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 $9,\,2012$

UW Medicine

UW MEDICINE BOARD

ANNUAL COMPLIANCE REPORT TO THE UW BOARD OF REGENTS

February 9, 2012

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EXECUTIVE SUMMARY

The sixth annual UW Medicine Board Compliance Report to the UW Board of Regents covers the 2011 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 (UWP) and Children's University Medical Group (CUMG). System-wide oversight is provided by the Chief Compliance Officer/Associate Vice President for Medical Affairs (CCO/AVPMA), and program functions are provided 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. In 2011, additional changes were made to align 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 (NWH) and Valley Medical Center (VMC).

In fiscal year 2011, the annual compliance budget was \$8 million and 60 FTEs were dedicated specifically to compliance functions (excluding VMC). These figures do not represent the full cost of time, effort and systems devoted to compliance 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 the success of the compliance programs. 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. A central hotline in the office of the CCO/AVPMA enables anonymous reporting of concerns.

In 2011, six compliance areas were the subject of comprehensive presentations to the UW Medicine Board Compliance Committee (UWMB CC). The presentations included general information about the regulatory framework (primary areas of scrutiny and recent developments) as well as UW Medicine-specific information about each area (program structure, accountabilities, audit workplans and results, educational efforts, complaints, repayments if applicable, and process improvements).

The largest compliance program for UW Medicine covers clinical billing. The program is based on rigorous internal audit activities that provide the foundation for identifying and mitigating clinical billing risks, and system-wide mandatory training that educates workforce members about billing rules. In 2011, there was significant external review activity associated with the national Medicare Recovery Audit Contractor Program. Senior leaders are apprised weekly of system-wide activity, including new requests, repayments and appeals. To date, external reviews have been conducted on 2,115 claims, representing approximately \$26 million in reimbursement; 251 claims representing \$724,000 have been repaid. In addition, 112 claims totaling approximately \$648,000 were

identified as underpayments to UW Medicine. The impact of this national program on staffing resources is significant and will require on-going assessment.

UW Medicine followed its response to the complex implantable device issues identified in 2010 with significant process improvements and education in 2011. Another facility billing area receiving both national and institutional attention was the medical necessity of hospital inpatient admissions. Efforts to improve internal processes and understanding of the rules commenced in 2011, and will continue in the next reporting period.

Clinical research billing is a nationally recognized focus area for academic health centers, and UW Medicine's work in this area has been recognized as a model for peer institutions. Audit results show a very low error rate (2.3%), but continue to provide critical information for on-going system and process improvements.

Information security represents another compliance risk receiving national attention. In 2011, UW Medicine dedicated its efforts to reworking its program structure, improving customer support, and enhancing education, outreach and collaboration. Information security management and planning involves continued coordination of efforts by UW Medicine Compliance and UW Medicine Information Technology (IT). Current work includes firewall improvements for workstations and expanded vulnerability management.

UW Medicine operates a mature **privacy and identity theft prevention** program, which includes mandatory orientation and job-specific education, audits of electronic patient records to verify that workforce accesses are appropriate, internal processes for ensuring patient rights, and timely management of complaints. All cases under investigation by the Office for Civil Rights in 2011 were closed without penalties or fines. New developments and changes in the regulatory environment are the focus of current internal planning and preparation. UW Medicine also developed and adopted a new policy and guidelines governing the use of social media.

The 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 (AKS)**, 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 2011, and directed its efforts toward standardizing the physician contracting process. There were no significant changes to the AKS in 2011.

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. Planning for implementation of the new rules is being led by the UW Provost with significant involvement by the School of Medicine. The current UW Medicine COI policy has been in place for two years, and is now being re-evaluated to determine if changes should be made in light of national developments.

Section III of the report provides detailed information about the major activities and issues occurring in 2011.

I. INTRODUCTION

A. Purpose of the Annual Report

Section 1.4.3 of the UW Medicine Board Bylaws requires an annual report to the University of Washington (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 (NWH)
- University of Washington Medical Center (UWMC)²
- Valley Medical Center (VMC)
- UW Neighborhood Clinics (UWNC)
- UW Physicians (UWP)
- UW School of Medicine (UW SoM)
- AirLift Northwest (ALNW)³

UW Medicine is also a corporate 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 SoM faculty physicians who are members of UWP or CUMG. UW SoM faculty physicians provide clinical service at SCH primarily through CUMG. UW 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.

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.

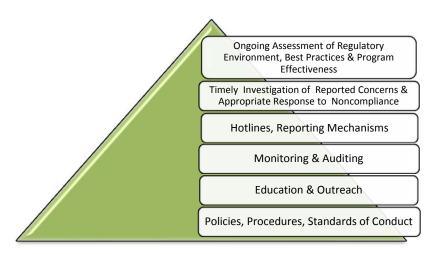
² The governance authority for hospital accreditation, operations, and quality of patient care at UWMC is vested in the UW Medicine Board. The UW Board of Regents retains authority for some financial matters and capital plant expansion at UWMC.

³ In July 2010, ALNW was dissolved as a 501(c)3 corporation, became a part of UW, and became a fully owned and operated entity of UW Medicine. All personnel of ALNW are UW or Seattle Children's employees.

II. UW MEDICINE COMPLIANCE PROGRAM

A. Program Components

All UW Medicine compliance programs include these core components:



In 2010, KPMG conducted a high-level review of the UW Medicine Compliance Program, excluding the practice plans and SoM. The report issued on March 30, 2011 confirmed that the program demonstrates the eight elements typically found in effective compliance programs, and the manner in which UW Medicine evidences its program activities is a leading practice.

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, 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 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** (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 and the charter for this committee are provided in *Attachments A and B*.

Dr. Paul G. 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 since the first compliance report to the Board of Regents in 2007 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 CCO/AVPMA. The UW Medicine compliance enterprise (see *Attachment C*) includes UW Medicine Compliance (responsible for all facility-related compliance except VMC), VMC Compliance, SoM Compliance (responsible for compliance issues involving SoM faculty, trainees, and staff), and the UWP and CUMG compliance programs (responsible for professional fee billing compliance in the practice plans).

1. Organizational Changes in 2011

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. Efforts in 2009–10 focused on centralizing oversight of facility-related compliance programs; in 2011, the Privacy/Identity Theft Prevention Program was centralized under the UW Medicine Compliance Officer (CO), who reports directly to the CCO/AVPMA. This change aligns the mission, vision, strategic planning, operating philosophy, policy structure, and education/outreach programs for all 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. The new structure also simplifies the interfaces between compliance officers for the practice plans, the facilities, and the SoM.

Integration of NWH compliance functions focused on bringing NWH billing claims into the UW Medicine system used for managing external review requests, and amending NWH privacy policies to conform to UW Medicine policies. Phase III of the integration process began in July, and will culminate in 2012 with UW Medicine Compliance assuming responsibility for oversight of the NWH compliance program. Early work has focused on billing compliance auditing, monitoring, and reporting. The compliance officer, the chief executive officer, and the chief operating officer for NWH are members of UW Medicine compliance committees and make semi-annual reports to the UW Medicine Board Compliance Committee.

The CCO/AVPMA led a team responsible for assessing compliance issues in the due diligence process preceding the strategic alliance with VMC that became effective on July 1, 2011. In August 2011, UW Medicine Compliance and VMC initiated discussions regarding integration, and are in the process of establishing a workplan, priorities, and timeline. VMC leaders and the compliance officer have been added to UW Medicine compliance committees, and will begin reporting compliance program activities in 2012.

2. Compliance Resources

As noted in previous reports, UW Medicine devotes significant resources to both organization-wide and entity-specific compliance efforts. In fiscal year 2011, the annual budget was \$8 million and there were 60 FTEs dedicated specifically to compliance functions (excluding VMC). This exceeds 2010 figures by \$1.4 million and 10 FTEs, but the increase is the result of including the information security program and NWH resources this year. Total funding and FTEs have remained relatively stable since 2007.

These figures do not represent the full cost of time, effort, and systems devoted to compliance-related 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 Program budget.

At the time of this report, there are 6.9 vacancies in funded compliance positions across LJW Medicine.

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 2011, NWH's hotline was merged into a central hotline maintained by the CCO/AVPMA. This line provides for anonymous reporting of compliance concerns. In 2012, this hotline will be the focus of an active marketing campaign to include the hospitals and clinics, ALNW, UWP and the SoM. In addition, each UW Medicine entity maintains a compliance helpline to answer compliance guestions.

III. KEY COMPLIANCE AREAS

The key compliance focus areas identified for 2011 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 in 2011 (see *Attachment E*), a content expert presented the following information on one of the focus areas:

- Relevant background (rules, agency involvement, general risks, consequences of noncompliance) and 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
 Education & Outreach
 Policy and Procedures
 Auditing & Monitoring

Reporting Mechanisms/ComplaintProcessReporting

Assessment

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

Focus area presentations are contained in the official committee records.

The following sections highlight major activities and developments that occurred in 2011, emphasizing regulatory changes, risk assessment and mitigation, education, and program improvements.

A. Clinical Billing

External Reviews. 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 audit programs established to identify billing errors and abusive or fraudulent billing practices. In 2011, external reviews were conducted on 2,115 claims (UWP, NWH, UWMC, HMC) representing approximately \$26 million in reimbursement. These audits, as well as those pending from 2010, resulted in the repayment of 251 claims for approximately \$724,000. UW Medicine successfully disputed 148 claim error findings totaling approximately \$149,000. There are 135 claims still in dispute representing \$614,000. In addition, 112 claims totaling approximately \$648,000 were identified as underpayments to UW Medicine. There have been no findings or repayments caused by missing records or missed deadlines, a testament to the diligent efforts of the response teams. The program will include Medicaid billing in 2012 and we expect to be impacted by this expansion with increasing numbers of audits. We are assessing our resources and work flows accordingly.

UW Medicine continues to reap the benefits of the external review software implemented in 2010, which facilitates robust tracking of audits and results, and provides the data needed for proactive assessment of risk areas and for summary reporting. UW Medicine leadership is informed about ongoing external review activities through a detailed weekly report, and the topic is a standing agenda item for UWMB CC meetings.

In other external reviews, HMC received notice of an OIG audit covering Medicare outpatient drug claims that met specific criteria (including the likelihood of billing errors) between April, 2008, and February, 2011. In spite of the nearly three-year timeframe, just 42 claims were selected, only two claims contained errors, and the total repayment was less than \$4,600.

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 two of these audits; one was closed following a report of no errors for UW Medicine claims; the other is still in progress.

Facility Billing. UW Medicine Compliance developed and executed its 2011 clinical billing audit plan using current Federal healthcare program oversight activity and Office of Inspector General (OIG) Work Plan focus areas to inform decisions and to help prioritize audit topics. Newly incorporated into the annual plan were audits to be completed in coordination with other compliance offices in the system. The Compliance Officers Group continued its work to establish system-wide audit processes/procedures, and this year developed standard audit report formats.

Following high dollar claim repayments for devices and related services in 2010, UW Medicine continued its focus on complex coverage and billing rules for special categories of implantable devices, including humanitarian and investigational devices. After improving processes and developing web-based resource materials, we implemented a training and communication campaign to provide staff and physicians with the information they need to maintain compliance with the rules.

Another high-priority facility billing focus in 2011 was medical necessity of hospital inpatient admissions. Medicare is currently the primary driver of this issue through its RAC program, denying payment for inpatient stays in cases where it believes that the patient could have been safely cared

for in a less intensive and thus less costly outpatient setting. UW Medicine is using this information to prioritize both compliance and operational activities in order to minimize risk.

Some services are paid by Medicare only when the patient has a particular condition or disease. UWMC discovered a problem that led to billing and payment for nutrition therapy in non-covered situations, and repaid \$89,000.

Professional Fee Billing. Since the conclusion of the Corporate Integrity Agreement (CIA) with the federal government⁵ in 2009, UWP and CUMG have operated separate but closely coordinated compliance programs. Policies and standards are aligned where appropriate, but 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 2011 included the following:

- CUMG completed all scheduled policy reviews/updates; trained every CUMG practitioner (through on-line modules and 37 live training sessions); and provided training and review to 63 new CUMG members.
- CUMG performed 414 practitioner audits, and responded to 8 internal inquiries with investigations and risk assessments.
- UWP conducted proactive risk assessments and completed scheduled risk-based audits on 97% of the physicians identified for review (496 physicians), second reviews on 79 physicians, prebilling reviews on all 75 practitioners new to UWP, and UWP professional fee coders (42).
- UWP achieved 100% completion of the mandatory training (including 1643 physician and nonphysician members and 258 UWP administrative employees). UWP increased the number of online modules to 46, and developed new specialty-specific modules.

B. Clinical Research Billing

Clinical research billing compliance is a nationally recognized risk area for academic health centers. UW Medicine's work in this area – including clear policies and procedures, mandatory training, and on-going audits - assures compliance with the complicated rules and continues to serve as a model for peer institutions.

Over the last year, UW Medicine evaluated and revised the committee structure that supports clinical research billing. A reorganized committee has been charged with continuous assessment and strengthening of operational processes, policies, tools and training to assure that the most efficient and effective systems are in place for clinical research billing.

The Clinical Research Billing Audit Program was established to determine compliance with UW Medicine policies and to verify that clinical services provided to research subjects are correctly billed. Studies are selected for audit according to pre-established risk criteria. Since inception of the program in 2007, 133 audits have been completed and only 2.3% of all charges reviewed were found to be incorrectly charged to patient accounts (a key metric.) This is a very low error rate and an excellent outcome.

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⁵ UWP and CUMG were the subject of federal criminal and civil investigations into allegations of fraudulent Medicare billing from 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.

Despite the low billing error rate, audit results continue to highlight areas for improvement in various processes, including development of accurate and complete study billing plans and charge capture transactions for drugs and certain procedures. Compliance will continue to monitor audit results to ensure that the refined processes are effective.

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

Information Security. ISP supports UW Medicine's mission while proactively assessing and managing information security risks in partnership with executive leadership. In 2011, the ISP completed a comprehensive review and revision of its policies, resulting in the development of three policies that establish the baseline requirements and standards for electronic data, computing devices and systems, and workforce members. These policies are slated for adoption in early 2012. The ISP refined its priorities to include a stronger commitment to customer support and services, and enhanced its education, outreach and collaboration efforts. Highlights of these efforts are included below.

Fducation/Outreach/Collaboration:

- served as a resource for UW and UW Medicine committees by providing input for project intake, architecture, identity and access management, and change control
- increased focus on service, with a stronger emphasis on communication, education, and topic-specific guidance
- created a problem solving partnership with UW IT services, departmental project teams, SoM IT staff, and faculty and staff throughout UW Medicine
- enhanced collaboration with the UW Chief Information Security Officer (CISO), and served on the UW Privacy and System Security (PASS) Council
- participated in the development of more clearly defined incident response procedures, established a weekly incident response conference call to review active issues, and expanded participation to reflect a more inclusive membership
- conducted security education and awareness activities for 80 system owners, who received job-specific training
- provided basic awareness training as part of new employee orientation (NEO) to 1440 new hospital staff members (NEO was expanded in 2011 to include physicians)
- NEO materials were shared with the SoM for use in its orientation process, and as a result system owner training is now available to all components of UW Medicine
- in collaboration with SoM IT, held brown bag sessions on mobile device encryption
- provided training to all help desks and front line responders to ensure that that calls related to mobile device encryption are handled in a consistent manner
- collaborated with the UW Medicine Privacy Program, SoM, and the CISO on incident response activities, completing more than sixteen forensics investigations

The ISP provides a central infrastructure for system firewall management; current work is focused on improving the workstation firewall solution. The ISP team expanded its Vulnerability Management Program to include departments and individual users and provide for both self-assessments and system assessments to proactively identify and remediate potential vulnerabilities. The ISP uses the same tools to identify vulnerabilities on Internet-facing systems.

In July 2011, a Security Information and Event Management (SIEM) system was implemented to collect system and enterprise security data. The SIEM has increased visibility into systems managed by the ISP and has identified several firewall misconfigurations. As additional sources of data are integrated into the SIEM, it is expected the tool will be able to correlate security events across UW Medicine, allowing for quicker and more efficient responses to potential security incidents.

Privacy/ Identity Theft Prevention. 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. Strategies for reminding workforce members of this material include annual refresher training and periodic system-wide awareness emails that provide practical guidance. Electronic patient records are routinely audited to verify that workforce accesses are appropriate. The program investigates complaints from patients and workforce members, issues findings, and works with entities to remediate operational gaps or systemic issues uncovered during investigations. Managers and program directors are responsible for pursuing appropriate disciplinary and corrective action. UW Medicine also operates an active program to deal with potential identity theft cases through its Patient Identification and Clarification Committees.

In 2011, the Office of Civil Rights (OCR) notified UW Medicine of several patient privacy complaints. We conducted thorough internal investigations and worked cooperatively with the agency. Each case was closed with satisfactory resolution and no penalties or fines. UW Medicine implemented several policy and operational improvements, and engaged in a system-wide, top-down awareness campaign to convey lessons learned from the cases.

The Department of Health and Human Services issued a notice of proposed rulemaking governing accounting of disclosures. The proposal discontinues the accounting of disclosures for research purposes, but requires that patients be provided a report of all electronic accesses to their patient information upon request. If finalized, the provision will require significant operational retooling in UW Medicine, and we are closely monitoring this development.

Federal law requires every provider who does business electronically to use the same transactions, code sets, and identifiers. CMS-issued upgrades to the current electronic transaction formats required operational changes to meet the January 2012 effective date. UW Medicine is also preparing for implementation of a new coding nomenclature system (ICD-10) in October 2013.

During this reporting period, Airlift Northwest, Summit Cardiology and Valley Medical Center were added to the UW Medicine covered entity designation for HIPAA purposes.

UW Medicine published a new policy and guidelines to address the growing use of social media by faculty, staff and students, and conducted education and outreach sessions throughout the system.

D. 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 the Stark Law in the past year, but a new self-disclosure protocol was established that provides for potential reductions in penalties when violations are voluntarily disclosed. UW Medicine did not detect or report any Stark violations in 2011. 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 have all unpaid faculty physicians sign standardized documentation identifying 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 health care program, or for purchasing an item or service (or recommending for purchase) that is reimbursable under federal health care 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.

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

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 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 the University. They also impose a training obligation on the University, require more University reporting to NIH, and require public accessibility to the information disclosed by researchers and the University's response to those disclosures. The new rules will take effect no later than August 2012. Compliance with the new rules, including review and revision of the UW Significant Financial Interest Policy and the development and implementation of training, will be managed by the UW Provost with significant participation from the SoM.

This was the second year 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. A key provision of this policy is that SoM faculty must disclose in advance the amount of compensation to be received for outside work.

The committee that developed the policy will conduct an in-depth review to consider whether any changes should be made in light of changes in the national landscape, particularly those involving faculty participation on vendor speaker bureaus, and the recent NIH rule revisions.

ATTACHMENT A

UW Medicine Board Compliance Committee: Fiscal Year 2011 Roster

Voting Members

Rich Jones - Board Member and Committee Chair

- 0
- President and CEO of the Washington Society of Certified Public Accountants Former member of the Board of the Fred Hutchinson Cancer Research Center; founding member and past Chair of the Board of SCCA 0
- Past officer and member of the Board of the Pacific Science Center 0
 - Retired Partner of Ernst & Young LLP

Jim Anderson – Board Member

0

- Chairman of Health Resources Northwest/Northwest Hospital (HRN/NWH) 0
- Serves as Chair of HRN/NWH Information Systems & Committee and Finance Committee
- Former Chairman of Strategic Planning Committee for the Board of Directors for Northwest Healthcare Insurance Services and Washington Casualty Company 0
 - Former Chairman of Budget Committee of the Board of Overseers of Whitman College. 0 0
- County Economic Development Council, and the Corporate Council for the Arts and Reality Based Learning. Former Board of Director of Pacific First Financial Corporation, Multicare Health System, Tacoma/Pierce

Shan Mullin, Board Member and Board Chair

- Former chair of the Fred Hutchinson Cancer Research Center and the SCCA boards, chair of the Norman Archibald Charitable Foundation board 0
- Board member of the Greater Seattle Chamber of Commerce; and Board member/Secretary of the SCCA Partner in the Seattle office of Perkins Coie law firm; Distinguished Alumni Award from UW Law School 2004 0

Julie Nordstrom - Board Member

- UW alumnus and former board member of Seattle Children's Home and Childhaven, volunteer at Seattle Children's 0
- Former associate, Stafford, Frey, Cooper and Stewart, and law clerk for Justice James Dolliver of the Washington Supreme Court 0

Bruce Pym - Community Member

- President and CEO of Elliott Cove Capital Management
- 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 0
 - 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
 - **UW alumnus**

Odell Guyton - Community Member

- Compliance Director for Microsoft; former Assistant U. S. Attorney; former Corporate Compliance Officer, University of Pennsylvania 0
 - Volunteer advisor for the UC System Regents and the Audit Committee on Compliance matters 0
 - Former member of the Board of Trustees, Moravian College 0

Dan Dubitzky - Community Member

- Lead counsel for the UW in its response to the now-completed Medicare fraud investigation 0
- of the Criminal Law Committee of the Federal Bar Association, and a lawyer's representative from the Federal Former board member of the Northwest Defender Association and the Tom Wales Foundation, previous Chair Bar Association to the Ninth Circuit Judicial Conference. 0
 - While in private practice, represented several Fortune 500 companies and corporate officers with clients from health care, fisheries, aerospace, architecture and timber 0

Non-Voting Members

UW Medicine

Paul Ramsey, MD - Chief Executive Officer, (UW Medicine), EVPMA (UW), Dean

Johnese Spisso – Chief Health System Officer (UW Medicine), VPMA (UW) Ruth Mahan - Chief Business Officer (UW Medicine) VPMA (UW)

Lori Oliver - Director of Legal & Business Matters (UW Medicine), AVPMA (UW) Sue Clausen – Chief Compliance Officer (UW Medicine), AVPMA (UW)

Lori Mitchell – Financial Operations Officer, UW Medicine

Lisa Westlund - Compliance Officer, UW Medicine Liz Shirley – Controller (UW Medicine), AVPMA (UW)

School of Medicine

Mark Green – Associate Dean for Business, SoM Noella Rawlings - Compliance Director, SoM

Dina Yunker - Assistant Attorney General (UW) Attorney General's Office

Practice Plans

Catherine Boelke - Executive Director, UWP Carlos Cruz - Compliance Officer, UWP Dr. Mika Sinanan - President, UWP

Education & Billing Compliance Committee, CUMG Dr. Mark Del Beccaro - Chair, Physician Billing, Sheryl Forrester - Compliance Officer, CUMG Rick Nielsen - Executive Director, CUMG

Margaret Peyton - General Counsel, UWP/CUMG

Meg Kerrigan - Executive Director, UW Neighborhood Clinics Bill Schneider - Chief Executive Officer, Northwest Hospital Cynthia Coronel – Compliance Officer, Northwest Hospital Stephen Zieniewicz - Executive Director, UWMC Eileen Whalen - Executive Director, HMC

Hospitals/Clinics

Rich Roodman - Chief Executive Officer, Valley Medical Center Christine Martin – Executive Director, Airlift Northwest

Colleen Nelson - Corporate Compliance & Privacy Officer, Valley Medical Center David Smith – General Counsel, Valley Medical Center Phuong Dao - Integrity Officer, SCCA

UW Medicine Board Annual Compliance Report: February 2012 $F\!-\!8.1/202\!-\!12$

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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 entities 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

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¹ Component entities include Harborview Medical Center (HMC), UW Medical Center (UWMC), Northwest Hospital (NWH), UW School of Medicine (UWSOM), Airlift Northwest (ALNW), UW Neighborhood Clinics (UWNC), and UW Physicians (UWP). 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 UW Medicine Chief Compliance Officer 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 President and the CEO/EVPMA/Dean.

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

- At least three Board members, including the Chairperson of the Board
- 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 (CHSO/VPMA);
- Chief Business Officer, UW Medicine/Vice President for Medical Affairs, University of Washington (CBO/VPMA);
- Chief Compliance Officer, UW Medicine/Associate Vice President for Medical Affairs, University of Washington (CCO/AVPMA);
- · Health System Financial Operations Officer for UW Medicine;
- Executive Directors of HMC, UWMC, ALNW, UWNC, UWP and CUMG;

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- Presidents of NWH, UWP and CUMG;
- Associate Dean for Business, School of Medicine;
- Director of Legal and Business Matters, UW Medicine/Associate Vice President for Medical Affairs, University of Washington;
- UWP/CUMG Legal Counsel;
- A UW Medicine Assistant Attorney General;
- Compliance officers for HMC, UWMC, NWH, UWP, CUMG, SCCA, UWSOM;
- Director of the UW Medicine Privacy and Identification Theft Prevention Program;
 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.

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 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

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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

Data

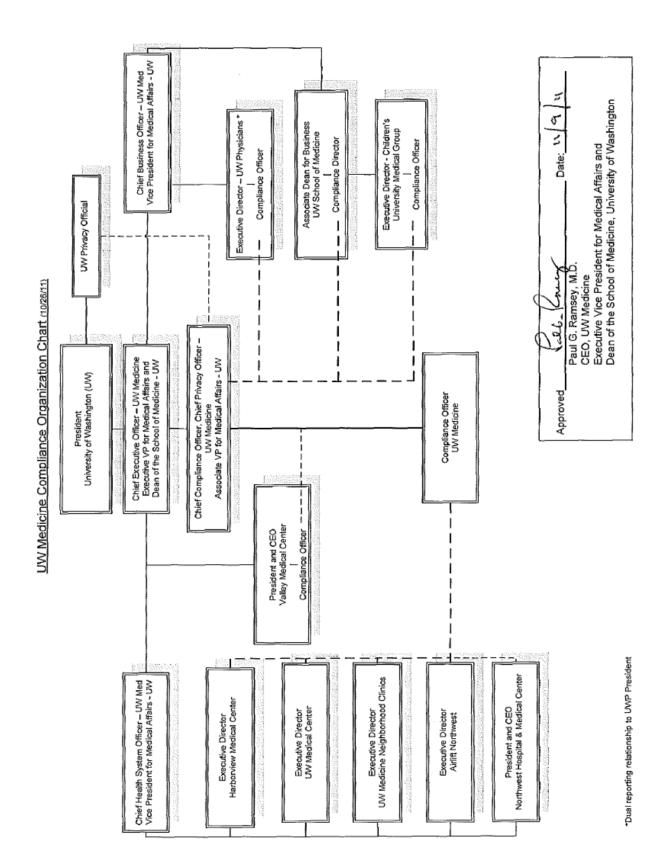
Approved by the UW Medicine Board

Chair of the UW Medicine Board

Date

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ATTACHMENT C



UW Medicine Board Annual Compliance Report: February 2012

ATTACHMENT D

UW Medicine Compliance Issues Channels of Communication

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 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 include community members, the UW Medicine Board Chair, and other UW Medicine Board members. Non-voting members include senior executive leaders and entity compliance officers. See Attachment A for the full roster.
UWP Business Excellence Committee, chaired by Thomas Payne, 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.
UW Medicine 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 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.	Members include the COO/AVPMA; executive directors and senior officers from the hospitals, clinics and ALNW; administrative directors from key operational units; the UW Medicine 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 Medicine compliance officers/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, and research compliance; and compliance officers from affiliates including Seattle Children's Hospital, Fred Hutch and SCCA.
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, ALNW), Financial Officers, SoM Assoc. Deans for Admin/Finance & Business Affairs, UW Medicine Chief of Staff/AVPMA, Director of Business & Legal Matters/AVPMA, Director of News & Community Relations/AVPMA
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, and 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 cinical health system entities (HMC, UWMC, NWH, VMC, UW Neighborhood Clinics, UWP, and ALNW) and other UW Medicine leadership
Security Program Executive Committee (SPEC), chaired by Johnese Spisso, CHSO/VPMA	SPEC provides executive direction for the UW Medicine Info Security Program, reviews and endorses security policies, strategic plans, annual budget requests and risk assessments.	Members include UW Medicine 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 E

UW Medicine Board Compliance Committee - Schedule 2011

Meeting Date	Focus Areas/Special Briefings	Focus Area	Reports
3	J. J	Presenter(s)	
January 10 9:30-11:30 am	Focus Area – External Review Office of Civil Rights Information Security Preview 2010 Annual Compliance Report	Lisa Westlund	Briefings
February 14 9:30-11:30 am	Focus Area – Information Technology Security • Office of Civil Rights • 2010 Annual Compliance Report Final	Johnese Spisso, Jim Fine, David Chou, Paul Henderson	Briefings Distribute FY 11 Qtr 1 & 2 reports
March	No meeting		
April 11 9:30-11:30 am	Focus Area – Clinical Billing Office Of Civil Rights External Review Activity 2010 Annual Compliance Report UWMB CC Charter	Lisa Westlund	Briefings
May	No meeting		
June 6 9:30-11:30 am	Focus Area – Clinical Trials Billing • External Review Activity • KPMG Review • Social Networking Policy	Lori Oliver	Briefings
July	No meeting		
August	No meeting		Distribute FY 11 Qtr 3 & 4 reports
September 12 9:30-11:30 am	Focus Area – Privacy/ID Theft Prevention Compliance Issue Management External Review Update Changes in Federal COI Rules	Sue Clausen, Richard Meeks	Briefings
October	No meeting		
November 14 9:30-11:30 am	Focus Area – Conflicts of Interest • External Review Update • 2012 Annual Compliance Report Timeline	Mark Green	Briefings
December	No meeting		