

VII. STANDING COMMITTEES

B. Finance, Audit and Facilities Committee

UW Medicine Board Annual Compliance Report

For information only.

Attachment

UW Medicine Board Annual Compliance Report to the UW Board of Regents,
February 14, 2013

UW MEDICINE BOARD



ANNUAL COMPLIANCE REPORT TO THE UW BOARD OF REGENTS

February 14, 2013

UW Medicine

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EXECUTIVE SUMMARY

The seventh annual UW Medicine Board Compliance Report to the University of Washington (UW) Board of Regents covers the 2012 calendar year, describes UW Medicine's compliance programs and key responsibilities and highlights the year's primary compliance activities.

UW Medicine is a large organization, consisting of eight owned or managed entities that operate in a highly regulated environment with a variety of compliance requirements and potential risks. UW Medicine's compliance programs include the eight elements typically found in effective compliance programs (including standards of conduct and safe reporting mechanisms and activities such as education, monitoring and auditing). Clearly defined roles and responsibilities for workforce members, supervisors and managers, senior leaders and compliance staff provide the foundation for a culture of compliance. 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 UW Physicians and Children's University Medical Group. System-wide oversight is provided by UW Medicine's chief compliance officer/UW associate vice president for medical affairs. Program functions are performed by compliance officers and staff throughout the organization.

UW Medicine continues to refine its structure and channels of communication to manage internal and external developments. Modifications made in 2012 aligned the vision, strategic planning and operating philosophy for all facility-related compliance efforts. The result is a scalable organizational configuration that will facilitate the integration of Northwest Hospital & Medical Center and Valley Medical Center.

In fiscal year 2012, the annual compliance budget was \$9 million with 66 FTEs dedicated specifically to compliance functions (excluding Valley Medical Center). These figures do not represent the full cost of time, effort and systems devoted to compliance activities throughout the organization. For example, considerable professional effort devoted to compliance by leadership and operational staff across UW Medicine is not included in the UW Medicine Compliance budget.

UW Medicine's formal communication channels support compliance efforts within each entity, enhance the sharing of information between entities and provide safe options for reporting compliance concerns or seeking assistance. Each compliance office has dedicated intake points for general questions, coding help and complaints. The central hotline in the office of the UW Medicine chief compliance officer/UW associate vice president for medical affairs enables anonymous reporting of concerns and was the focus of an extensive outreach campaign in 2012.

Five compliance areas (clinical billing, information security, privacy, Stark/Anti-Kickback and conflicts of interest) were the subject of comprehensive presentations to the UW Medicine Board Compliance Committee in 2012. These presentations included general information about the regulatory framework as well as UW Medicine-specific information regarding each compliance area.

The largest compliance area for UW Medicine is **clinical billing**. The program's rigorous internal audit activities provide the foundation for identifying and mitigating clinical billing risks; system-wide mandatory training educates clinical practitioners about billing rules. In 2012, the Centers for Medicare and Medicaid Services (CMS) expanded the claim volume thresholds for the national Medicare Recovery Audit Contractor (RAC) Program, increasing the external audit activity experienced by UW Medicine. During this

reporting period the RAC auditors reviewed 4,279 claims representing approximately \$50 million in reimbursement; they alleged overpayments on 746 claims representing roughly \$4.5 million. Most of the denials have been for inpatient care that the auditor believed could have been safely provided in the less intensive and less costly outpatient setting. The medical necessity of inpatient admission has generated significant national debate. In response to industry concerns regarding this issue, CMS announced its intention to review and clarify/change the rules defining inpatient criteria. UW Medicine provided input to national organizations that conveyed academic medical center concerns to CMS.

A Medicaid audit of hospital outpatient observation services billing led to repayments by all four UW Medicine hospitals for a total of \$616,000. In addition, UW Medical Center repaid Medicaid \$1.3 million for incorrectly coded neonatal intensive care unit services.

CMS and the U.S. Department of Health & Human Services partnered on a letter to the heads of hospital industry groups, warning of potential misuse of electronic medical record functionality that may inflate billed services and generate potential overpayments. UW Medicine was already assessing internal practices to reduce this risk, but is conducting further analysis as a result of the letter.

Clinical research billing continues to be a nationally recognized focus area for academic health centers. UW Medicine has devoted significant efforts to this area, and its approach is considered to be among best-practices for academic health centers. Audit results continue to show a very low error rate (2.5 percent), but also identify areas for on-going system and process improvements. These activities are overseen by an operational leadership committee.

Information security incidents continue to capture national attention. In 2012, the UW Medicine Information Security Program developed and implemented a new policy set and related standards and guidance. UW Medicine also undertook a comprehensive data stewardship campaign, which clarified roles and responsibilities for protecting confidential information, required training throughout the system, and provided tools for unit heads and managers to ensure expectations are conveyed consistently to all workforce members.

UW Medicine continues to expand its vulnerability management program, system security review process, enhanced border protection, security event management and risk assessment in support of regulatory requirements.

UW Medicine's compliance program includes mandatory orientation, job-specific education, auditing and monitoring, and internal processes to facilitate patient rights under the **privacy and identity theft prevention** laws. In 2012, the Office for Civil Rights opened only one new investigation of UW Medicine.

The UW School of Medicine, UW Physicians, and UW Medicine Compliance jointly manage compliance with the **Stark Law**, which prohibits physician self-referrals, and the **Anti-Kickback Statute**, which prohibits any person from accepting remuneration for referring an individual for items or services covered by federal healthcare programs. UW Medicine reported no Stark violations in 2012, and directed its efforts toward standardizing the physician contracting process.

Situations that may create **conflicts of interest** (COI) arise in various contexts (including acceptance of gifts, outside professional work, research, authorship, relationships with vendors, and purchasing). Numerous

regulations and policies govern COI, and compliance efforts involve several UW offices. In 2011, the National Institutes of Health (NIH) adopted substantive changes to the COI rules for research to lower the disclosure threshold and to increase the requirements related to institutional oversight. The UW, under leadership of the Office of Research with assistance from the UW School of Medicine, substantially revised its policy on research conflict to comply with the new NIH requirements. The current UW Medicine COI policy, which addresses non-research COIs, has been in place for three years. The policy's purpose and intent was reaffirmed during a recent evaluation, and a small number of targeted changes were recommended to help strengthen the policy. The revisions are awaiting final approval by SoM leadership.

Section III provides detailed information about major activities and issues occurring in 2012.

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:

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

B. UW Medicine Structure

UW Medicine includes the following owned or managed entities:

- Harborview Medical Center (HMC)¹
- Northwest Hospital & Medical Center (NWH)
- Valley Medical Center (VMC)
- University of Washington Medical Center (UWMC)²
- UW Neighborhood Clinics (UWNC)
- UW Physicians (UWP)
- UW School of Medicine (SoM)
- Airlift Northwest (ALNW)³

¹ 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 most 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 All personnel of ALNW are UW or Seattle Children's employees.

UW Medicine is also a corporate member of two non-profit corporations: Children’s University Medical Group (CUMG), a pediatric practice plan founded with Seattle Children’s (Children’s), and the Seattle Cancer Care Alliance (SCCA) founded with Children’s and the Fred Hutchinson Cancer Research Center (FHCR). UW Medicine closely collaborates and partners with each entity’s compliance program. All physician clinical services at the SCCA are provided by UW SoM faculty physicians who are members of UWP or CUMG. SoM faculty physicians provide clinical service at Children’s primarily through CUMG. The SoM 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.

II. UW MEDICINE COMPLIANCE PROGRAM

A. Program Components

All UW Medicine compliance programs include these core components:



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 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,

⁴ See uwmedicine.washington.edu/Global/policies/Pages/default.aspx

implementing and enforcing policies, monitoring compliance and providing personal support of compliance initiatives.

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 **UW Medicine chief compliance officer and UW associate vice president for medical affairs** provides system-wide oversight and coordination, is a member of UW Medicine's senior leadership team and the UW Medicine Executive Compliance Committee (ECC), serves as an ex-officio member of all entity-specific compliance committees, staffs the UW Medicine Board Compliance Committee and attends all UW Medicine Board meetings.

The **UW Medicine Board Compliance Committee** (UW Medicine Board 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 UW Medicine Board CC members and the charter for this committee are provided in *Attachments A and B*.

The **UW Medicine Executive Compliance Committee** includes the senior leadership from each UW Medicine entity, as well as representatives from key stakeholder groups (e.g., risk management, health information management and patient financial services). This group receives detailed compliance reports, approves UW Medicine system-wide compliance policies and ensures that there are adequate resources and operational involvement directed to compliance initiatives.

Paul G. Ramsey, M.D., CEO, UW Medicine, executive vice president for medical affairs and dean of the UW SoM 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

Since 2005, coordination of system-wide activities and initiatives has been provided by the chief compliance officer/associate vice president for medical affairs. The UW Medicine compliance enterprise (see *Attachment C*) includes UW Medicine Compliance (responsible for all facility-related compliance except VMC), VMC Compliance, UW SoM Compliance (responsible for compliance issues involving SoM faculty, trainees and staff), and UWP and CUMG compliance programs (responsible for professional fee billing compliance in the practice plans).

1. Organizational Changes in 2012

UW Medicine Compliance continued to refine its structure and reporting relationships in response to various internal and external factors, including staffing changes, shifting workloads, increased regulatory activity, and new strategic alliances. In 2012, privacy and identity theft prevention compliance was centralized under the UW Medicine compliance officer, who reports directly to the chief compliance officer/associate vice president for medical affairs. This change aligns the mission, vision, strategic planning, operating philosophy, policy structure and education/outreach programs for the majority of facility-related compliance efforts. It maximizes utilization of internal expertise, centralizes accountability and provides for a more vertical, scalable structure that will facilitate the integration of new entities.

UW Medicine Compliance assumed full responsibility for oversight of NWH compliance functions in 2012. Former NWH compliance staff are now UW employees, and compliance education provided to NWH workforce members is the same as that provided at UWMC and HMC. At VMC, integration efforts in 2012 focused on privacy and identity theft prevention, and incorporating external review data into UW Medicine reports.

2. Compliance Resources

UW Medicine devotes significant resources to both organization-wide and entity-specific compliance efforts. In fiscal year 2012, the annual budget was \$9 million and there were 66 FTEs dedicated specifically to compliance functions (excluding VMC). This exceeds 2011 figures by \$1 million and six FTEs, primarily because figures reported this year include the information security program and NWH resources.

These figures do not represent the full cost of time, effort and systems devoted to compliance-related activities throughout the organization. For example, this budget does not include considerable time and effort spent by a large number of faculty and staff who serve in administrative positions and have operational responsibilities that are critical for success of the compliance programs.

3. Channels of Communication

UW Medicine has established numerous formal communication channels (see *Attachment D*) 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 program priorities.

Workforce members must also have safe communication and reporting channels. In



2012, the central hotline maintained by the chief compliance officer/associate vice president for medical affairs, which provides for anonymous reporting of compliance concerns, was the focus of a comprehensive outreach campaign to the hospitals and clinics, ALNW, UWP and the SoM. In addition, UWP and CUMG both maintain a helpline to answer compliance questions. The majority of inquiries, requests for consultation and complaints are conveyed directly to compliance staff across the UW Medicine enterprise.

III. KEY COMPLIANCE AREAS

The key compliance focus areas identified for 2012 included the following:

- *Clinical billing (covering facility and professional fee billing for all clinical services, including research)*
- *Information security*
- *Privacy/identity theft prevention*
- *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 in 2012 (see *Attachment E*), a content expert led an interactive session on a specific focus area. Presentations focused on key concepts, primary risks, mitigation strategies, and emerging issues; these are contained in the official committee records.

The following sections highlight major activities and developments that occurred in 2012.

A. Clinical Billing

External Reviews. The Medicare Recovery Audit Contractor (RAC) program is the largest of multiple federal and state billing audit programs impacting UW Medicine. Early in 2012, the Centers for Medicare and Medicaid Services increased the per entity claim volume for the program, which significantly increased the number of UWP, NWH, UWMC, HMC and VMC claims selected for review. In 2012, 4,279 claims representing \$49,675,915 million in reimbursement were reviewed, compared to 2,673 claims representing \$33,744,050 in 2011.

To date, RAC auditors have alleged overpayments for 746 of the claims reviewed in 2012, representing just over \$4.5 million dollars. Most of the denials have been for inpatient care that the auditor believed could have been safely provided in the less intensive and less costly outpatient setting. The medical necessity of inpatient admission has generated significant national debate. In response, CMS recently announced that it would review the rules and consider changes or clarifications. UW Medicine provided input through a national project that developed recommendations for CMS on this topic and established an internal cross-entity, cross-functional group to oversee internal process improvement efforts.

CMS selected NWH for a national demonstration project that allows participating hospitals to rebill services as an outpatient claim when a one to two day inpatient stay is denied for medical necessity. This is not allowed under current rules, and a denial usually results in the loss of all or most of the inpatient payment. Since January 2012, NWH has averaged a 43 percent payment recapture rate under the project.

The Washington Department of Social and Health Services (DSHS) implemented its Medicaid RAC program in 2012 as anticipated but is currently reviewing only critical access hospital claims. DSHS has not announced a timeline for expanding the program to other types of claims. However, the existing (non-RAC) audit program already reviews claims from acute care hospitals, and in 2012, found hospital outpatient observation billing errors that resulted in a collective \$616,000 repayment for the four UW Medicine hospitals. The problems leading to the errors have since been addressed. DSHS also initiated audits of other inpatient claims at all four hospitals, but there are no results yet.

UW Medicine continues to reap the benefits of software purchased in 2010 that facilitates robust tracking of RAC audits and results and provides data needed for proactive assessment of risk areas and summary reporting. In 2012, NWH external review activity was fully integrated into central processes for external review administration and tracking.

All external review activities are reported in detail to the UW Medicine Executive Compliance Committee; reports are maintained in the official committee files.

Facility Billing. The annual facility billing audit plan now includes UWMC, HMC and NWH. The most significant facility billing repayment during this reporting period was \$1.3 million dollars repaid to DSHS by UWMC for overpayments caused by coding errors for neonatal intensive care unit services. Improvements to operational processes addressed the issue, and follow-up audits confirmed the effectiveness of the changes.

In fall 2012, the U.S. Department of Health & Human Services and the Office of Inspector General partnered on a letter to several high profile industry groups, highlighting potential pitfalls of electronic medical records, including misuse of copy and paste functions that could result in upcoding evaluation and management services. Although our billing audit and education activities already focus on these types of services, we are exploring additional methods for identifying high-risk coding patterns that may necessitate increased scrutiny.

Professional Fee Billing. UW Medicine Compliance assumed responsibility for professional fee billing compliance at NWH in mid-2012. Audits completed by former NWH staff have been reviewed, and that assessment is being used to establish education and audit priorities for 2013.

Since 2009, UWP and CUMG have operated separate but closely coordinated compliance programs covering professional fee billing for practice plan members. Policies and standards are aligned where appropriate, but they are designed to address the unique risks of the respective clinical practices and complement specific medical staff processes, facility systems and controls. Both practice plans engage in rigorous auditing, on-going risk assessment,

mandatory training and investigations of reported or observed billing issues. Efforts in 2012 included the following:

- CUMG completed all scheduled policy reviews/updates; trained all 456 CUMG practitioners; and, provided training and review to 62 new CUMG members.
- CUMG completed 100 percent of their scheduled reviews (383 practitioner audits) and responded to six internal inquiries with investigations and risk assessments.
- UWP conducted proactive risk assessments and completed scheduled risk-based audits on 98 percent of the physicians identified for review (910 physicians). They also conducted second reviews on 43 physicians, pre-billing reviews on all 135 practitioners new to UWP and 13 UWP professional fee coders.
- UWP achieved 100 percent completion of the mandatory training (including 1,991 physician and non-physician members and 252 UWP administrative employees).

Clinical Research Billing. UW Medicine has devoted significant efforts toward the development of efficient and effective compliance and operational programs for clinical research billing. Our approach, considered to be among best practices for academic health centers, is based on the following core elements:

- Guiding policies, standards, processes and tools to support compliant billing and mandatory training for clinical research staff;
- Centralized operational support (provided by the Clinical Research Billing and Budget Support Office within the SoM);
- An oversight committee charged with continuous assessment of processes, and strengthening of internal controls and systems, as needed;
- Compliance audits to determine if policies and procedures are being followed, and verify that services provided to research subjects are correctly billed.

Since 2007, 158 audits have been completed, showing a very low error rate (2.5 percent). UW Medicine also uses audit results to identify the need for process improvements throughout the life cycle of a clinical research study. In 2012, audits highlighted opportunities for enhancing application of the UW Medicine research effort policy, improving the scheduling process for research-related clinical visits and budget development modifications to prevent risk under the Medicare Secondary Payor rules.

B. Information Security and Privacy

The UW Medicine chief health system officer and vice president for medical affairs serves as the UW privacy official. The UW Medicine Information Security Program (ISP) operates under the direction of the UW Medicine chief information officer, who reports to the UW Medicine chief health systems officer/vice president of medical affairs. Privacy protection and identity theft prevention are part of the system-wide compliance program under direction of the chief compliance officer/associate vice president for medical affairs, who serves as chief privacy officer for UW Medicine and has a dotted line relationship to the UW privacy official for privacy and identity theft prevention. The ISP and UW Medicine Compliance are responsible for developing and maintaining their respective policies,

providing related education and outreach, monitoring and auditing compliance and reporting regularly to appropriate leadership groups. UW Medicine Compliance investigates all privacy, identity theft and information security complaints.

Information Security. The ISP continues to proactively manage information security risks in partnership with executive leadership. In March 2012, the ISP revised its program vision and issued a new policy set that defines baseline requirements and standards for electronic data, computing devices and systems and workforce members. The program includes strategic and pervasive educational efforts and expanded the delivery of technical services. The ISP also completed a high-level risk assessment in 2012 and a separate risk assessment in support of meaningful use requirements.

UW Medicine developed and implemented a comprehensive, top-down data stewardship campaign to clarify roles and responsibilities for protecting confidential information, provide training throughout the system and develop tools to help unit heads and managers conveying consistent expectations to all workforce members.

The ISP provided on-site encryption advice during data stewardship training sessions, held system-wide Q&A sessions, updated the core competencies module and collaborated with UW Purchasing and the Attorney General's Office on data security agreements. New employee orientation was expanded in 2012 to include physicians, and the ISP participated in orientation sessions for more than 1,200 new hospital staff members.

In 2012, the ISP also implemented an encrypted email monitoring system and auto-forwarding email controls, completed three system security reviews, expanded enrollment in the Vulnerability Management Program to four entities (and increased coverage from 324 to 12,201 devices) and expanded Enterprise Intelligence (analyzing more than 50,000,000 events from more than 10,000 devices spread across UW Medicine). There were 10 digital forensics investigations and 24 security incidents.

The Exposure Management service is improving the effectiveness of UW Medicine's intrusion prevention systems, providing centralized management and troubleshooting for non-data center firewalls and providing assistance to departments looking to improve their workstation firewalls.

The Security Information and Event Management (SIEM) system, implemented in 2011, collects system and enterprise security data for analysis and correlation. The SIEM has increased visibility into systems across UW Medicine and processes over 50,000,000 events per day. The SIEM's alerting and reporting functions are being integrated into day-to-day security operations, and they took on additional importance in the last quarter of 2012 as events recording access to personal health information (PHI) were imported.

Privacy/Identity Theft Prevention. The protection of privacy at UW Medicine is supported by a mature policy framework, mandatory education, auditing, timely responses to complaints and internal processes for meeting patient rights requests. UW Medicine

manages potential identity theft cases through its Patient Identification and Clarification Committees.

As in past years, most policy violations involved the accidental disclosure of patient information (such as referral notes to the wrong physician or copies of health information mistakenly sent to someone other than the patient). Operational improvements are the primary focus for reducing the frequency of these events. There were several incidents involving the loss of portable devices containing patient information which resulted in nine privacy breaches and the notification of 334 patients.

One patient complaint was received in 2012 from the Office of Civil Rights (OCR). We conducted a thorough internal review and provided a timely response. There has been no further contact from the OCR on this case, or on a second case that remains open from the prior year. The OCR closed another existing case from the prior year without any fines, penalties or other corrective actions.

UW Medicine initiated clinical area walk-through audits in 2012 to evaluate compliance with policies governing privacy and information security, and to assess the effectiveness of related education and outreach activities. These audits have been successful in providing clinic managers with practical advice about improving the protection of patient privacy.

Several federal rules are pending finalization. We are closely monitoring developments because some proposed provisions would require significant retooling of UW Medicine operations.

VMC was added to the UW Medicine covered entity designation for purposes of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Notice of Privacy Practices document was revised accordingly.

C. Stark/Anti-Kickback

The Stark Law prohibits physicians from referring Medicare/Medicaid patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless a regulatory exception applies. There were no significant changes to Stark in the past year. UW Medicine did not detect or report any Stark violations in 2012. Compliance with Stark is managed jointly by the SoM, UWP and UW Medicine Compliance. In the past year, efforts focused on standardizing the physician contracting process, including finalizing a physician services contract manual and contract templates. Planned activities for the coming year include:

- Continue work project to standardize documentation for faculty physicians engaged in teaching and other activities throughout the WWAMI region to clearly identify all services provided and compensation or benefits received
- Continue to review any remuneration the UW provides to non-faculty, community physicians for compliance with Stark

The Anti-Kickback Statute (AKS) prohibits the knowing and willful payment or acceptance of remuneration for referring an individual for items or services covered by a federal healthcare program, or for purchasing (or recommending for purchase) an item or service that is reimbursable under federal healthcare programs. Unlike Stark, the AKS applies not only to physicians but also to non-physicians and entities. There were no significant changes to the AKS in the past year. During 2012, educational efforts focused on the UW procurement and purchasing offices.

Planned risk mitigation activities for the coming year include:

- 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
- Continue to develop and refine guidance regarding purchase contracts with vendors

D. Conflict of Interest

Conflicts of interest 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 Policy for Faculty on Potential Financial Conflicts of Interest With Commercial or Non-Profit Entities
- 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 2011, the National Institutes of Health (NIH) modified rules governing disclosure of financial interests in research. These changes expand the definition of significant financial interest by lowering the threshold for disclosure, require researchers to disclose interests related to all their institutional responsibilities rather than just those related to their research, require disclosure in advance rather than after the fact and shift the burden of determining whether a conflict exists from the researcher to UW. They also impose a training obligation on UW, require more UW reporting to NIH and require public accessibility to the information disclosed by researchers and UW's response to those disclosures. The new rules became effective on August 24, 2012. The UW Office of Research, with significant assistance from the SoM, substantially revised the Significant Financial Interest Policy (GIM 10) to comply with these new rules. The UW also implemented an on-line Financial Interest Disclosure System (FIDS) for disclosure of significant financial interest and on-line financial conflict of interest training in 2012, as part of the changes to address the new NIH requirements.

This was the third year of the new UW Medicine COI policy. The purpose of the policy is to ensure that 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. A key provision of this policy is that faculty must disclose in advance the amount of compensation to be received for outside work.

The committee that developed the policy has recently conducted an in-depth review to determine its effectiveness and whether any changes should be made. The committee reaffirmed the policy's purpose and intent, and recommended a small number of targeted changes to help strengthen the policy including a prohibition on faculty participation on speakers' bureaus, a limit on faculty endorsement of commercial products, and the inclusion of guidance relating to industry interaction with the school and departments ("Institutional COI"). The revisions are awaiting final approval by SoM leadership.

IV. LOOKING FORWARD: 2013

Planning for compliance program activities is an on-going process which involves all program areas identified in Section IIA1 (including auditing, development and modification of policies, and education). Our compliance priorities are heavily influenced by the increasingly dynamic external regulatory environment (including new and changing rules, workplans and audit priorities established by regulatory agencies and programs) as well as our own audit findings and risk assessments.

In 2013, we expect to focus on four major areas:

1. Sustaining a proactive, risk-based internal audit and monitoring program for clinical billing and privacy protection, while continuing to meet the demands of external review programs.
2. Participating in system-wide initiatives including ICD-10, meaningful use, Accountable Care Organization development, and Learning Management System deployment.
3. Completing the integration of Northwest Hospital and Valley Medical Center compliance functions.
4. Continuing to enhance information security through on-going education and refinement of internal tools and controls.

Attachment A

UW Medicine Board Compliance Committee: Fiscal Year 2012 Roster

Voting Members

Rich Jones, board member and committee chair

- o President and CEO of the Washington Society of Certified Public Accountants
- o Former member of the Board of FHCRC; founding member and past 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

Jim Anderson, board member

- o Chairman of Health Resources Northwest/Northwest Hospital (HRN/NWH)
- o Serves as chair of HRN/NWH Information Systems & Committee and Finance Committee
- o Former chairman of Strategic Planning Committee for the Board of Directors for Northwest Healthcare Insurance Services and Washington Casualty Company
- o Former chairman of Budget Committee of the Board of Overseers of Whitman College.
- o Former board of director of Pacific First Financial Corporation, Multicare Health System, Tacoma/Pierce County Economic Development Council and the Corporate Council for the Arts and Reality Based Learning.

Shan Mullin, board member (and board chair until July 2012)

- o Former chair of FHCRC and 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 SCCA
- o Partner in the Seattle office of Perkins Coie law firm; Distinguished Alumni Award from UW Law School 2004

Gary Kohlwes, community member

- o Community trustee appointed to the Valley Medical Center Board
- o Served on the Valley Medical Center Board of Commissioners
- o Former member of the Washington Pacific Insurance SP Board
- o Past superintendent of the Renton School District
- o Past board member of Renton Chamber of Commerce, Seattle Country Day School & First Savings Bank Northwest

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 FHCRC, member of the FHCRC 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 and 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 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 healthcare, fisheries, aerospace, architecture and timber

Non-Voting Members

UW Medicine

Paul G. Ramsey, M.D., CEO, UW Medicine, executive vice president for medical affairs, and dean of the UW SoM
Johnese Spisso, chief health system officer, UW Medicine, and vice president for medical affairs, University of Washington
Ruth Mahan, chief business officer, UW Medicine, and vice president for medical affairs, University of Washington
Lori Mitchell, chief financial officer, UW Medicine, and vice president for medical affairs, University of Washington
Sue Clausen, chief compliance officer, UW Medicine, and associate vice president for medical affairs, University of Washington
Lori Oliver, director of legal and business matters, UW Medicine, associate vice president for medical affairs, University of Washington
Liz Shirley, enterprise finance officer, UW Medicine, associate vice president for medical affairs, University of Washington
Lisa Westlund, compliance officer, UW Medicine

School of Medicine

Mark Green, associate dean for business
Noella Rawlings, compliance director

Hospitals/Clinics

Eileen Whalen, executive director, Harborview Medical Center
Stephen Zieniewicz, executive director, UW Medical Center
Meg Kerrigan, executive director, UW Neighborhood Clinics
Cindy Hecker, interim executive director, Northwest Hospital
Christine Martin, executive director, Airlift Northwest
Rich Roodman, chief executive officer, Valley Medical Center
Colleen Nelson, compliance officer, Valley Medical Center
Traci Pranzini, interim integrity officer, SCCA

Practice Plans

Mika Sinanan, M.D., president, UW Physicians
Catherine Boelke, executive director, UW Physicians
Carlos Cruz, compliance officer, UW Physicians
Robert Sawin, M.D., president, CUMG
Patricia Adams, interim executive director, CUMG
Sheryl Forrester, compliance officer, CUMG

Attorney General's Office

Dina Yunker, assistant attorney general, University of Washington

Non-Profit Entities General Counsel

Margaret Peyton

VMC General Counsel

David Smith

Attachment B

UW Medicine Board Compliance Committee Charter

Committee Name

UW Medicine Board Compliance Committee

Committee Establishment and Authority

Section 4.4 of the UW Medicine Board Bylaws establishes and defines the authority of the UW Medicine Board Compliance Committee.

Committee General Duties

In conformance with Section 4.4.1 of the UW Medicine Board (UWMB) Bylaws, the Committee is responsible for reviewing and evaluating the compliance programs of UW Medicine component entities¹ and preparing the Chairperson of the UWMB to advise the Board of Regents, the President, and the Chief Executive Officer, UW Medicine, Executive Vice President for Medical Affairs, University of Washington, and Dean, University of Washington School of Medicine (CEO/EVPMA/Dean) regarding the implementation and effectiveness of UW Medicine Compliance Programs. The Committee will participate in the development of the annual UWMB compliance report to the UW Board of Regents in conformance with Section 1.4.3 of the UWMB Bylaws.

Although not specifically provided for in the UWMB Bylaws, the Committee shall keep the UWMB informed of its activities and findings concerning the implementation and effectiveness of UW Medicine Compliance Programs. Such duty anticipates a report from the Chair of the Compliance Committee (or other member of the Committee if the Chair is not available) to the UWMB at the next meeting of the UWMB following a meeting of the Compliance Committee.

Committee Specific Duties and Responsibilities

Duties of the Committee include but are not limited to advising on the following (UWMB Bylaws, Section 4.4.1):

- *key compliance policies;*
- *compliance program infrastructure and reporting relationships;*
- *scope of authority of key positions;*
- *ongoing assessment of compliance risks and the effectiveness of mitigation activities; and*

¹ Component entities include Harborview Medical Center (HMC), Northwest Hospital & Medical Center (NWH), Valley Medical Center (VMC) UW Medical Center (UWMC), , UW Neighborhood Clinics (UWNC), UW Physicians (UWP), UW School of Medicine (UWSOM) and Airlift Northwest (ALNW). Because UW Medicine also has part ownership of Children's University Medical Group (CUMG) and the Seattle Cancer Care Alliance (SCCA), these entities participate on the Committee.

- *level of resources dedicated to the compliance programs.*

In addition, the Committee will:

- *monitor the progress of new initiatives, process improvement projects, and programs developed in response to UW Medicine compliance reviews and risk assessments;*
- *receive reports of relevant noncompliance and misconduct as the Chief Compliance Officer, UW Medicine/Associate Vice President for Medical Affairs, University of Washington (CCO/AVPMA) deems appropriate, including summary reports on compliance items reported on the UW Medicine Hot Line reporting system and the resolution of those matters*
- *make recommendations to improve the effectiveness of UW Medicine compliance programs; and*
- *review and evaluate, at least annually, the performance of the Compliance Committee, including fulfillment by the committee of this charter, the adequacy of this charter and submit any proposed recommendations for change to the UW Medicine Board for their review and approval.*

Committee Member Composition

In conformance with Section 4.4.2 of the UWMB Bylaws, the Chairperson of the Committee is appointed by the Chairperson of the Board, with the approval of the CEO/EVPMA/Dean.

The voting members of the Committee are appointed by the Chairperson of the Board in consultation with the CEO/EVPMA/Dean. Voting members include:

- *At least three Board members, including the Chairperson of the Board or designee*
- *Up to three community members who are not members of the Board.*

Board members and community members will be appointed to the Committee for a term of one year, which may be renewed annually. Any vacancies that occur will be filled in the same manner as the initial appointments to the Committee.

The following non-voting individuals are also invited to attend the Committee meetings on a regular basis:

- *CEO/EVPMA/Dean*
- *Chief Health System Officer, UW Medicine/Vice President for Medical Affairs, University of Washington;*
- *Chief Business Officer, UW Medicine/Vice President for Medical Affairs, University of Washington;*
- *CCO/AVPMA;*
- *Controller, UW Medicine/Associate Vice President for Medical Affairs, University of Washington*

- *Director of Legal and Business Matters, UW Medicine/Associate Vice President for Medical Affairs, University of Washington*
- *Health System Financial Operations Officer, UW Medicine/Associate Vice President for Medical Affairs, University of Washington;*
- *Executive Directors of HMC, UWMC, UWNC, UWP, ALNW, and CUMG;*
- *Chief Executive Officer of VMC*
- *Presidents of NWH and UWP;*
- *Chairman of the Physician Education, Billing and Compliance Committee for CUMG;*
- *Associate Dean for Business, School of Medicine;*
- *;*
- *General Counsel for UWP, CUMG, and VMC;*
- *Assistant Attorney General for UW;*
- *Compliance Officer(s)/director(s) for UW Medicine, VMC UWP, UWSOM, CUMG and SCCA;*
- *and*
- *Other non-voting individuals invited by the Committee Chair.*

Committee Member Requisite Skills and General Qualifications

Committee members are selected for the following skills and qualifications:

- *The highest ethical standards and integrity;*
- *A willingness to act on and be accountable for Committee decisions;*
- *The ability to provide informed and thoughtful counsel to senior leaders and compliance officers;*
- *A history of achievement that reflects superior standards;*
- *Loyalty and commitment to driving the success of UW Medicine; and*
- *A background that provides a portfolio of experience and knowledge commensurate with UW Medicine's needs.*

Committee Decision-Making Processes

In conformance with Section 4.4.4 of the UWMB Bylaws, a majority of voting Committee members will constitute a quorum for the purpose of making official decisions and taking formal actions. Other types of decision-making will be based on member consensus.

Committee Reporting Requirements

The Committee shall report meeting proceedings and recommendations to the UW Medicine Board at the Board's regularly scheduled meetings.

Committee Member Obligations

- *Members shall attend the majority of scheduled Committee meetings and notify the Committee Chair when circumstances prevent attendance.*
- *Members will review germane materials in advance of each Committee meeting.*
- *Members will not act as an agent for any person or organization where such an act would create a conflict of interest with the terms of service to the Committee.*
- *Members will recuse themselves from discussions or decisions that may represent a potential conflict of interest.*
- *Members will safeguard the confidentiality and security of information obtained during the course of their Committee service.*

Annual Committee Goals, Objectives and Performance Measures

- **Goal:** *Maintain awareness of UW Medicine compliance program activities, including policy development, risk assessment, education/outreach, auditing/monitoring, handling of complaints, and corrective actions.*

Performance Measure: *The Committee receives and reviews at least two comprehensive written reports per year from each UW Medicine Compliance Officer, and members have opportunities to ask questions and provide feedback on program activities.*

- **Goal:** *Maintain awareness of UW Medicine's primary compliance risks, mitigation strategies, and compliance work plans.*

Performance Measure: *The primary risk areas are identified annually. At each meeting of the Committee, significant time is devoted to an in-depth review of at least one risk area, led by an appropriate content expert. Members have opportunities to ask questions and provide feedback.*

- **Goal:** *Maintain awareness of emerging compliance issues facing UW Medicine.*

Performance Measure: *Each meeting of the Committee will include briefings about emergent issues, changes in the regulatory environment, and late-breaking or urgent developments. Additionally, each meeting will reserve an executive session for briefings of a sensitive nature. Members have opportunities to ask questions and provide feedback.*

Committee Administrative Matters

In conformance with Section 4.4.3 of the UWMB Bylaws, the Compliance Committee meets at the call of the Chairperson as often as necessary, but not less than quarterly, to perform its duties. The annual schedule of meetings (including planned focus areas) is developed and distributed at the beginning of each fiscal year. This schedule is updated as necessary. Material referenced in the schedule is provided to Committee members one week in advance of the relevant meeting.

The Committee is staffed by the CCO/AVPMA.

Voting members of the Committee are oriented to their roles and responsibilities in a joint meeting with the Committee Chair and the CCO/AVPMA.

Written minutes are maintained of each Compliance Committee meeting. Minutes shall accurately record the topics discussed, decisions reached, and attendance of Committee members and guests. Official documentation of each meeting, including minutes, supporting handouts, and presentation materials, shall be maintained by the office of the CCO/AVPMA.

The Committee Charter will be reviewed annually.

Other Committee Items

None.

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Approved by the Committee and Recommended to the UW Medicine Board



Committee Chair

1/12/12
Date

Approved by the UW Medicine Board

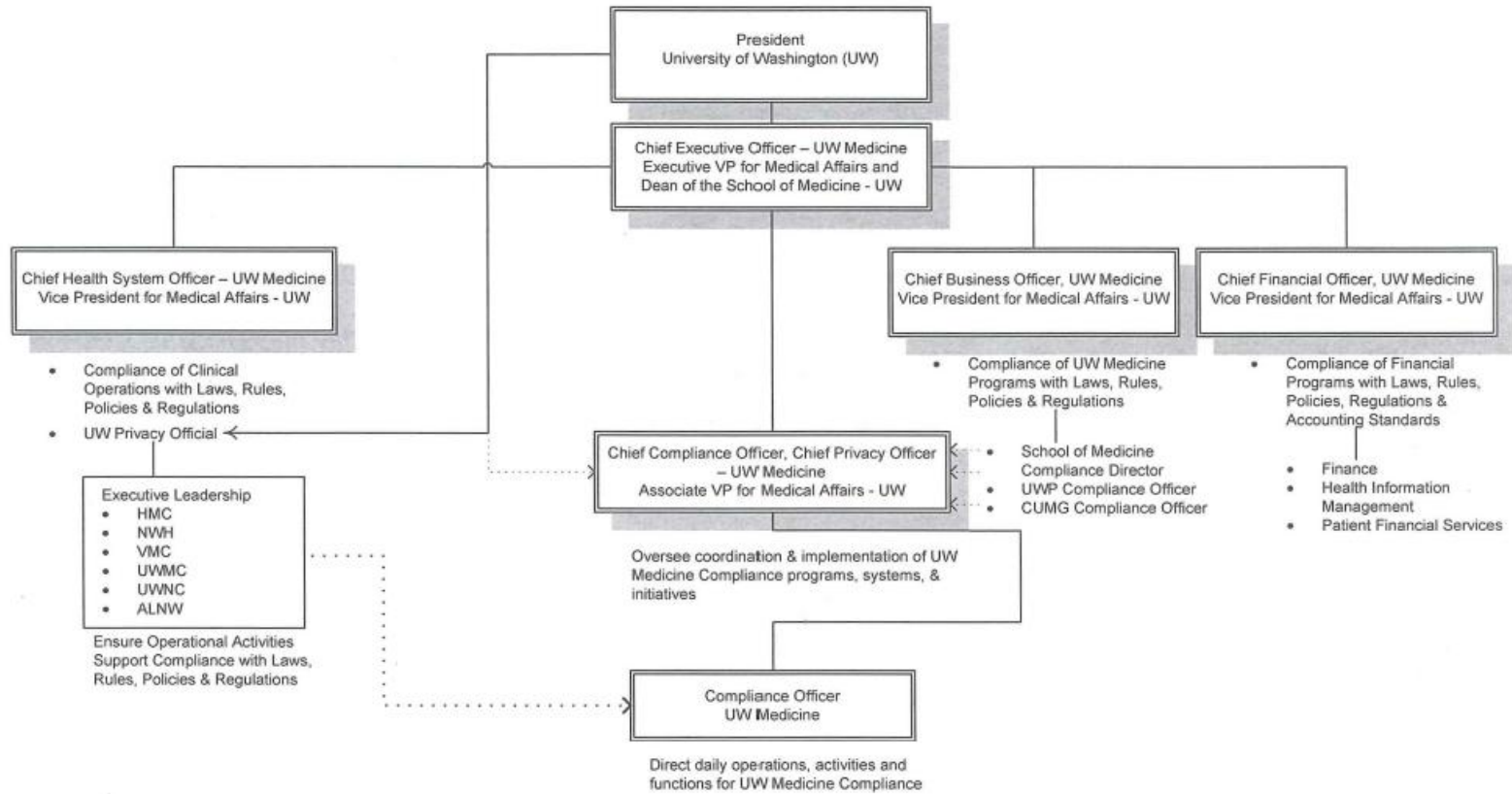


Chair of the UW Medicine Board

1/12/12
Date

Attachment C

UW Medicine Compliance Organization Chart (12/18/12)



Approved Paul G. Ramsey Date: 1/18/13
 Paul G. Ramsey, M.D.
 CEO, UW Medicine
 Executive Vice President for Medical Affairs and
 Dean of the School of Medicine, University of Washington

Attachment D

UW Medicine Compliance Issues Channels of Communication

Committee/Chair	Committee Role	Members and Attendees
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 per year, receives semi-annual 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: community members, the UW Medicine board chair and other UW Medicine board members. Non-voting attendees: senior executive leaders and entity compliance officers. See Attachment A for the full roster and Attachment B for the Committee Charter.
UWP Business Excellence Committee, chaired by John Bramhall, M.D. CUMG Physician Billing & Education Compliance Committee, chaired by Jack Salerno, M.D.	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.	Executive leaders, physicians, clinical department representatives, legal counsel, training and operational staff, the practice plan compliance officers, the SoM compliance director, and the chief compliance officer/associate vice president for medical affairs.
UW Medicine Executive Compliance Committee, chaired by Johnese Spisso, chief health system officer, UW Medicine, and vice president for medical affairs, UW	This committee serves as a forum for engaging key executives from the health system in 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.	Executive directors and senior officers from the hospitals, clinics and ALNW, administrative directors from key operational units, the chief compliance officer/associate vice president for medical affairs, the UW Medicine compliance officer, and a representative from the attorney general's office.
Compliance Officers Group, chaired by Sue Clausen, chief compliance officer, UW Medicine, and associate vice president for medical affairs, UW	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 compliance and related content experts from UW Medicine Compliance, ITHS, Pharmacy, Laboratory, Patient Financial Services, UW and UW Medicine information security; School of Dentistry, health sciences administration, risk management, environmental health and safety, animal and human research protection programs and affiliated organizations.
UW Medicine Operations and Finance Committee, chaired by Paul Ramsey, CEO, UW Medicine, and dean of the UW SoM	This committee provides a venue for engaging senior leaders in the evaluation of, and response to, UW Medicine-wide compliance issues.	Members include the vice presidents for medical affairs, vice dean for clinical affairs, UWP president, executive directors (HMC, UWMC, UWNC, UWP, ALNW), financial officers, school associate deans for administration/finance and business affairs, UW medicine chief of staff/associate vice president for medical affairs and director of business and legal matters/associate vice president for medical affairs.
Executive Clinical Leadership, chaired by Johnese Spisso, chief health system officer, UW Medicine, and vice president for medical affairs, UW	This group provides clinical operations leadership for UW Medicine, develops/implements strategic operating & financial plans and addresses related issues (e.g., access management, coordination of care, process improvement, human resources, regulatory affairs, recruitment/retention needs, space planning, and information technology).	Members include the Executive Leadership Team from UW Medicine clinical health system entities (HMC, NWH, VMC, UWMC, UWNC, UWP and ALNW) and other UW Medicine leadership.
Security Program Executive Committee (SPEC), chaired by Johnese Spisso, chief health system officer, UW Medicine, and vice president for medical affairs, UW	SPEC provides executive direction for the UW Medicine Information Security Program, reviews and endorses security policies, strategic plans, annual budget requests and risk assessments.	Members include the chief business officer/vice president for medical affairs, director of security & networking, chief compliance officer/associate vice president for medical affairs, chief information officer, director of Health Science Risk Management, UWP President, executive directors (HMC, UWMC, UWNC) and UW chief information security officer.

Attachment E

UW Medicine Board Compliance Committee - Schedule 2012

Meeting Date	Focus Areas/Special Briefings	Focus Area Presenter(s)	Reports
January 9 9:30-11:30 am	Focus Area – Stark/Anti-Kickback Special Session: Physician Leaders for Practice Plan Compliance Committees	Noella Rawlings Drs. Mika Sinanan, Tom Payne and Mark DelBeccaro	Briefings <ul style="list-style-type: none"> • Preview of 2011 Annual Compliance Report • UW Medicine Board CC Charter • External Review Activity
February	No meeting		
March	No meeting		
April 16 9:30-11:30 am	Focus Area – Information Security	Paul Henderson	Briefings <ul style="list-style-type: none"> • 2011 Annual Compliance Report • External Review Activity • FY 12 Qtr 1 & 2 reports
May	No meeting		
June 25 9:30-11:30 am	Focus Area – Clinical Billing	Lisa Westlund	Briefings <ul style="list-style-type: none"> • Compliance UW Internal Audit Interface • Privacy Updates • External Review Activity
July	No meeting		
August	No meeting		
September 10 9:30-11:30 am	Focus Area – Privacy/Identity Theft Prevention	Sue Clausen	Briefings <ul style="list-style-type: none"> • Compliance Channels of Communication • Compliance Hotline Report • External Review Update • FY 12 Qtr 3 & 4 reports • Changes in Federal COI Rules
October	No meeting		
November 5 9:30-11:30 am	Focus Area – Conflicts of Interest Special Session: UWMC Leadership	Mark Green Steve Zieniewicz, Dr. Tom Staiger, Grace Parker	Briefings <ul style="list-style-type: none"> • ICD-10 Status Report • External Review Update
December	No meeting		