatric Therapeutic Procedures. COMAR provides guidance on the coverage and billing of IOP services. The billing of PHP services has gained the attention of the Office of Inspector General (OIG) and was included in its FY 2011 Work Plan. The Compliance Department will conduct an audit of FY 2012 to determine if IOP and PHP psychiatric services rendered in the JHH outpatient clinic locations satisfy COMAR requirements and, when applicable, Medicare documentation and billing requirements for coverage and payment of these services.
Johns Hopkins Outpatient Pharmacy at Weinberg Follow-up of Medicare Part D Claims
Medicare Part B do not cover most outpatient prescription drugs if covered under Part D. Drugs covered under Medicare Part B should not be considered for payment under Medicare Part D. The Office of Inspector General’s FY2011 Work Plan includes a review of Medicare Part D to validate whether there were duplicate payments made by Medicare Part A or Part B. Based on the OIG review, the Compliance Department will conduct a follow-up review of oral anti-emetic drug claims billed to Medicare Part D at the Johns Hopkins (JH) Outpatient Pharmacy at Weinberg. In July 2009, the Compliance Department conducted an initial audit of the Johns Hopkins Hospital Outpatient Pharmacies Medicare Part B Items Reimbursement and discovered the JH Outpatient Pharmacy at Weinberg and the Weinberg Outpatient Clinic were billing Medicare Part B for oral anti-nausea medication. During this time, Medicare issued a rule regarding when to bill Part B or Part D for a drug regimen of Emend (aprepitant), an oral anti-nausea drug used to alleviate chemotherapy induced nausea-vomiting and instructed providers to bill Part D when Emend was not prescribed in accordance with Part B coverage guidelines. The Compliance Department applied the rule for all oral antiemetic drugs and instructed the Weinberg Outpatient Clinic to bill Medicare Part B when administering an intravenous antiemetic drug while an oral antiemetic was also prescribed and the JH Outpatient Pharmacy at Weinberg was instructed to submit its claim to Medicare Part D. In FY2012, the Compliance Department will conduct a follow up review of the JH Outpatient Pharmacy at Weinberg claims for oral anti-nausea medications covered under Medicare Part D.

C. HOWARD COUNTY GENERAL HOSPITAL

HCGH Blood Transfusion Services Follow Up Audit
Based on the focus of blood transfusion services by Highmark Medicare Services, the Compliance Department conducted an audit of blood and blood product transfusion services at Howard County General Hospital (“HCGH”) in FY2010. The focus of this audit included the facility’s compliance with Medicare coverage, documentation and billing requirements for providing blood and blood product transfusion services and Health Services Cost Review Commission (“HSCRC”) rules for calculating transfusion services. A review of the department’s policies as well as Charge Description Master (“CDM”) was also performed.

The audit determined a 40% error rate with regard to the billing of blood and blood product transfusion services. This error appears to be a result of the department’s standard practice of calculating transfusion time based on the length of the entire visit rather than transfusion stop and stop time, as outlined by the Health Services Cost Review Commission (“HSCRC”) rules for reporting billable transfusion time. Corrective actions were implemented upon identification of the error and a repayment was made to the Medicare Program for the transfusion services billed in error. The Compliance Department will conduct a follow-up audit of these services in FY2012 to ensure appropriate billing for blood and blood product services at HCGH.

3 See MLN Matters, SE0910, June 2009.
**HCGH ED Visit Level Follow-up Audit**

CMS requires that hospitals have a standardized method of calculating and reporting time associated with evaluation and management services provided in the emergency room. The HSCRC also provides guidelines on ED billing. In FY09 at the request of senior management at HCGH, Navigant Consulting, Inc. ("NCI") was engaged to review a sample of medical records of Emergency Department ("ED") encounters at HCGH in order to assess the effects of implementing a new ED leveling system based upon clinical care time provided to each patient. The findings identified several inconsistencies based on documentation in the medical record and Clinical Care Time ("CCT") reported on the charge ticket. This is an important factor because CCT determines the ED visit level. Once corrective actions were implemented, NCI performed a follow-up audit of ED visit levels, which in turn dictates the charge on the patient claim. While the results of this follow-up audit showed improvement in several key areas, there continued to be inconsistencies in documentation practices.

In order to determine the effectiveness of the corrective actions implemented as a result of the NCI audits, the Compliance Department conducted a follow-up audit of ED services in FY10. This audit identified similar findings from the previous NCI audits with regard to inconsistencies in documentation of services in the medical record, as well as incomplete documentation of services on charge sheets. Additionally, an area of concern related to the department maintaining a set of internal guidelines for services commonly provided in this area was identified. The audit identified the fact the Department had not developed internal reporting guidelines. These internal guidelines, as required by the HSCRC, are to be used for the purpose of maintaining consistency when reporting similar services for all patients. In order to assist HCGH ED management in development of these internal guidelines, the Compliance Department, in conjunction with Johns Hopkins Hospital ("JHH") ED personnel, conducted an Emergency Department workshop for HCGH ED staff. HCGH ED administrative staff has responded to the audit findings with a corrective action plan to address medical record and charge sheet documentation, implementation of a self-auditing process and development of internal guidelines.

At the request of executive management at HCGH, the Compliance Department will conduct a follow-up probe audit in FY2012 of ED services at HCGH to evaluate the effectiveness of the corrective action plan implemented by Emergency Department management in response to the previous audit.

**HCGH Pain Management Services Audit**

The Office of Inspector General ("OIG") and the Centers for Medicare and Medicaid Services ("CMS") have identified pain management services as an area at high risk for billing errors in FY09. The Medicare Administrative Contractor ("MAC") Highmark Medicare Services has published two Local Coverage Determinations ("LCDs") specifically related to several pain management procedures originally in 2008, with recent revisions effective in February 2011.

- L27540 – Trigger Point Injections
- L27512 – Transforaminal Epidural, Paravertebral Facet and Sacroiliac Joint Injections

Howard County General Hospital ("HCGH") senior management has noted an increase in these procedures over the past year. The Compliance Department will conduct an initial audit in
FY2012 of pain management procedures at HCGH to determine compliance with the corresponding local coverage decision and general documentation guidelines for billing.

**HCGH Medical Nutrition Therapy ("MNT") Follow-Up Audit**

MNT services are covered by Medicare for people with diabetes or renal disease when referred by a doctor. These services can be provided by a registered dietitian or nutrition professional and include a nutritional assessment and counseling to assist beneficiaries manage diabetes or kidney disease. Benefits include 3 hours of one-to-one counseling the first year and 2 hours in subsequent years. Medicare requires that dietitians providing MNT services in the hospital obtain individual Part B billing numbers which must be reassigned to the facility in order to bill the hospital facility charge.

The Compliance Department conducted an audit of nutritional services provided in the Diabetes Management Program at HCGH in FY09. The audit determined that while MNT services were being provided to members of the community, they were not provided to Medicare beneficiaries. This was largely due to a low Medicare population requiring MNT services and difficulty tracking patients’ allowable benefit time. As a result of this audit finding, Diabetes Management Program management stopped providing MNT services completely until an electronic tracking system was implemented in order to track benefit time. This system was expected to be fully operational by the beginning of 2010 when it was anticipated MNT services could resume. The HCGH Diabetes Management Program is expected to resume MNT services by the end of 2011; therefore, the Compliance Department will conduct a follow up audit in FY2012 to verify that the facility continues to follow the necessary credentialing and Medicare provider enrollment process for coverage and billing of nutrition services.

**HCGH Wound Care Services Follow-Up Audit**

Wound care involves evaluation and treatment of a wound, identifying the potential causes of delayed wound healing and modification of a plan for treatment. An initial audit of wound care services was performed at Howard County General Hospital ("HCGH") in FY 2009 in accordance with Highmark Medicare Services Local Coverage Determination ("LCD"), LCD L L27547. The audit identified some opportunities for improvement as it relates to the documentation of surgical debridement procedures. While documentation of these procedures included a number of the required elements as outlined in the Highmark Wound Care LCD, it was determined that several key components were either missing entirely or inconsistently documented. As a result, a small sample of claims required adjustment of charges that were billed in error.

Effective January 2011, the American Medical Association ("AMA") has made Current Procedural Terminology ("CPT") coding changes to surgical debridement codes based on depth and surface area of wounds. Additionally, Highmark has revised the Wound Care Services LCD to reflect these changes. In FY2012, the Compliance Department will revisit this area at HCGH to ensure compliance with coverage criteria and documentation guidelines.
D. SUBURBAN HOSPITAL

Suburban Hospital Cardiac Rehabilitation Follow Up Audit
Cardiac Rehabilitation is a comprehensive, outpatient, medically supervised program that includes medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. This service is covered pursuant to a National Coverage Determination (“NCD”). Typically, rehabilitation services are initiated within 1-3 weeks following a cardiac event and provide appropriate cardiac monitoring. Medicare coverage of cardiac rehabilitation programs is considered reasonable and necessary only for patients who: (1) have a documented diagnosis of acute Myocardial Infarction (“MI”) within the preceding 12 months; or (2) have had coronary bypass surgery; or (3) have stable angina pectoris; or (4) have had heart valve repair/replacement; or (5) have had percutaneous transluminal coronary angioplasty (“PTCA”) or coronary stenting; or (6) have had a heart or heart-lung transplant. Cardiac Rehabilitation programs are billed “incident to” physician services. Medicare has also recently clarified its direct supervision and “incident to” requirements which may also impact this audit.

The Compliance Department conducted an audit of cardiac rehabilitation services at Suburban Hospital in FY11. From this audit the Compliance Department learned that cardiac rehabilitation initial evaluations were being billed at the highest E/M visit level (level five) without supporting documentation of the time spent conducting the evaluation. These evaluations should be billed in accordance with the five point visit level scale established by the HSCRC for the evaluation and management portion of a clinic visit. The amount of clinical care time provided during the E/M portion of the visit determines the visit level. In addition to this finding, there were other findings related to the Medicare conditions of coverage for cardiac rehabilitation services. The Compliance Department will conduct a follow up audit in FY12 to determine compliance with the billing requirements for cardiac rehabilitation services.

Suburban Ultrasound Services Audit
The billing of ultrasound services has gained the attention of the Office of Inspector General (OIG). In a recent audit conducted by the OIG, several issues were identified as being problematic, including the presence of documented physician orders for the diagnostic tests, documentation of medical necessity and covered indications for the tests, and duplicate billing. The OIG recommended that Medicare contractors monitor ultrasound claims for these issues more closely. The Centers for Medicare and Medicaid Services (“CMS”) agreed with the OIG’s recommendation and has also directed the Recovery Audit Contractors (RAC) to pay close attention to ultrasound claims.

Additionally, to address some of these issues, Highmark Medicare Services has three Local Coverage Determinations (“LCDs”) that are specific to these services:
- L30271 Non-Vascular Extremity Ultrasound
- L27506 Non-Invasive Peripheral Venous Studies
- L27504 Non-Invasive Cerebrovascular Arterial Studies

The Compliance Department will conduct an initial audit of Non-Vascular Extremity Ultrasounds, Non-Invasive Peripheral Venous Studies, and Non-Invasive Cerebrovascular
Arterial Studies at Suburban Hospital in FY2012 to determine compliance with the corresponding local coverage decision and general documentation guidelines for billing.

**Suburban Partial Hospitalization Mental Health Services Audit**
A partial hospitalization program ("PHP") is an intensive outpatient program of psychiatric services that hospitals may provide to individuals in lieu of inpatient psychiatric care. The program is to provide individuals who have mental health conditions with an individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. Medicare spending for PHP services has increased over the years. The billing of PHP services has gained the attention of the Office of Inspector General (OIG) and was included in its FY 2011 Work Plan. In particular, the OIG will determine if payments for PHP psychiatric services in hospital outpatient departments met Medicare requirements based on documentation supporting psychiatric services, including patient plans of care, and physician supervision and certification requirements.

In FY2012, the Compliance Department will conduct an initial audit of the PHP at Suburban Hospital to determine compliance with these and any other applicable requirements.

**Suburban Free Standing Ambulatory Surgery Center Audit**
Ambulatory Surgical Center (ASC) means any distinct entity that operates exclusively for the purposes of providing surgical services to patients not requiring hospitalization. ASC are one of the fastest growing settings for ambulatory surgery in the Medicare program and CMS is responsible for the oversight of care provided in this health care setting. In FY2012, the Compliance Department will conduct an initial audit to verify that these services were documented and billed appropriately.

**Suburban Eye Surgeries Audit**
In July 2008, the Maryland Medicare Administrative Contractor (MAC), Highmark Medicare Services established a new Local Coverage Determination (LCD) related to cataract surgery. The LCD issued by the MAC is LCD 27479 – cataract surgery. Suburban Hospital has had several focused reviews in the past year in this area. As a result of the MAC’s increased instruction and ongoing monitoring and review of cataract surgeries, the Compliance Department has scheduled an audit in FY 2012 of cataract surgeries performed at Suburban Hospital to determine compliance with Medicare documentation, coverage, and billing requirements.

**Suburban Breast Reconstruction Outpatient Surgery Audits**
Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. The Medicare program will pay for breast reconstruction surgery following removal of a breast for any medical reason. Program payments will not be made for breast reconstruction surgery for cosmetic reasons. The use of breast reconstruction surgery has increased, and as a result, it has become a focus area for Medicare. In FY2012, the Compliance Department will conduct an initial audit of breast reconstruction surgeries at Suburban Hospital to determine compliance with Medicare billing requirements.
E. JOHNS HOPKINS HOME CARE GROUP

JHHCG Home Health Face to Face Requirement Audit
The face-to-face requirement is part of the Patient Protection and Affordable Care Act (PPACA) and requires physicians to perform face-to-face encounters on home health patients as part of the home health certification. While PPACA originally required compliance with this requirement by January 1, 2011, CMS had delayed enforcement of the requirement until April 1, 2011. In FY2012, the Compliance Department will conduct an initial review of home health services provided to Medicare patients to validate documentation to support the actual face to face encounter is on file.

Johns Hopkins HHS & PAH Medicaid Home Health Agency Claims Audit
Federal regulations at 42 CFR § 440.70 and 42 CFR part 484 set standards and conditions for HHAs’ participation. Providers must meet criteria, such as minimum number of professional staff, proper licensing and certification, review of service plans of care, and proper authorization and documentation of provided services. The Office of Inspector General’s FY 2011 Work Plan includes a review of Medicaid home health agency (HHA) claims to determine whether providers have met applicable criteria to provide services. In FY2012, the Compliance Department will conduct a similar review at Johns Hopkins Home Health Services to validate adherence with HHA conditions of participation.

JHHCG DME & IV Credit Balance Review Follow Up Audit
Based on the FY2011 Work Plan, the Office of Inspector General has conducted prior audits and has found Medicaid overpayments in patients’ accounts with credit balances. The Social Security Act, § 1902(a)(25); Federal regulations at 42 CFR part 433, subpart D; various State laws; and CMS’s State Medicaid Manual, Pub. No. 45, pt. 3, § 3900.1, require that Medicaid be the payer of last resort and that providers identify and refund overpayments received in a 60 day time period. In FY2012, the Compliance Department will conduct a follow-up review of Johns Hopkins Pharmaquip and Pediatrics at Home claims to determine whether there are Medicaid overpayments in patient accounts with credit balances and the overpayment has not been refunded within 60 days.

JHHCG Review of DMEPOS Supplier Standard#28 Audit
As a condition of billing the Medicare Program, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers are required to comply with 30 supplier standards. These standards were developed in order to provide some uniformity among supplier practices and attendant protection to the beneficiaries utilizing these items. 65 FR 60366, (October 11, 2000). CMS has added four new standards to the current list of supplier standards effective September 27, 2010. The newly added Standard #28 requires that “a supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f)” and including the national provider identification (NPI) number of the physician or non-physician practitioner. These records must be maintained for 7 years. (42 CFR §424.57(e)(28).) In FY2012, the Compliance Department will look at both Johns Hopkins Pharmaquip Medicare DME and IV claims to validate adherence to the newly added standard by maintaining ordering and referring documentation.
Johns Hopkins Pharmaquip Medicare CPAP Compliance Follow-Up Audit
In January 2011, the Johns Hopkins Health System Corporate Compliance Department (“Compliance Department”) conducted an initial review of Johns Hopkins Pharmaquip (“JHPQ”) Durable Medical Equipment (“DME”) rental items such as oxygen, Positive Airway Pressure (“PAP”) devices, wheelchairs, hospital beds and monthly supplies to validate that the required documentation was secured in the patient’s medical record in accordance with the corresponding local coverage determination (“LCD”) coverage criteria. As a Medicare condition of coverage, a patient’s medical record must reflect the need for any item or service provided and may include the physician’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. Evidence of such documentation must be available upon request by the Centers for Medicare and Medicaid Services (“CMS”) for auditing purposes. The Compliance Department did not find any issues with the initial audit review of the PAP devices and did not report any identified concerns. Recently, the JHPQ DME Respiratory Director made a request for the Compliance Department to conduct a follow up review of JHPQ Medicare claims for PAP devices. In accordance with the Medicare policy (L11528) for PAP devices, the review will look for evidence of documentation of the face to face encounter between the patient and physician from the 61st to 90th day of PAP therapy. In conjunction with this audit, the Compliance Department will review the process of securing dispensing orders and signatures on written orders, plans of care, prescriptions and other supporting documentation which require a legible signature to ensure its validity.

F. SIBLEY HOSPITAL

Sibley Outpatient Infusion Services Audit
In 2008, the Centers for Medicare and Medicaid Services (“CMS”) and Highmark Medicare Services expressed concern about the correct billing of infusion services to providers. These services are subject to a set of CPT coding rules, which are complex and not well understood by providers. In addition, the difference in monetary value of the codes is significant. Thus, incorrect coding creates a significant risk for overpayment. An initial audit of infusion services will be conducted at Sibley in FY2012 and the scope of the audit will include verification of proper documentation of time (infusion codes are time based), correct CPT coding, and the correct usage of the hierarchy of CPT codes.

Sibley Inpatient Rehabilitation Services and 3-Day Qualifying Stay SNF Audit
Patients that require intense, multi-disciplinary, coordinated care to improve their ability to function may need inpatient rehabilitation services. Medicare covers rehabilitative care provided in an inpatient hospital when the patient requires a more coordinated, intensive program of multiple services (e.g. PT, OT) than is generally found outside of the hospital. However, in order to be covered by Medicare, several requirements must be met including: a preadmission screening for the appropriateness of inpatient rehabilitation care, physician orders and an admission and discharge assessment of function. Patients receiving this specific type of care

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4 See LCDs for Hospital Beds (L5049) Oxygen Equipment (L11468), Continuous Positive Airway Pressure Devices (L11528), Manual Wheelchairs (L11465), Glucose Monitors (L11530), Ostomy Supplies (L11502), and Urological Supplies (L5080).
must be closely supervised by a physician and receive an intense level of rehabilitative services of at least 3 hours per day.

In order to qualify for post-hospital extended care services, Medicare beneficiaries must have been an inpatient in a hospital for a medically necessary stay of at least three consecutive calendar days. Time spent in observation status or in the emergency room prior to (or in lieu of) an inpatient admission does not count towards the 3-day qualifying inpatient stay. Additionally, the patient must have been transferred to a participating Skilled Nursing Facility ("SNF") for extended care services within 30 days after discharge from the hospital. (Medicare Benefit Policy Manual Chapter 8 §20.1) The Compliance Department will conduct an audit for medical necessity of Medicare beneficiaries transferred to a SNF in accordance with Medicare coverage guidelines at Johns Hopkins Bayview Medical Center.

As evidenced by their actions in demonstration states and their upcoming Work Plan, the RAC contractors will be focusing on inpatient rehabilitation services. Highmark Medicare Services, the hospital’s Medicare Contractor has also focused on these services and provided focused training sessions on this topic over the past year. In order to ensure that the Sibley inpatient rehabilitation unit is indeed meeting the criteria for Medicare coverage a thorough audit of medical record documentation is required. In FY 2012, the Compliance Department will perform such a review.

**Sibley ED Visit Billing Audit**

The Centers for Medicare and Medicaid Services ("CMS") requires that hospitals have a standardized method of calculating and reporting time associated with evaluation and management services provided in the emergency department ("ED"). CMS requires that each facility develop unique internal guidelines to report clinic and ED services based on the hospital resource use and assign the applicable Current Procedural Terminology ("CPT") coding that corresponds to the visit level. As part of the FY 12 Work Plan, the Compliance Department has scheduled an audit of ED visit billing at Sibley to verify if the documentation in the medical record supports the ED visit levels billed in accordance with CMS requirements.

**G. POTOMAC HOME HEALTH AGENCY**

Potomac Home Health Care is a full service, Medicare certified home health agency which provides a comprehensive range of home care services in Maryland and Washington, D.C through a non-profit joint venture between Suburban Hospital and Sibley Memorial Hospital. The Potomac Home Health Care Services include skilled nursing, infusion therapy, nutrition education, medical social work, physical therapy, occupational therapy, and speech language therapy. Medicare defines in Chapter 7 of the Medicare Benefit Policy Manual, Publication 100-02 the coverage and documentation requirements associated with the home health services benefit. In FY 2012, the JHHS Compliance Department will conduct a probe audit of clinical services billed by the Potomac Home Health Programs to verify if documentation supports Medicare coverage and payment of these services. In conformance with the standard JHHS audit processes, the audit will also review practitioner licenses and certifications to verify that they were current at the time services were rendered.
H. CARDIOVASCULAR SPECIALISTS OF CENTRAL MARYLAND (JHHS)

National nomenclature for professional billing reflected in the Current Procedural Terminology ("CPT") book requires certain complex rules to be followed to describe the encounter between a patient and a physician correctly. The Office of the Inspector General ("OIG") and Center for Medicare and Medicaid Services ("CMS") have been continuously focusing on these areas of the physician billing for the last 15 years, recovering Medicare funds improperly paid due to incorrect billing.

In FY2012, the Compliance Department will review the following risk areas of the physician billing for the Cardiovascular Specialists of Central Maryland practice:

- correct coding of the visit level
- correct coding of the procedure performed
- correct assignment of modifier 25, when a claim is billed for an office visit and a procedure performed on the same day for the same patient

In all three areas, the supporting documentation for the encounter will define the accuracy of coding and billing.

I. HCGH OB/GYN ASSOCIATES SERIES (JHHS)

Professional Billing – Modifier 25 Rules and Correct Coding of Patient’s Encounters Audit

National nomenclature for professional billing reflected in the Current Procedural Terminology ("CPT") book requires certain complex rules to be followed to describe the encounter between a patient and a physician correctly. The Office of the Inspector General ("OIG") and Center for Medicare and Medicaid ("CMS") have been continuously focusing on these areas of the physician billing for the last 15 years and recovering Medicare funds improperly paid due to incorrect billing. In FY 2012, the Compliance Department will review the following three major risk areas of the physician billing in this practice:

- correct assignment of modifier 25, when a claim is billed for an office visit and a procedure performed on the same day for the same patient
- correct coding of the visit level
- correct coding of the procedure performed

In all three areas, the supporting documentation for the encounter will define the accuracy of coding and billing.