

VII. STANDING COMMITTEES

B. Finance, Audit and Facilities Committee

UW Medicine Board Annual Compliance Report

This report is for information only.

Attachment

UW Medicine Board Annual Compliance Report to the UW Board of Regents,
February 17, 2011

UW MEDICINE BOARD

ANNUAL COMPLIANCE REPORT TO THE UW BOARD OF REGENTS

February 17, 2011

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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)
- Harborview Medical Center (HMC)¹
- University of Washington Medical Center (UWMC)²
- Northwest Hospital and Medical Center
- UW Neighborhood Clinics (UWNC)
- 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 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.

² 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.

³ In July 2010, AirLift Northwest (ALNW) dissolved its 501C3 status and became a fully owned and operated entity of UW Medicine. All personnel of ALNW are UW 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 these three focus areas.

Understanding the compliance risks. Risk assessment is a concurrent and continuous dynamic process. UW Medicine evaluates the regulatory environment in light of numerous changes and 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 2010, UW Medicine focused on six primary risk areas (including clinical billing, clinical research billing, 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's compliance programs include elements required by the US Federal Sentencing Guidelines, described in Section IIA. In addition, the programs incorporate learnings from industry best practices. Section III highlights program elements within each of the key compliance areas.

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:

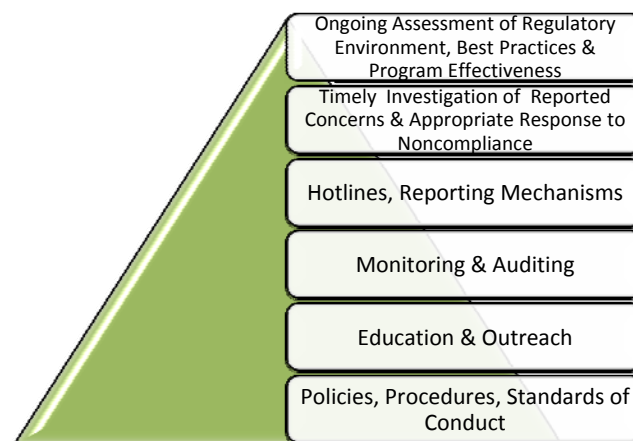
- Compliance accountability is clear for individuals and management.
- The organizational culture – trust, safety, and openness of communication – supports compliance.
- The compliance function is integrated for all of UW Medicine, and leadership comes from the CEO of UW Medicine.
- Business systems 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 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.

Section II describes the well-defined accountabilities and openness of communication inherent in the UW Medicine culture. The proactive identification of risks and the improvements in systems and reporting mechanisms outlined in Section III serve as further evidence of UW Medicine's continued progress in promoting a culture of compliance. 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.

II. UW MEDICINE COMPLIANCE PROGRAM

A. Program Components

UW Medicine compliance programs include the following core elements:



B. Roles and Responsibilities

A culture of compliance relies on clearly defined roles and accountabilities. UW Medicine expects all **faculty, staff, students, trainees, and volunteers** 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. UW Medicine is seen as a national leader among its peers for its policies on professional conduct and conflicts of interest⁴.

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>

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 2010.

1. Organizational Changes in 2010

Practice Plans. Two separate compliance programs for the practice plans were established in 2009. In 2010, UWP and CUMG focused on efforts to ensure coordination of key policy issues. In order to ensure effective communication, each plan's compliance committee now includes the other plan's physician chair and compliance officer as members.

Health System. UW Medicine continued to consolidate compliance functions for the hospitals, UW Neighborhood Clinics, and Airlift Northwest. 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. The CCO/AVPMA staff offices are housed in one location to improve efficiency and resource management. The centralized structure has resulted in numerous efficiencies and service improvements, particularly in the following areas:

- intake, triage, referral and tracking of inquiries and complaints
- education and outreach
- environmental scanning and response planning
- external review requests
- communication between executive leadership and compliance experts
- risk assessment
- reporting
- resource utilization and monitoring

In May, 2010, UW Medicine completed the first steps necessary to integrate Northwest Hospital's (NWH) compliance functions by bringing it under the University of Washington's covered entity status under the Health Insurance Portability and Accountability Act (HIPAA). Phase II of the integration process has begun, focusing on billing compliance, including auditing, monitoring, and reporting. The compliance officer, the chief executive officer, and the chief operating officer for NWH are all members of UW Medicine compliance committees and make quarterly reports to the UW Medicine Board Compliance Committee.

2. Compliance Resources

As noted in previous reports, UW Medicine devotes significant resources to both entity-wide and entity-specific compliance efforts. Total funding and FTEs have remained relatively stable since 2007. In 2010, the annual budget was \$6.6 million and there were 49 FTEs dedicated specifically to compliance functions.

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.

A new UWP Compliance Officer was appointed in February, 2010, after a national recruitment. At the time of this report, there are five vacancies in funded compliance positions across UW Medicine.

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. Each UW Medicine entity provides a compliance helpline to answer compliance questions. In 2010, five hotlines previously operated by the hospitals and clinics were merged into a central hotline maintained by the CCO/AVPMA. This line provides for anonymous reporting of compliance concerns. In 2011, this hotline will be the focus of an active marketing campaign to include the hospitals and clinics, ALNW, UWP, NWH, and the School of Medicine.

III. KEY COMPLIANCE AREAS

The key compliance focus areas identified for 2010 include the following:

Clinical Billing (Facility & Professional Fee)

Clinical Research Billing

Information Security

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 IIC3 above. At each meeting of the UW Medicine Board Compliance Committee between December 2009, and December 2010 (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 2010.

A. Clinical Billing

Internal Auditing and Monitoring. Following the restructure of UW Medicine Compliance in 2009, the newly formed Hospitals and Clinics Compliance unit began to merge previously separate hospital audit plans. Federal program activity and Office of Inspector General (OIG) Work Plan focus areas received the highest consideration in this process. The end result was a single statement of prioritized work, as well as a new policy that establishes UW Medicine-wide audit standards and methodologies. The Compliance Officers Group continues work on a policy to formalize timeframe expectations for audits and related investigative work leading to federal payor repayments. These efforts will facilitate system-wide consistency, reducing the potential for confusion and risk.

External Reviews. UW Medicine has always been subject to external billing reviews (e.g., Medicare contractor audits and comprehensive error rate testing). In 2010, the Center for Medicare and Medicaid Services (CMS) initiated the Medicare Recovery Audit Contractor (RAC) program in Washington State. RAC is one of the latest federal and state programs established to identify billing errors and abusive or fraudulent billing practices. The RAC external audit program expanded to include Medicaid billing in January, 2011.

In 2010, external reviews were conducted on 315 claims (UWP, NWHMC, UWMC, HMC, ALNW, and CUMG) representing approximately \$461,000 in reimbursement. The audits resulted in the repayment of 233 claims and approximately \$185,000 in repayments. UW Medicine successfully disputed 28 claims totalling approximately \$110,000. The remainder of claims are still in dispute. In addition, 15 claims totalling approximately \$150,000 were underpayments to UW Medicine. UW Medicine has not missed a response deadline, a testament to the extensive planning efforts and efficient execution by the response teams.

UW Medicine implemented new software to assist with the external review process in 2010. It provides the ability to record and monitor the status of claims and enables proactive data-mining on UW Medicine claims so that areas targeted for review by external regulators can be identified and corrected in advance. It also captures the work effort involved in response to external reviews and produces summary reports for resource planning purposes.

In December, 2009, UWMC and HMC received notice of an OIG audit covering Medicare outpatient claims that met specific criteria (including the likelihood of billing errors) between January, 2006, and June, 2009. In spite of the extremely large number of claims submitted, UW Medicine had only seven claims selected. Three claims contained errors. The total repayment for these three claims was less than \$35,000, and they were determined to be isolated mistakes.

Noridian Administrative Services, the contractor for payment of Medicare claims, conducted several probe audits of billing for targeted hospital services during the year. UW Medicine hospitals were included in this activity, but because of high accuracy rates, Noridian closed each UW Medicine audit with no further action required. Noridian also conducted a UWMC review of the steps required by Medicare for "Medicare as Secondary Payer" screening; UWMC is completing process improvement work in response to the review.

UW Medicine leadership is kept informed about ongoing external review activities through a weekly summary report distributed by UW Medicine Compliance.

Facility Billing. A new policy that establishes internal billing rules based on timely medical record documentation was approved in July, 2010, by the Executive Compliance Committee.

Noridian contacted HMC about a medical device coverage issue in 2010, which led to a series of process improvements for device billing across the system. HMC completed case-specific reviews and made repayments to Medicare for roughly \$1,000,000 and UWP repaid the surgeon's claims for the related cases.

A second facility billing focus in 2010 was hospital outpatient observation services. Due to complex and frequently changing billing rules for this service, it is a high risk area that has been the subject of ongoing training, auditing and claim correction activities.

Noridian provided valuable input to UW Medicine regarding its experience with higher risk billing areas based on the claims data it processes and interaction with providers within its jurisdiction. UW Medicine is using this information to prioritize both compliance and operational activities.

Professional Fee Billing. The five-year UWP and CUMG Corporate Integrity Agreement (CIA) with the Federal government came to a successful close in 2009⁵. While each of the practice plans has continued with elements of the compliance program structure required under the CIA, the plans have also adopted additional program features, or modified the structure established under the CIA, reflecting the increased flexibility to maintain a program better designed to address risk. Program efforts included the following:

- CUMG updated 15 policies and created one new policy, trained every CUMG practitioner (through on-line modules and 40 live training sessions); and trained 70 new CUMG members.
- CUMG performed 294 practitioner audits; led the response to external inquiries including a Medicaid Integrity Program review of 108 records; and conducted a review of 28 reported concerns.
- UWP conducted proactive risk assessments, and completed scheduled risk-based audits on 100% of the physicians identified for review (393 physicians). Sixteen physicians did not meet the standard and required second reviews. UWP conducted pre-billing reviews on all providers new to UWP (93 new providers) and all 42 UWP professional fee coders.
- UWP training activity was extensive; there was 100% completion of the mandatory training (including 1646 physician and non-physician members and 252 UWP administrative employees). UWP increased the number of online modules to 36, and developed new specialty-specific modules.

B. Clinical Research Billing

UW Medicine has reported annually on the significant efforts it devotes to clinical research billing compliance, a nationally recognized focus area for academic health centers. UW Medicine's work in clinical research billing compliance serves as a model for peer institutions. Principal Investigators (PIs) and study staff on active clinical research studies are subject to clear policies and procedures, mandatory training, and on-going audits in order to assure compliance with the complicated rules.

As part of the new hospital billing system implemented in August, 2010, a training module was introduced to facilitate the clinical research charge capture process. The extensive planning and design effort resulted in a relatively simple process change for end users. The new module features greatly enhanced charge routing logic, minimizing the number of human decisions/actions required to produce accurate clinical research billing.

UWMC resolved an issue stemming from the process for billing federal grant budgets for clinical research services in 2010. Federal research rates are based on the hospital's cost report, which is filed each year but not finalized until after a lengthy review process by Medicare. Due to the lengthy review, provisional research rates are used until the cost report is finalized. Sometimes the final rates differ slightly from the provisional rates, due to changes made to the cost report by Medicare. NIH clarified that such differences require retrospective adjustments of charges made to the grants using provisional rates. UWMC made the required adjustments for the past five years and implemented an annual process to do so going forward.

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.

The Clinical Research Billing Audit Program established in 2007 was 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, 111 audits have been completed. The key error rate, incorrect charges to patient accounts, remains low (3.18%). The audit results continue to highlight areas for process improvement. As a result of audit findings, the Clinical Research Budget and Billing Department now adds Research Care Plans to the electronic medical records of patients who are enrolled in research studies. This increases patient safety and reduces the need for research staff to perform this task throughout the course of the study.

C. Information Security and Privacy

The UW Medicine Information Security Program (ISP) operates under the direction of the UW Medicine Information Security Officer, who reports to the UW Medicine Chief Information Officer. The UW Medicine Privacy and Identity Theft Prevention Programs (ITPP) operate under the direction of the Director of Privacy/ITPP Programs, who reports to the CCO/AVPMA. Both programs are responsible for developing and maintaining program-specific respective policies, providing related education and outreach, monitoring and auditing compliance with their respective policies, and reporting regularly to appropriate leadership groups. Privacy program staff are responsible for investigating all privacy, ITPP, and information security complaints.

In 2010, staff from both programs collaborated with the UW Chief Information Security Officer (CISO) and the UW Facility Security Officer to develop a policy and process for managing security incidents across the enterprise.

Information Security. In 2010, a new top level committee (the Security Program Executive Committee [SPEC]) was established for oversight of the ISP.

The ISP framework was revised based on standards promulgated by the International Organization for Standardization (ISO), an international standard-setting organization. The framework includes three functions (Governance, Security Services and Implementation) which are used to determine security and compliance requirements, disseminate requirements to specific individuals, and monitor their progress in mitigating technology risks and complying with regulations. The Governance function has documented 99 security strategies in preparation for rewriting existing security policies to ensure that policies are relevant, achievable, focused on improvement, and align with the maturity level of the enterprise security control environment.

ISP staff served as a resource for institutional boards with responsibilities for project intake, architecture, identity and access management, and change control. The ISP also provided consultation to IT services, departmental project teams, and UW Medicine departments covering topics such as policy interpretation, control evaluation and remediation, process improvement, and risk analysis.

The UW Medicine ISP met regularly with the UW Office of the CISO, participated on the UW Privacy and System Security (PASS) Council, and collaborated on several important initiatives, including risk transfer language for 3rd party contracts, a new UW Information Security and Privacy Policy Framework, a new UW Information Security and Privacy Incident Management Policy and uniform

incident response procedures, a new UW Privacy policy, and quarterly CISO security risk assessments.

Security education and awareness activities were conducted for 122 System Owners, who received job-specific training, and 728 new hospital staff members, who received basic awareness training as part of new employee orientation. System Owner training is publicized and available to all components of UW Medicine. Security awareness training for new staff of other UW Medicine entities will be provided as the time slots become available.

The ISP provides a central infrastructure for firewall management and consults with System Owners to help ensure compliance with access control requirements. The Windows server firewall management system was upgraded in 2010; in 2011, the Windows workstation firewall management systems will be upgraded in order to make the System Owners more self-sufficient.

The ISP collaborated with the UW Medicine Privacy Program on incident response activities, completing more than twenty forensics investigations. Capacity was doubled with the addition of a staff member, and the infrastructure was expanded by adding licenses for EnCase Enterprise application. The ISP is staffed with 8 FTEs, 3 of which are or will be under recruitment, including the Information Security Officer position.

Privacy/ Identity Theft Prevention Programs. These programs are supported by a mature policy framework. 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 regularly to provide useful reminders and practical guidance about protecting patient privacy.

The American Recovery and Reinvestment Act (ARRA) of 2009 established new reporting requirements for privacy breaches, including an annual accounting to the Department of Health and Human Services, notification of local media for breaches involving more than 500 patients, and notification of patients under certain circumstances. The Privacy Program spent most of 2010 revising policies and implementing operational changes, and was prepared to meet the new requirements by the enforcement dates. The Privacy Program continues to monitor the regulatory environment for on-going developments in this area.

In July, 2009, the UW Board of Regents approved UW Medicine policies to implement the so-called Red Flag Rules that required financial institutions and creditors to develop and implement written identity theft prevention programs. The Federal Trade Commission delayed enforcement of the rules several times, and in late December, 2010, Congress passed the Red Flag Program Clarification Act which limits the definition of "creditor" to those who regularly obtain or use consumer reports, furnish information to consumer reporting agencies, or advance funds. UW Medicine will take this development under consideration, but is proceeding with implementation of a uniform system-wide process for verifying patient identity at all clinical visits.

Federal law 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. UW Medicine will also need to implement a new coding nomenclature system (ICD-10) by 2013.

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

During this reporting period, the privacy program completed its management response to audit findings issued by UW Internal Audit Office in late 2009. Northwest Hospital was added to the UW hybrid entity for HIPAA compliance, and is in the process of modifying its privacy policies to conform to UW Medicine standards.

In December, 2010, UW Medicine finalized a draft of guidelines and best practices to address the growing use of social media by faculty, staff and students. These guidelines will be published in 2011.

D. 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 a regulatory exception applies. The health care reform legislation imposed changes to the Stark laws, primarily in the area of physician-owned facilities and patient notification when certain imaging tests are provided in a clinic setting. On a positive note, the legislation directed the government to develop a voluntary reporting mechanism to include reduction on penalties if a Stark violation is self-reported. Compliance with Stark is being managed jointly by the School of Medicine, UWP, and the hospitals and clinics. Planned activities for 2011 include the following:

- Complete work project to have all faculty physicians sign standardized documentation identifying services provided and compensation or benefits received
- Continue efforts to systemitize physician services contracting process, including finalizing physician services contract manual and contract templates
- Continue to review any benefits the UW provides to non-faculty, community physicians for compliance.

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. The federal health care reform legislation included a change that reversed federal caselaw, lowering the threshold for a violation. Under the new definition of "intent", a violation may be established even if the individual has no actual knowledge of the AKS statute or a specific intent to violate the AKS. Additionally, AKS violations are now automatically considered false claims under the False Claims Act.

In 2010, guidance and standard processes were developed to address the potential AKS risk in connection with vendor support of educational activities. Planned risk mitigation activities for 2011 include the following:

- Continue to review and develop policies and procedures on disclosure of conflicts in connection with drug and device purchases
- Continue to develop and refine guidance regarding vendor support of educational and research activities

E. 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
- Entity level policies on specific conflict issues such as Vendors in Clinical Areas and Drug and Device Purchasing
- UWP Conflict of Interest Policy
- CUMG Conflict of Interest Policy

In 2010, the National Institutes of Health proposed significant changes to the rules regarding the disclosure of financial interests in research. The proposed changes, if adopted, would expand the definition of significant financial interest, shift the burden of determining whether a conflict exists from the researcher to the University, and require reporting research conflicts on a public University website. Last year also was the first year of implementation of the new UW Medicine COI policy. The purpose of the policy is to ensure that SOM faculty avoid, or disclose and address, perceived or real conflicts of interest between their 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. In 2010, 350 faculty submitted almost 900 requests for outside work including serving on scientific advisory boards, and as consultants, speakers, instructors, and editors. In addition, the SOM and the hospitals developed working procedures to address a variety of issues related to industry support of educational events.

IV. SUMMARY

Compliance staffing and budget levels remained steady in 2010. UW Medicine continued refining its organizational structure to provide maximum utilization of resources and effective oversight of system-wide compliance efforts. During this period, a shared clinical billing audit plan and standard audit methodology was implemented. Numerous compliance lines were consolidated, and a central anonymous hotline was established. The integration of Northwest Hospital's (NWH) compliance functions began by including NWH officials in key compliance and leadership groups, and bringing NWH under the UW covered entity for HIPAA. Phase II of the NWH compliance integration process is underway, focusing on billing auditing, monitoring, and reporting.

Senior leaders and operational units were engaged throughout the year in risk identification and mitigation, problem solving, and the implementation of internal controls. Program staff continued to engage in proactive efforts to address regulatory developments, effectively planning and preparing for new external clinical billing reviews, new reporting and response requirements for privacy breaches, and changes to rules governing physician referrals, vendor relationships and disclosure of financial interests in research.

UW Medicine is seen as a leader among its peers in addressing issues such as conflict of interest and clinical research billing. The research billing audit program established in 2007 continued to be highly successful in identifying and resolving billing errors. Although the three-year error rate is low, the program has been invaluable in informing process improvement projects and identifying the educational needs of researchers.

The outlook for 2011 includes the likelihood of increased external billing reviews, heightened scrutiny of internal controls for privacy protection and information security, and continued national attention on conflicts of interest.

Attachment A

UW MEDICINE BOARD COMPLIANCE COMMITTEE: FISCAL YEAR 2011 ROSTER

Voting Members

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

Shan Mullin, Board Member and Board Chair

- 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

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

Bruce Pym - Community Member

- o President and CEO of Elliott Cove Capital Management
- 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

UW Medicine

Paul Ramsey, MD – Dean (SOM), CEO, (UW Med), EVPMA (UW)
Johnese Spisso - CHSO (UW Med), VPMA (UW)
Ruth Mahan – CBO (UW Med) VPMA (UW)
Sue Clausen - CCO/CPO (UW Med), AVPMA (UW)
Lori Oliver – Director of Legal & Business Matters (UW Med), AVPMA (UW)
Lori Mitchell – HSFOO (UW Med)
Lisa Westlund - Compliance Officer, UW Med Hospitals and Clinics
Richard Meeks - Director, UW Med Privacy/ID Theft Prevention

School of Medicine

Mark Green – Associate Dean for Business, SOM
Vacant - Compliance Director, SOM

Attorney General's Office

Dina Yunker - Assistant Attorney General (UW)

Practice Plans

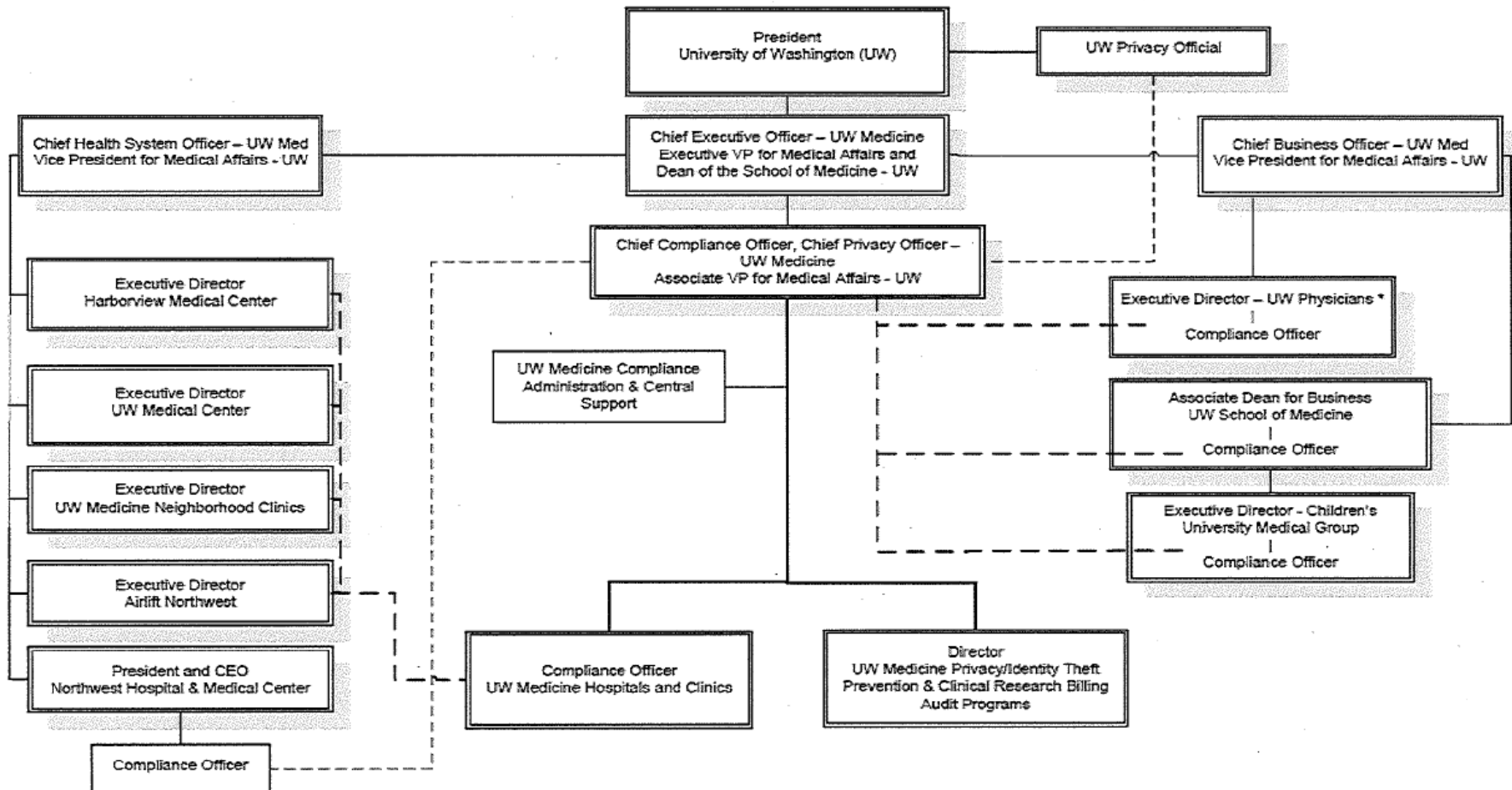
Dr. Mika Sinanan - President, UWP
Catherine Boelke - Executive Director, UWP
Carlos Cruz – Compliance Officer, UWP
Dr. Mark Del Beccaro – Chair, Physician Billing, Education & Billing Compliance Committee, CUMG
Rick Nielsen - Executive Director, CUMG
Sheryl Forrester - Compliance Officer, CUMG
Margaret 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
Bill Schneider, CEO, Northwest Hospital & Medical Center
Cynthia Coronel – Compliance Officer, Northwest Hospital & Medical Center
Christine Martin – Executive Director, Airlift Northwest
Phuong Dao - Integrity Officer, SCCA

Attachment B

UW Medicine Compliance Organization Chart



*Dual reporting relationship to UWP President

Approved <u>Paul G. Ramsey</u> Paul G. Ramsey, M.D. CEO, UW Medicine Executive Vice President for Medical Affairs and Dean of the School of Medicine, University of Washington	Date: <u>1/23/11</u>
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ATTACHMENT C

Channels of Communication for UW Medicine Compliance Issues

Committee/Chair	Committee Role	Membership
UW Medicine Board Compliance Committee, chaired by Rich Jones (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 staffs 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 committee is convened by the Chief Health System Officer/VPMA, and serves as a forum for engaging key executives from the health system compliance planning, policy approval, problem-solving, and risk assessment activities. The group works 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; the UW Med hospitals/clinics CO; the Privacy/ITPP Director; 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 compliance officers and directors, and compliance representatives from ITHS, Pharmacy, Laboratory, Patient Financial Services, and information security; compliance representatives from the School of Dentistry, UW information security, health sciences, risk management, environmental health and safety, animal and human research protection programs, research compliance; and compliance officers from affiliates, including Seattle Children's Hospital, Fred Hutch.
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 Dean for Clinical Affairs, UWP President, Executive Directors (UWMC, HMC, UWNC, UWP), Chief Financial Officers, SOM Director of Business Affairs, AVP for Community Relations.
Executive Clinical Leadership, chaired by Johnese Spisso, CHSO/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 (HMC, UWMC, NWH, UW Neighborhood Clinics, UWP, and ALNW).
Security Program Executive Committee (SPEC), chaired by Johnese Spisso, CHSO/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, UWNC), UW CISO, Asst VP for Med Ctr. HR

ATTACHMENT D

UW MEDICINE BOARD COMPLIANCE COMMITTEE - SCHEDULE 2010

Meeting Date	Focus Areas/Special Briefings	Focus Area Presenter(s)	Reports
December 7, 2009 9:30-11:30 am	<ul style="list-style-type: none"> Focus Area – Information Security Annual Compliance Report Draft 	Johnese Spisso Sue Clausen	Briefings
January 11 9:30-11:30 am	Focus Area - Clinical Billing Compliance Program <ul style="list-style-type: none"> OIG Workplan RAC Update Clinical Research Billing Audit Results 	Lisa Westlund	Briefings OIG Workplan
February 22 9:30-11:30 am	Focus Area – Privacy <ul style="list-style-type: none"> Clinical Research Billing Audit RAC Activity Executive Compliance Committee OIG Outliers 	Sue Clausen/Richard Meeks	Briefings Distribute FY 10 Qtr 2 reports
March	No meeting		
April 5 9:30-11:30 am	Focus Area – Clinical Research Billing <ul style="list-style-type: none"> External Review Activity 	Bruce Ferguson/Richard Meeks	Briefings
May	No meeting		Distribute FY 10 Qtr 3 reports
June 21 9:30-11:30 am	Focus Area – Stark/Anti-Kickback Statute <ul style="list-style-type: none"> External Review Activity UWP Training Report 	Mark Green	Briefings
July	No meeting		
August	No meeting		Distribute FY 10 Qtr 4 reports
September 13 9:30-11:30 am	Focus Area – Conflict of Interest <ul style="list-style-type: none"> OCR Requests External Review Update 	Mark Green	Briefings
October 18	No meeting		
November 1 9:30-11:30 am	Focus Area - Research Compliance <ul style="list-style-type: none"> Office for Civil Rights Cases: Update External Review Update 	Stephanie Steppe	<ul style="list-style-type: none"> Briefings Preview Annual Compliance Report Draft
December	No meeting		Distribute FY 11 Qtr 1 reports