

VII. STANDING COMMITTEES

B. Finance, Audit & Facilities Committee

UW Medicine Board Annual Compliance Report

INFORMATION

The UW Medicine Board Bylaws require an annual report to the UW Board of Regents regarding the effectiveness of UW Medicine compliance programs, which includes but is not limited to, the following topics:

- Status of the compliance program infrastructure and reporting relationships
- Level of resources dedicated to the compliance programs
- Scope of authority of key positions
- Key compliance policies and issues
- Current assessment of compliance risks

This report is for information only.

BACKGROUND

Since the UW Medicine Board Compliance Committee was established in 2000, UW Medicine has devoted significant efforts toward identifying and understanding compliance risks, establishing comprehensive and responsive programs, and promoting a culture of compliance.

UW Medicine uses external and internal audit results, complaints and settlements as well as internal training feedback and guidance from regulators to identify risk areas which become the focus of our compliance programs. In 2009, UW Medicine focused on six primary risk areas (including clinical billing, clinical research billing, post-Corporate Integrity Agreement (CIA) compliance, privacy, information security, Stark and Anti-Kickback compliance, and conflicts of interest), based on the likelihood and impact of noncompliance. Although these were not the only compliance risks addressed by UW Medicine, they were the focus of comprehensive planning, implementation, and reporting.

ANALYSIS

The attached report identifies several key events occurring during the past year. These include:

- The five-year UW Physicians (UWP) and Children's University Medical Group (CUMG) CIA with the Federal government came to a successful close in 2009. The CIA established compliance standards for professional fee billing, including training and auditing requirements, reviews by independent

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B. Finance, Audit and Facilities Committee

UW Medicine Board Annual Compliance Report (continued p. 2)

external organizations, and annual reporting to the Office of Inspector General (OIG). Results of the independent external review identified a 98.12% confirmation rate for audits conducted by UWP/CUMG auditors. The final annual CIA report was accepted in May and the OIG confirmed conclusion of the CIA on August 4, 2009. In anticipation of the CIA completion, the UWP Compliance Program was re-designed as a “Business Excellence Program” to embrace the philosophy of excellence in business and include a broader scope of standards and expectations.

- UW Medical Center (UWMC) concluded all reviews and repayments associated with short stay visits and outlier reimbursements.
- The Medicare contractor, Noridian, placed both hospitals in “provider review” status, which means that it will conduct pre-payment reviews for billing comprehensive metabolic panels at UWMC, and billing a low-level facility visit at the same time as a procedure at Harborview Medical Center (HMC).
- HMC was one of ten institutions selected by the OIG to learn about hospital practices for the detection, prevention, reporting, and billing of adverse events. The OIG was on site for several months observing hospital systems. Results showed that HMC’s processes were appropriate, and no findings or recommendations were made.
- In November 2007, HMC received a subpoena from the OIG seeking information and documents related to price-setting practices and Medicare outlier payments. The OIG and the Department of Justice (DOJ) have been investigating outlier billings nationally. HMC demonstrated to the OIG’s and DOJ’s satisfaction that no improper conduct had occurred and the investigation was closed in the Fall of 2009.
- To date, 77 audits of clinical trials have been completed. The key error rate, incorrect charges to patient accounts, remains very low (1.9%). The audit results continue to highlight areas for process improvement.
- UW Medicine adopted a new Conflict of Interest policy in 2009. The purpose of the policy is to ensure that School of Medicine (SOM) faculty avoid, or disclose and address, perceived or real conflicts of interest between responsibilities as faculty and their outside activities while encouraging appropriate relationships between faculty and industry to the extent they further the mission of UW Medicine. The policy addresses such issues as consulting, service on boards and advisory panels, and other outside work;

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speeches, meetings, and travel funded by outside entities; gifts; food and beverages; teaching activities; and outside support for educational events.

The report also identifies three areas of compliance activity associated with new Federal initiatives. These include:

- The Center for Medicare and Medicaid Services (CMS) contracted with HeathDataInsights to manage the Medicare Recovery Audit Contractor (RAC) program in Washington State. RAC is one of the numerous federal and state programs established to identify billing errors and abusive or fraudulent billing practices. A similar external audit program for Medicaid billing is expected to begin in 2010.
- The American Recovery and Reinvestment Act (ARRA) of 2009, enacted early in 2009, established new requirements governing the privacy and information security of patient information. It also extends civil and criminal penalties to individuals, requires detailed reporting of breaches to affected patients, annual notification of breaches to the Department of Health and Human Services, and notification of local media for breaches involving more than 500 patients. A workgroup to address these and other ARRA requirements has been established, and is in the process of managing the UW Medicine response.
- In July 2008, the Federal Trade Commission (FTC) issued the Red Flag Rules, requiring financial institutions and creditors to develop and implement written identity theft prevention programs. UW Medicine Compliance worked with upper campus to develop policies in response to the regulations. The Board of Regents approved the policies in July, 2009. The FTC has delayed enforcement of the rules several times; the new deadline for implementation is June 1, 2010. UW Medicine has already completed the bulk of its implementation work, and serves as a model for peer institutions.

Attachment

UW Medicine Board Annual Compliance Report: February, 2010

UW MEDICINE BOARD

ANNUAL COMPLIANCE REPORT TO THE UW BOARD OF REGENTS

February 18, 2010

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I. INTRODUCTION

A. Purpose of the Annual Report

Section 1.4.3 of the UW Medicine Board Bylaws requires an annual report to the UW Board of Regents regarding the effectiveness of UW Medicine compliance programs, which includes but is not limited to, the following topics:

- Status of the compliance program infrastructure and reporting relationships
- Level of resources dedicated to the compliance programs
- Scope of authority of key positions
- Key compliance policies and issues
- Current assessment of compliance risks

B. UW Medicine Structure

UW Medicine includes the following owned or managed entities:

- University of Washington School of Medicine (UWSOM)
- University of Washington Physicians (UWP)
- UW Medicine Neighborhood Clinics (UWPN)
- University of Washington Medical Center (UWMC)¹
- Harborview Medical Center (HMC)²
- AirLift Northwest³

UW Medicine is also a founding member of two non-profit corporations: a pediatric practice plan, Children's University Medical Group (CUMG) founded with Seattle Children's Hospital (SCH), and the Seattle Cancer Care Alliance (SCCA) founded with the Fred Hutchinson Cancer Research Center (FHCRC) and SCH. All physician clinical services at the SCCA are provided by UW Medicine faculty physicians who are members of UWP or CUMG. UW Medicine faculty physicians provide clinical service at SCH primarily through CUMG. UW Medicine also has regular faculty physicians employed at the Puget Sound Veterans Administration Health System hospitals and the Boise VA Medical Center, which are part of the Veterans Administration, a federal agency. A key element tying the affiliated entities to UW Medicine is that they are staffed primarily by UW Medicine faculty who must meet UW Medicine standards and compliance expectations for patient care, teaching, and research activities.

¹ The governance authority for hospital accreditation, operations, and quality of patient care at UWMC is vested in the UW Medicine Board. The UW Board of Regents retains authority for some financial matters and capital plant expansion at UWMC.

² Harborview Medical Center (HMC) is owned by King County and governed by a Board of Trustees appointed by King County. Pursuant to a management contract between King County, the Board of Trustees and the UW Board of Regents, UW Medicine manages HMC and provides physician services through UWP. All personnel at HMC, including faculty physicians, are employed by the UW.

³ AirLift Northwest (ALNW) is a non-profit 501C3 organization governed by the founding partners of HMC, UWMC and Seattle Children's Hospital. All personnel of ALNW are UW employees or Seattle Children's employees.

C. Executive Overview

Since the UW Medicine Board Compliance Committee was established in 2000, UW Medicine has continued to refine, reassess and improve its compliance programs. Efforts throughout the years have focused on understanding the compliance risks, establishing comprehensive and responsive programs, and promoting a culture of compliance. UW Medicine continues to make significant strides in all three focus areas.

Understanding the compliance risks. Risk assessment is an on-going, dynamic process. UW Medicine evaluates the regulatory environment in light of numerous sources of input, including audit results, complaints and settlements, investigation outcomes, training feedback, national developments, and guidance from regulators. This information is used to identify risk areas which become the focus of leadership, compliance and operations in the venues and communication channels described in Section II of this report. In 2009, UW Medicine focused on six primary risk areas (including clinical billing, clinical research billing, post-CIA compliance, privacy, information security, Stark and Anti-Kickback compliance, and conflicts of interest), based on the likelihood and impact of noncompliance. Although these were not the only compliance risks addressed by UW Medicine, they were the focus of comprehensive planning, implementation and reporting. Section III of this report highlights key developments in these areas, including proactive efforts to manage evolving regulatory demands, improved internal controls, and enhanced systems.

Establishing comprehensive and responsive programs. UW Medicine compliance programs are comprehensive, and include elements required by the US Federal Sentencing Guidelines. Section IIA identifies the programmatic foundation of UW Medicine compliance efforts, and these elements are highlighted throughout the discussion of key compliance areas in Section III.

Promoting a culture of compliance. In our first presentation to the UW Board of Regents in February 2007, we conveyed the characteristics of a culture of compliance:

- Compliance accountability is clear for individuals and management.
- The organizational culture – trust, safety, and openness of communication – supports compliance.
- The compliance function is integrated for all of UW Medicine, and leadership comes from the CEO of UW Medicine.
- Business systems and processes support faculty, staff, students, and trainees to meet compliance requirements, especially with regard to documenting and coding accurately and efficiently.
- Compliance concerns are respected and immediately addressed, investigated, and where necessary, resolved effectively.
- The organization has the ability to anticipate and prevent problems through strong risk assessment and compliance planning processes.
- UW Medicine is seen as a national leader in ethics and compliance, comparable to its leadership position in research, teaching, and patient care.

Evidence of UW Medicine's progress in promoting a culture of compliance is reflected throughout this report, from the well-defined accountabilities, openness of communication, and integration of compliance functions for the hospitals and clinics described in Section II to the proactive identification of risks and the improvements in systems and reporting mechanisms outlined in Section III.

UW Medicine's compliance efforts are successful because they include the required program components, defined roles and responsibilities, and a structure that includes both formal reporting relationships and channels of communication. Taken together, these elements ensure senior-level

executive support, reduce duplication of effort, enhance the flow of information throughout the system, and promote effective system-wide responses and best-practice models to address a dynamic regulatory environment.

Although compliance is an aspirational goal, and there will always be the need for continuous improvement, UW Medicine is proud of its efforts and achievements, and the work described in this report.

II. UW MEDICINE COMPLIANCE PROGRAM

A. Program Components

UW Medicine compliance programs for all content areas include the following core elements:

- Policies, procedures, and standards of conduct
- Education and outreach activities to inform UW Medicine faculty, staff, students, and trainees about their responsibilities and rights
- Monitoring and auditing activities to detect noncompliance and assess the effectiveness of internal controls
- Mechanisms (including hotlines) that invite and enable safe reporting of compliance concerns
- Timely and appropriate responses to compliance issues, investigation of reported concerns, and protection of complainant rights
- Appropriate administrative and management responses to noncompliance when it occurs, including sanctions and corrective actions
- On-going assessment, analysis, and response to emerging risks and regulatory developments
- Process improvement projects to enhance compliance efforts or implement operational controls
- Regular evaluations of program effectiveness

B. Roles and Responsibilities

A culture of compliance relies on clearly defined roles and accountabilities. UW Medicine expects all **faculty, staff, students, and trainees** to meet the professional, ethical and regulatory standards associated with their individual roles. Specifically, they are expected to understand and adhere to compliance policies and procedures, participate in required training, fulfill recordkeeping requirements, report compliance concerns, seek clarification when questions arise, and respond in a timely manner to requests for information associated with internal audits or investigations. These expectations are conveyed in new employee orientations, mandatory and voluntary training, regular communications from compliance officers and senior leaders, "Integrity at Work" brochures, and the Codes of Conduct for UWP and CUMG. In addition, UW Medicine adopted a Policy on Professional Conduct for faculty, staff, students, and trainees⁴ during this reporting period, and is seen as a leader among its peers in addressing this issue.

Staff in **management or supervisory positions** have additional responsibilities, including communicating compliance expectations, ensuring that personnel complete training, implementing and enforcing policies, monitoring compliance, and providing personal support of compliance initiatives.

⁴ See <http://uwmedicine.washington.edu/Global/policies/Pages/default.aspx>
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Compliance Officers and staff in compliance support roles lead the development of effective internal controls, respond to compliance inquiries, investigate allegations of noncompliance, monitor compliance, conduct audits, and participate in the development and delivery of compliance training.

The **Chief Compliance Officer, UW Medicine and Associate Vice President for Medical Affairs, University of Washington** (CCO/AVPMA) provides system-wide oversight and coordination, is a member of UW Medicine's senior leadership team, serves as an ex-officio member of all compliance committees, and staffs the UW Medicine Board Compliance Committee.

The **UW Medicine Board Compliance Committee** (UWMB CC) is advisory to the UW Medicine Board with regard to the following: strategic planning, program development, organizational structure and resource allocation associated with UW Medicine compliance efforts; the role of UW Medicine compliance programs; advocacy and support for compliance efforts; risk assessment; and analysis of urgent, emergent and on-going compliance issues. The current roster of UWMB CC members is provided in ***Attachment A***.

Dr. Paul Ramsey, Chief Executive Officer, UW Medicine, Executive Vice President for Medical Affairs and Dean of the School of Medicine, University of Washington (CEO/EVPMA/Dean) has delegated additional specific responsibilities for **key senior leadership positions**; these responsibilities are reflected in the written job description for each position.

C. Program Structure

Numerous compliance program structural changes have occurred over the years to enhance the collaboration between entities, clarify roles and responsibilities, establish accountabilities, and create effective communication channels. Since 2005, coordination of system-wide activities and initiatives has been provided by the Chief Compliance Officer, UW Medicine and Associate Vice President for Medical Affairs, University of Washington (CCO/AVPMA). The current organization chart presented in ***Attachment B*** reflects the following changes that occurred in 2009.

1. Organizational Changes in 2009

Practice Plans. Historically, UWP and CUMG operated under one compliance program. In response to the growth of CUMG membership and Seattle Children's Hospital (SCH), CUMG leaders began evaluating the need for a separate compliance program in 2008. After a thorough review and broad-based engagement of physicians and executive leaders from SCH and UW Medicine, CUMG established its own compliance office in July, 2009. Existing policies from the former UWP/CUMG compliance program were retained by CUMG, and both practice plans will continue to coordinate key policy issues.

Hospitals and Clinics. Historically, UW Medicine hospitals and clinics operated entity-based compliance programs. Early in 2009, to improve coordination and establishment of best-practice models across the clinical entities, Johnese Spisso (Clinical Operations Officer, UW Medicine and Vice President for Medical Affairs, University of Washington [COO/VPMA]), worked with the CCO/AVPMA and Executive Directors for HMC, UWMC, UWPN, and ALNW to consolidate system-wide compliance functions for those entities. Upon approval by senior leadership, reorganization began in July, 2009. The new structure centralizes compliance activities for shared risk areas in the UW Medicine health system and enhances the

compliance interface with risk management, quality improvement, and The Joint Commission. Key features of the new structure include the following:

- Oversight for all hospital and clinic compliance functions, the clinical research billing audit program, and UW Medicine privacy/identity theft prevention programs are centralized under the CCO/AVPMA.
- Compliance staff offices have been centralized at the UW Medicine South Lake Union facility to improve efficiency and resource management.
- Responsibility for designing and implementing system-wide hospital and clinic compliance programs for clinical billing/documentation, Emergency Medical Treatment and Active Labor Act (EMTALA), Stark/Anti-Kickback, and hospital-related research compliance is assigned to one compliance officer who reports to the CCO/AVPMA and has a "dotted-line" reporting relationship to the entity executive directors.
- Responsibility for ensuring program integrity, including the implementation of system-wide education/outreach activities, and the receipt of inquiries and complaints, is assigned to a director-level position reporting to the CCO/AVPMA.

These changes have resulted in numerous efficiencies and service improvements:

- Standardization of best practices across all clinical entities
- Clarification of reporting relationships and accountabilities
- Streamlined communication between executive leadership and compliance experts
- A standard approach to monitoring and implementing regulatory changes
- Simplification of the intake, logging, referral, and reporting of compliance concerns from the clinical system
- Consistent messaging to all UW employees in the employee orientation (on-boarding) process
- General compliance education is now tracked in a new learning management system that enables training content to be centrally assigned, delivered, and tracked
- A comprehensive website maintained by UW Medicine Compliance provides full access to compliance policies, procedures, guidance, and tools (<http://depts.washington.edu/comply/>)
- Replacement of several entity-based committees with a joint compliance committee of hospital and clinic executive leaders provides a system-wide venue for assessing compliance risk, planning, allocating resources, and ensuring effective operational responses to emerging issues

2. Compliance Resources

As noted in previous reports, UW Medicine devotes significant resources to both entity-wide and entity-specific compliance efforts. The annual budget for 2009 was \$6.3 million. Total funding and FTEs have remained relatively stable since 2007, when the annual budget was \$6.5 million. FTEs dedicated specifically to compliance functions increased from 47 in 2007 to 49 in 2009. Salaries and benefits increased from \$4.7 million in 2007 to \$5.4 million in 2009. However, there have been reductions in external consulting budgets (which rose from \$815,000 in 2007 to more than \$1 million in 2008, and fell to \$385,000 in 2009), and funding for supplies/operations/equipment (which fell from \$1 million in 2007 to \$492,000 in 2009). These figures do not represent the full cost of time, effort, and systems devoted to compliance-related activities throughout the organization. For example, professional effort devoted to compliance by leadership and operational staff across UW Medicine is not included in the UW Medicine Compliance Program budget.

The UWP Compliance Officer resigned in November, 2009. An interim Compliance Officer has been named, and recruitment for a permanent replacement is underway. During the interim period, the CCO/AVPMA and UW Medicine Compliance staff are providing additional support and assistance to UWP as needed.

At the time of this report, there are only three vacancies in funded compliance positions across UW Medicine. While recruiting and maintaining quality staff continues to be a priority, it does not represent the significant risk experienced in the prior two reporting periods.

3. Channels of Communication

UW Medicine has established numerous communication channels (see **Attachment C**) to support compliance efforts within each entity and enhance the sharing of information between entities. These groups provide a venue for compliance officers and senior leaders to identify risks and mitigation strategies, respond proactively to emerging issues, report on the status of projects and initiatives, and strategize about key program priorities.

Workforce members must also have safe communication and reporting channels. Numerous hotlines and helplines at UW Medicine enable confidential reporting of compliance concerns and provide answers to compliance questions. During this reporting period, existing lines for HMC, UWMC, UWPN and Privacy/HIPAA were consolidated into one helpline maintained by UW Medicine Compliance. Both practice plans continue to maintain their own helplines. In October, 2009, the School of Medicine launched a new helpline for regulatory issues involving research, educational programs, finance/business, environment and safety, information management, and international projects.

III. KEY COMPLIANCE AREAS

The key compliance focus areas identified for 2009 include the following :

Clinical Billing (Facility & Professional Fee)

Clinical Research Billing

Post-Corporate Integrity Agreement Compliance for Practice Plans

Information Security and Privacy

Stark/Anti Kickback

Conflicts of Interest

Although these were not the only risk areas for UW Medicine, they were the focus of significant attention throughout the system, and within the communication venues described in Section IIA3 above. At each meeting of the UW Medicine Board Compliance Committee in 2009 (see **Attachment D**), a content expert presented the following information on one of the focus areas:

- Relevant background (rules, agency involvement, general risks, consequences of noncompliance)
- Primary areas of scrutiny and recent developments, if any
- How the compliance issue affects UW Medicine
- Internal controls to reduce risk, focusing on the eight elements of an effective compliance program:

| | |
|--|-----------------------|
| High Level of Involvement | Policy and Procedures |
| Education & Outreach | Auditing & Monitoring |
| Reporting Mechanisms/Complaint Process | Sanctions |
| Assessment | Reporting |
- Special initiatives or planned program changes; individuals responsible for oversight, implementation and enforcement; relevant timelines or project milestones
- How and when the committee will be apprised of future developments regarding the issue

Focus area presentations are contained in the official committee records. The following section highlights major activities and developments that occurred in 2009.

A. Clinical Billing

Risk Assessment Efforts. Following completion of the clinical reimbursement risk statements and review of internal controls in 2008, compliance and financial officers met in 2009 to identify possible areas of collaboration and coordinate efforts. They concluded that although both groups focused on similar stages in the revenue cycle, each group identified different risks. Compliance officers discussed risk statements with entity leaders and operational units to assess further the effectiveness of internal controls, and identify opportunities for improvement. This dialogue is part of the on-going work done in compliance committees for the hospitals, clinics and practice plans, and culminates in comprehensive, prioritized compliance workplans. In 2010, the hospitals and clinics will consolidate their workplans.

Internal Auditing and Monitoring. Auditing and monitoring activities are essential components of a robust compliance program to mitigate risk and help determine the effectiveness of training and internal controls. The hospitals, clinics and practice plans all conduct internal audits based on their established workplans. Both hospitals contract with an external company that conducts independent audits for documentation, coding, and billing. In 2009, the Compliance Officers Group developed a draft policy establishing UW Medicine-wide audit standards and methodologies. The draft is undergoing review by the CCO/AVPMA and will be finalized in 2010. The group has also begun work on a policy that formalizes timeframe expectations for audits and related investigative work leading to federal payor repayments. These efforts will enable meaningful analysis and reporting of audit results from a system-wide perspective.

External Reviews. The Center for Medicare and Medicaid Services (CMS) contracted with HeathDataInsights to manage the Medicare Recovery Audit Contractor (RAC) program in Washington State. RAC is one of the numerous federal and state programs established to identify billing errors and abusive or fraudulent billing practices. A similar external audit program for Medicaid billing is expected to begin in 2010. As evidence of its ability to prepare proactively for emerging risks, UW Medicine devoted extensive resources and planning to prepare for these external reviews. Each entity created a RAC taskforce, developed response protocols that will be triggered when an external audit notice is received, and assigned ownership for each step. UW Medicine purchased and is implementing data-mining software that enables the hospitals, clinics, practice plans and SCCA to evaluate claims data in the same way as the RAC contractor. As new topics are identified by CMS for RAC review, compliance staff conduct proactive risk assessments to identify and correct any problems. This work, coordinated through the Compliance Officers Group under direction of the CCO/AVPMA, is expected to be a major compliance focus area for 2010.

Facility Billing. During this reporting period, UWMC concluded all reviews and repayments associated with short stay visits and outlier reimbursements. The Medicare contractor, Noridian, placed both hospitals in "provider review" status, which means that it will conduct pre-payment reviews for billing comprehensive metabolic panels at UWMC, and billing a low-level facility visit at the same time as a procedure at HMC.

HMC was one of ten institutions selected by the Office of the Inspector General (OIG) to learn about hospital practices for the detection, prevention, reporting and billing of adverse events. The OIG was

on site for several months observing hospital systems. Results showed that HMC's processes were appropriate, and no findings or recommendations were made.

In November 2007, Harborview received a subpoena from the OIG seeking information and documents related to price-setting practices and Medicare outlier payments. The OIG and the Department of Justice (DOJ) have been investigating outlier billings nationally. Harborview demonstrated to the OIG's and DOJ's satisfaction that no improper conduct had occurred and the investigation was closed in the Fall of 2009.

Professional Fee Billing. The five-year UWP and CUMG Corporate Integrity Agreement (CIA) with the Federal government came to a successful close in 2009⁵. The CIA established compliance standards for professional fee billing, including training and auditing requirements, reviews by independent external organizations, and annual reporting to the OIG. Results of the independent external review identified a 98.12% confirmation rate for audits conducted by UWP/CUMG auditors. The final annual CIA report was accepted in May, and the OIG confirmed conclusion of the CIA on August 4, 2009.

During this reporting period, the School of Medicine, UWP and the Office of Graduate Medical Education partnered to produce on-line documentation and coding training for residents and fellows.

B. Post-CIA Compliance Planning

In anticipation of the CIA completion, the UWP Compliance Program was re-designed as a "Business Excellence" program" to embrace the philosophy of excellence in business and include a broader scope of standards and expectations. Specific goals were discussed with the UW Medicine Board Compliance Committee, and the new program was approved by the UWP Board of Trustees in late Spring, 2009. The compliance committee charter was revised, and the committee renamed as the Business Excellence Committee. It continues to meet monthly and reports to the UWP Board of Trustees. Programmatic changes include more emphasis on risk assessment, audit feedback for new physicians, and focused reviews of potential risks. The education program enhancements include expansion of required on-line training modules, customized required training for all new UWP Members, and new department-specific education plans. UWP maintains a confidential reporting line and a coding help line.

CUMG's post-CIA compliance program is building on the solid foundation of policies established for the practice plans during the CIA. In 2009, CUMG developed a compliance structure and related position descriptions; recruited, hired and trained staff; enhanced integration of CUMG education and outreach efforts with Seattle Children's Hospital; and began addressing risk areas unique to the pediatric setting. CUMG has also implemented a new compliance helpline, is in the process of refining existing policies, and has participated in the development of a UW Medicine auditing methodology currently under consideration.

⁵ UWP and CUMG were the subject of Federal criminal and civil investigations into allegations of fraudulent Medicare billing between 1999-2004. Launched by a "whistleblower" lawsuit filed under the False Claims Act, the criminal investigation concluded with guilty pleas by two nationally prominent UW Medicine physicians. The civil investigation culminated in a \$35 million settlement and the negotiated CIA.

C. Clinical Research Billing

Clinical research billing continues to be a nationally recognized focus area for academic health centers. Medicare's National Coverage Decision (NCD) in 2000 was intended to pave the way for greater Medicare beneficiary participation in clinical trials. Preliminary work in this area at UW Medicine commenced in 2001. Task forces were established to identify how best to implement the NCD and prevent billing errors, a Director of Clinical Research Compliance was hired in 2004, and a new office charged with supporting and overseeing the clinical trial budgeting and billing system was established in 2005.

UW Medicine implemented a series of procedural and coding enhancements at the clinic level in 2007 and 2008 to enhance its systems for ensuring compliance with federal requirements, including the Clinical Trials Policy released in 2007 by the Centers for Medicare and Medicaid Services (CMS). Principal Investigators (PIs) and study staff on active clinical research studies have been trained in the new procedures, and effective January 1, 2009, studies cannot be initiated until PIs and staff have completed the requisite training. UW Medicine also began a new comprehensive Clinical Research Staff training program including required curricula in Good Clinical Practices, research billing compliance principles, and correct coding and documentation procedures.

The Clinical Research Billing Audit Program was established in 2007. The program is designed to determine compliance with UW Medicine policies governing clinical research billing, and verify that clinical services provided to research subjects are correctly billed. Studies to be audited are selected according to pre-established risk criteria. To date, 77 audits have been completed. The key error rate, incorrect charges to patient accounts, remains very low (1.9%). The audit results continue to highlight areas for process improvement.

The conduct of clinical research requires attention to complex regulations, including those governing financial accounting of federal dollars and separation of usual patient care costs from research costs in the delivery of professional services. In 2009, UW Medicine developed a policy and comprehensive guidance to clarify compliance requirements for charging effort or professional fees to a clinical research study. The policy overlays a foundation of existing UW faculty effort policies, and provides PIs and study teams with information about the interplay of federal funding principles and third party payer insurance rules, and guidelines for allocating costs accurately, including effort. This policy and related guidelines were the focus of training efforts conducted in the Fall of 2009⁶. UW Medicine's work in clinical research billing compliance serves as a model for peer institutions.

D. Information Security and Privacy

These programs work closely together to manage the receipt and handling of incidents. Both programs participated in the development of a new UW Information Security and Privacy Policy Framework which will be finalized in 2010. Staff from both programs also collaborated with the UW Chief Information Officer and the UW Facility Security Officer to develop a UW-wide policy and process for managing security incidents across the enterprise. During this reporting period, both programs established workplans and timelines in response to audit findings issued by the UW Internal Audit Office.

⁶ Training materials are located at <https://depts.washington.edu/somcomp/training.htm>
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Information Security. The UW Medicine Information Security Program (ISP) operates under the direction of the UW Medicine Chief Information Security Officer, reporting to the CCO/VPMA. A revised operating plan and governance structure was adopted in October, 2009, and the program is now governed by a newly established Security Program Executive Committee, chaired by the CCO/VPMA. Organizational changes in the program were made to improve focus and increase effectiveness.

A functional specification was designed in 2009 for a new web-based Information Security Assurance Database (ISADB) that will be developed and deployed in 2010. It will be used to help track UW Medicine educational activities and system owner compliance with security policies. Work has also begun on the development of an inventory of information assets, and a process for maintaining the inventory on a regular basis.

The ISP provides information security training for new employees, and System Owner/System Operator training for those directly responsible for systems. ISP staff also work with UW Technologies staff on ongoing identity management initiatives.

Privacy. The UW Medicine Privacy and Identity Theft Prevention Programs operate under the direction of the CCO/AVPMA. In 2009, the program was reorganized to integrate operations, provide centralized leadership, and respond to new regulatory developments. All workforce members receive mandatory orientation regarding privacy compliance, and workforce members who handle clinical information receive additional required job-related training. System-wide awareness emails are broadcast monthly to provide useful reminders and practical guidance about protecting patient privacy. In 2010, UW Medicine will assess the feasibility of moving the HIPAA training platform to a new learning management system that is being used for clinical billing.

The American Recovery and Reinvestment Act (ARRA) of 2009, enacted early in 2009, establishes new requirements governing the privacy and information security of patient information. It also extends civil and criminal penalties to individuals, requires detailed reporting of breaches to affected patients, annual notification of breaches to the Department of Health and Human Services, and notification of local media for breaches involving more than 500 patients. A workgroup to address these and other ARRA requirements has been established, and is in the process of managing the UW Medicine response. This work will continue in 2010.

In July 2008, the Federal Trade Commission (FTC) issued the so-called Red Flag Rules, requiring financial institutions and creditors to develop and implement written identity theft prevention programs. UW Medicine Compliance worked with upper campus to develop policies in response to the regulations. The Board of Regents approved the policies in July, 2009. The FTC has delayed enforcement of the rules several times; the new deadline for implementation is June 1, 2010. UW Medicine has already completed the bulk of its implementation work, and serves as a model for peer institutions.

HIPAA requires every provider who does business electronically to use the same transactions, code sets, and identifiers. Last year we reported that CMS intended to upgrade the current electronic transaction formats by April, 2010. That timeline has been delayed until January 2012. Code sets are used to identify specific diagnoses and clinical procedures on claims and encounter forms. UW Medicine will also need to implement a new coding nomenclature system (ICD-10) by 2013 to be in

compliance. The UW Medicine leadership team is monitoring developments, participating in the national dialogue, and has begun work to prepare for these changes.

Last year's report noted that questions were raised about the use of patient information in blogs and books. A review of relevant cases and research on the wide range of issues associated with authorship was completed in 2009. The report, recommendations, and draft guidance will be evaluated by senior leadership early in 2010.

E. Stark/Anti-Kickback

The Stark Law prohibits a physician from referring Medicare/Medicaid patients for certain designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies. Compliance with Stark is being managed jointly by the School of Medicine, UWP, and the hospitals and clinics. Planned activities for 2010 include the following:

- Have all faculty physicians sign specific documentation identifying services provided and compensation or benefits received
- Roll out a physician services contract manual and templates to clinical department directors
- Continue to improve hospital support processes and accompanying timelines
- Review any benefits provided to non-faculty, community physicians for compliance
- Continue due diligence regarding arrangements in which the hospitals may contract with a third party (especially when the third party is a physician-owned entity) to provide and bill for a given service.

The Anti-Kickback Statute (AKS) prohibits the knowing and willful payment or acceptance of any remuneration for referring an individual for an item or service covered by a federal health care program or for purchasing an item or service (or recommending for purchase) reimbursable under federal health care programs. Unlike Stark, the AKS applies not only to physicians, but also to non-physicians and entities.

Potential AKS risk areas include relationships between drug or device manufacturers and persons in a position to make or influence referrals and/or purchasing decisions. Planned risk mitigation activities for 2010 include the following:

- Review/develop policies and procedures on disclosure of conflicts in connection with drug and device purchases
- Develop guidance regarding vendor offers to loan equipment
- Develop guidance regarding vendor gifts to support educational mission
- Develop guidance on managing research related Stark risk, including residuals
- Develop guidance on Conflict of Interest and AKS as it relates to non-faculty members of the workforce

F. Conflict of Interest

Conflicts of interest (COI) are governed by a significant number of regulations and policies, including but not limited to the following:

- State Ethics in Public Service Act and University Policy on Employee Conflict of Interest
- University Outside Professional Work Policy
- University Significant Financial Interest Disclosure Policy (GIM 10)
- UW Medicine Ghost Authorship Policy
- UWMC, HMC, and Seattle Children's Hospital Policies on Vendors in Clinical Areas and Drug and Device Purchasing

In order to address the wide-ranging COI issues, UW Medicine adopted a new COI policy in 2009. The purpose of the policy is to ensure that SOM faculty avoid, or disclose and address, perceived or real conflicts of interest between responsibilities as faculty and their outside activities while encouraging appropriate relationships between faculty and industry to the extent they further the mission of UW Medicine. The policy addresses such issues as consulting, service on boards and advisory panels, and other outside work; speeches, meetings, and travel funded by outside entities; gifts; food and beverages; teaching activities; and outside support for educational events.

Key provisions of the policy include the requirement to disclose in advance the amount of compensation to be received for outside work. The policy was developed by the CEO/EVPMA/Dean after significant input from chairs, faculty, and other internal and external stakeholders. It is posted on the UW Medicine website with FAQ's (provide web link here). Implementation challenges and remaining work include improvement of reporting mechanisms, and improved systems for record keeping and access to information.

IV. SUMMARY

UW Medicine's efforts have continued to advance its understanding of risks, the robust nature of its compliance program components, and its culture of compliance. In 2009, advancements were made in the education and auditing programs, reporting avenues for workforce members, and system-wide integration of compliance functions for the hospitals and clinics. UW Medicine successfully and proactively responded to new risk areas and acquired new technology to prepare for and manage external reviews.

This report also identifies specific work to be accomplished in 2010 in the areas of external reviews, transaction and code set changes, privacy, information security, Stark/Anti-Kickback, and conflict of interest. In 2010, UW Medicine will enhance its system-wide integration of policies, education, audit planning and methodologies, assessment of program effectiveness, and proactive programs designed to mitigate existing and emerging risks.

Attachment A

UW MEDICINE BOARD COMPLIANCE COMMITTEE: FISCAL YEAR 2010 ROSTER

Voting Members

Shan Mullin, Committee Chair – Board Member

- o Vice chair of the UW Medicine Board
- o Former chair of the Fred Hutchinson Cancer Research Center and the SCCA boards, chair of the Norman Archibald Charitable Foundation board
- o Board member of the Greater Seattle Chamber of Commerce; and Board member/Secretary of the SCCA
- o Partner in the Seattle office of Perkins Coie law firm; Distinguished Alumni Award from the UW Law School 2004

Charlotte Guyman - Board Chair

- o UW alumnus and former general manager of MSN Internet sales and marketing for Microsoft
- o Developed learning software and the pioneering internet travel application, Expedia; general manager of Kids and Games software for Microsoft, director of international and consumer division marketing, and since 2003, a director for Berkshire Hathaway, Inc.

Rich Jones - Board Member

- o President and CEO of the Washington Society of Certified Public Accountants
- o Member of the Board of the Fred Hutchinson Cancer Research Center and Chair of the Board of SCCA
- o Past officer and member of the Board of the Pacific Science Center
- o Retired Partner of Ernst & Young LLP

Julie Nordstrom – Board Member

- o UW alumnus and former board member of Seattle Children's Home and Childhaven; volunteer at Seattle Children's
- o Former associate, Stafford, Frey, Cooper and Stewart, and law clerk for Justice James Dolliver of the Washington Supreme Court

Paul Ramsey, MD – Board Member

- o CEO, UW Medicine, Executive Vice President for Medical Affairs, UW, and Dean, UW School of Medicine

Bruce Pym - Community Member

- o Former President of the King County Bar Association, Board Chair of the King County United Way, member of the Board for the Seattle Repertory Theatre and the Board of Trustees, UW Law School Foundation, and Board Chair of the 5th Avenue Theatre Association
- o Long-time member of the Fred Hutchinson Cancer Research Center Board, member of the Hutch board committee charged with oversight of the conflict of interest litigation, and first chair of the Patient Protection Oversight Committee
- o UW alumnus

Odell Guyton - Community Member

- o Compliance Director for Microsoft; former Assistant U. S. Attorney; former Corporate Compliance Officer, University of Pennsylvania
- o Volunteer advisor for the UC System Regents and the Audit Committee on Compliance matters
- o Former member of the Board of Trustees, Moravian College

Dan Dubitzky - Community Member

- o Lead counsel for the UW in its response to the now-completed Medicare fraud investigation
- o Former board member of the Northwest Defender Association and the Tom Wales Foundation, previous Chair of the Criminal Law Committee of the Federal Bar Association, and a lawyer's representative from the Federal Bar Association to the Ninth Circuit Judicial Conference.
- o While in private practice, represented several Fortune 500 companies and corporate officers with clients from health care, fisheries, aerospace, architecture and timber

Non-Voting Members

Practice Plans

- Mika Sinanan - President, UWP
Catherine Boelke - Executive Director, UWP
Beth DeLair - Interim Compliance Officer, UWP
Robert Sawin - President, CUMG
Rick Nielsen - Executive Director, CUMG
Sheryl Forrester - Compliance Officer, CUMG
Margaret Peyton - General Counsel, UWP/CUMG

Hospitals/Clinics

- Eileen Whalen - Executive Director, HMC
Stephen Zieniewicz - Executive Director, UWMC
Meg Kerrigan - Executive Director, UW Medicine Neighborhood Clinics
Phuong Dao - Interim Integrity Officer, SCCA

School of Medicine

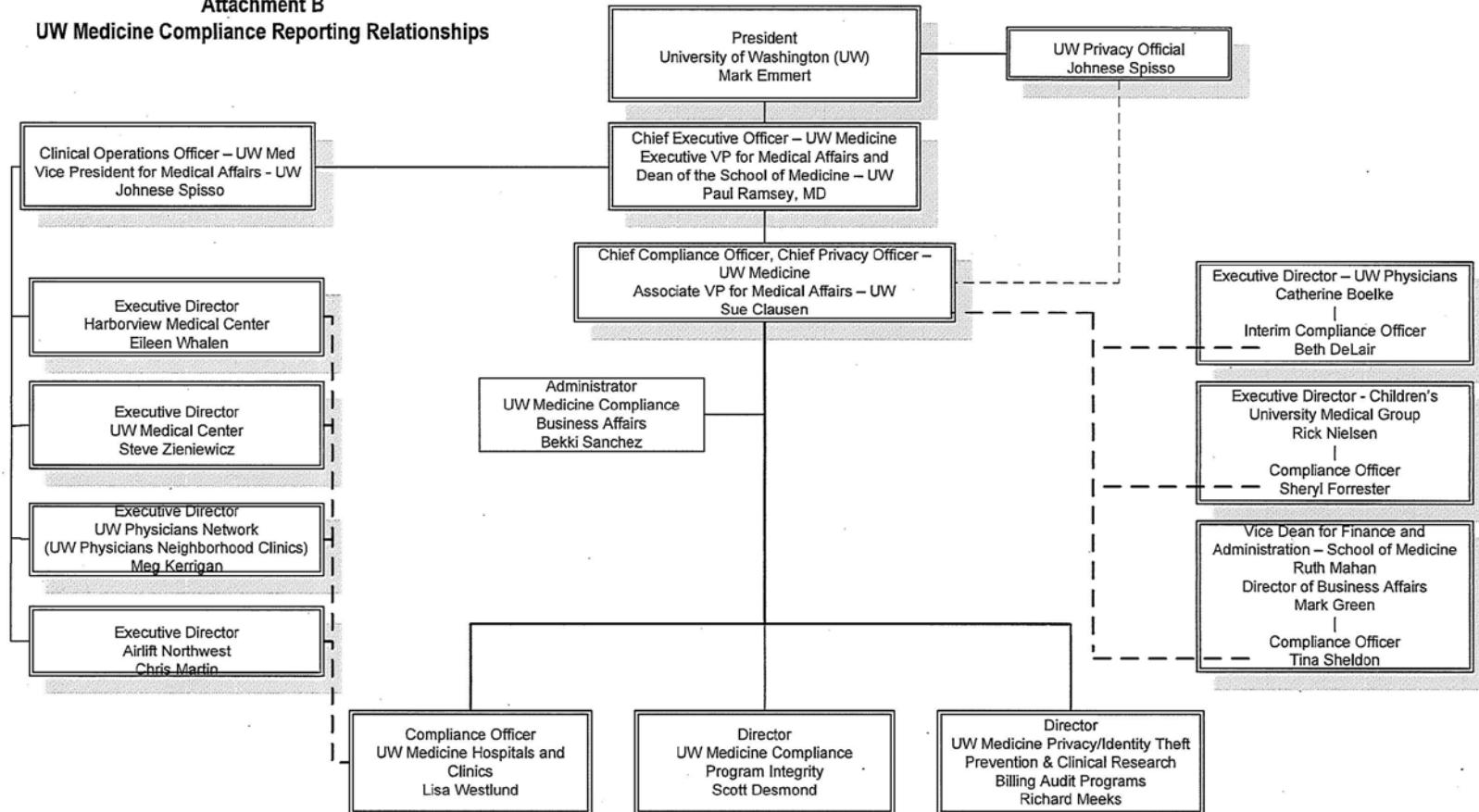
- Ruth Mahan - Vice Dean for Administration & Finance
Larry Robinson - Vice Dean, Clinical Affairs and Graduate Medical Education
Mark Green - Director of Business Affairs, School of Medicine (SOM)
Tina Sheldon - Compliance Officer, SOM

UW Medicine

- Johnnese Spisso - COO (UWMed), VPMA (UW)
Bruce Ferguson - CFO (UWMed), VPMA (UW)
Sue Clausen - CCO/CPO (UWMed), AVPMA (UW)
Lisa Westlund - Compliance Officer, UW Med Hospitals and Clinics
Richard Meeks - Director, Privacy/ID Theft Prevention (UW Med)
Scott Desmond - Director, Program Integrity (UW Med Compliance)

Attorney General's Office: Lori Oliver - Assistant Attorney General, UW

Attachment B
UW Medicine Compliance Reporting Relationships



Approved *Paul G. Ramsey* Date 1/15/10
 Paul G. Ramsey, MD
 CEO, UW Medicine
 Executive Vice President for Medical Affairs and
 Dean of the School of Medicine, University of Washington

ATTACHMENT C

Channels of Communication for UW Medicine Compliance Issues

| Committee/Chair | Committee Role | Membership |
|--|--|--|
| UW Medicine Board Compliance Committee, chaired by Shan Mullin (UW Medicine Board member) | This committee has a wide scope of advisory responsibilities including strategic planning, advocacy and support for compliance efforts, and assessment of progress on major compliance matters. The group meets approximately 8 times/year, receives quarterly reports regarding entity-specific program activities, and is briefed at each meeting about urgent, emergent and on-going issues. Minutes of each meeting are provided to the UW Medicine Board. | Voting members include community members, the UW Medicine Board Chair, and Paul Ramsey (CEO, UW Medicine). Non-voting members include senior executive leaders and entity compliance officers. See Attachment A for the full roster. |
| UWP Business Excellence Committee, chaired by Bruce Sangeorson, MD CUMG Physician Billing & Education Compliance Committee, chaired by Mark DelBeccaro, MD | These committees provide a venue for engaging administrative, clinical and operational leaders in the planning, problem-solving, and risk assessment activities associated with key compliance initiatives. The committees work closely with compliance and operations staff to assess risk, establish compliance standards, monitor program effectiveness, implement effective educational and outreach activities, and endorse policies and standards. | Members include executive leaders, physicians, clinical department representatives, legal counsel, training and operational staff, the practice plan compliance officers, the SOM compliance director, and the CCO/AVPMA. |
| Hospital and Clinic System Executive Compliance Committee | This new committee will replace the HMC and UWMC hospital compliance committees in December 2009. Co-convened by the Hospital & Clinics Compliance Officer and the CCO/AVPMA, the committee will serve as a forum for engaging key executives from the hospitals, clinics and ALNW. compliance planning, problem-solving, and risk assessment activities. The group will work closely with UW Medicine Compliance to evaluate urgent and emergent issues, monitor progress toward resolution of compliance issues, and establish strategies for communicating and enforcing expectations to staff. | Members include the COO/AVPMA; executive directors and senior officers from the hospitals, clinics and ALNW; administrative directors from key operational units; and a representative from the AGO. |
| Compliance Officers Group, chaired by Sue Clausen, CCO/AVPMA | This group provides a forum for engaging entity compliance officers in the identification of and response to regulatory developments, assessment of risks, and development of mitigation strategies. Subgroups provide a venue for working collaboratively on mutual concerns, establishing system-wide standards, and coordinating the handling of urgent/emergent issues that involve multiple entities. | Members include the UW Med hospital/clinics compliance officer, and compliance staff representing privacy, SOM, practice plans, SCCA, ITHS, Pharmacy, Laboratory, Patient Financial Services, School of Dentistry and UW Research Compliance. |
| UW Medicine Operations and Finance Committee, chaired by Paul Ramsey, CEO/EVPMA/Dean | This committee provides a venue for engaging senior leaders in the evaluation of, and response to UW Medicine-wide compliance issues. | Members include the CCO/AVPMA, VPs for Medical Affairs, Vice Deans for Admin/Finance and Clinical Affairs, UWP President, Executive Directors (UWMC, HMC, UWPN, UWP), Chief Operating Officers, Chief Financial Officers, SOM Director of Business Affairs, AVP for Community Relations. |
| Clinical Research Billing Oversight Group, chaired by Bruce Ferguson, CFO/VPMA | This committee provides a venue for engaging senior leaders in strategic planning and problem-solving, communicating the status of clinical research billing process improvement projects, assessing risk, reviewing and endorsing policies, and generating communications necessary to support the process improvements or enforce policies. | Members include Executive Directors (UWMC, HMC, UWP); Vice Deans for Research, Admin/Fin, Clinical Affairs; UWP President, UW Human Subjects Division, Dept. of Medicine, AGO, SCCA, FHCRC, CCO/AVPMA, UW Med Hospital/Clinics Compliance Officer |
| Executive Clinical Leadership, chaired by Johnese Spisso, COO/VPMA | This group provides clinical operations leadership for UW Medicine System, develops/implements strategic operating & financial plans, addresses related issues (e.g., access management, coordination of care, process improvement, HR, regulatory affairs, recruitment/retention needs, space planning, IT) | Members include the Executive Leadership Team from UW Medicine Clinical Health System entities-Harborview Medical Center, UW Medical Center, UW Neighborhood Clinics, UW Physicians and AirLift Northwest. |
| Security Program Executive Committee (SPEC), chaired by Johnese Spisso, COO/VPMA | SPEC provides executive direction for the UW Med Info Security Program, reviews and endorses security policies, strategic plans, annual budget requests and risk assessments. | Members include UW Med Director of Security & Networking, CCO/AVPMA, CIO, SOM Vice Dean for Admin/Fin, Director of Health Science Risk Mgmt, UWP President, Executive Directors (UWMC, HMC, UWPN), UW CISO, Asst VP for Med Ctr. HR |

ATTACHMENT D

UW MEDICINE BOARD COMPLIANCE COMMITTEE - SCHEDULE 2009

| Meeting Date | Focus Areas/Special Briefings | Focus Area Presenter(s) | Reports |
|---|---|--|---|
| January 12 10:00-11:30 am 11:30-noon Board Meets | <ul style="list-style-type: none"> • OIG Workplan – upper campus response • Executive Session - HMC <p>Ad Hoc Discussion Session: focus areas, annual schedule, agenda planning, meeting structure, reporting strategies</p> | | <ul style="list-style-type: none"> • CIA Update • Annual Compliance Report • CO Updates |
| February 23 9:30-11:30 am | <ul style="list-style-type: none"> • Focus Area – Conflict of Interest • Executive Session • Special Briefing: CUMG post-CIA planning | <ul style="list-style-type: none"> • Mark Green • Kristin Miles/SAAG • Mark Del Beccaro | <ul style="list-style-type: none"> • Briefings • CIA Update • Distribute FY09 2nd Quarter Reports** |
| March | No CC meeting ***** Board Retreat 3/1-2 ***** | | |
| April 6 9:30-11:30 am | <ul style="list-style-type: none"> • Focus Area – Clinical Research Billing • Special Briefing: Red Flag Rules | <ul style="list-style-type: none"> • Bruce Ferguson • Sue Clausen | <ul style="list-style-type: none"> • Briefings • CIA Update • UWP Business Excellence Plan |
| May | No CC meeting | | Distribute FY09 3 rd Quarter Reports |
| June 22 Board Meets 6/1 | <ul style="list-style-type: none"> • Focus Area – Post-CIA Compliance Programs: UWP and CUMG • Special Briefing: Preparation for External Reviews (RACs, etc.) | <ul style="list-style-type: none"> • Mika Sinanan, Bob Sawin • Lisa Westlund | <ul style="list-style-type: none"> • Briefings |
| July | No CC meeting | | Briefings by mail |
| August | No CC meeting | | Distribute FY09 4 th Quarter Reports; briefings by mail |
| September 14 | Focus Area – Privacy Special Briefing: Compliance Reorganization | Sue Clausen | Briefings RAC update - Westlund |
| October 26 | Focus Area - Stark/Anti-kickback | Mark Green | Briefings |
| November | No CC meeting | | Distribute FY10 1 st Quarter Reports |
| December 7 | <ul style="list-style-type: none"> • Focus Area – Information Security • Annual Compliance Report Draft | <ul style="list-style-type: none"> • Johnese Spisso • Sue Clausen | Briefings |