UW MEDICINE BOARD

ANNUAL COMPLIANCE REPORT TO THE UW BOARD OF REGENTS

FEBRUARY 2007

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BACKGROUND

UW Medicine Structure ¹

UW Medicine represents the institutional collaboration of several legally separate, but closely affiliated entities. The UW Medicine entities include the UW School of Medicine and two non-profit corporations, the University of Washington Physicians (UWP) and the University of Washington Physician Network (UWPN). UW Medicine is also a founding member of two other non-profit corporations: Childrens University Medical Group (CUMG) and the Seattle Cancer Care Alliance (SCCA). UW Medicine has a contractual relationship with Children's Hospital and Regional Medical Center to provide faculty physicians for the hospital through CUMG.

UW Medicine also includes the University of Washington Medical Center (UWMC) and Harborview Medical Center (HMC). 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. Harborview Medical Center (HMC) is owned by King County and governed by a Board of Trustees appointed by King County. Pursuant to a contract between King County, the Board of Trustees and the University Board of Regents, UW Medicine provides operational management of HMC and provides physician services through UWP. All personnel at HMC, including faculty physicians, are employed by the University of Washington. UW Medicine also has faculty physicians employed at the area Veterans Administration hospitals, which are part of the Veterans Administration, a Federal agency.

A key element tying all of these entities together and to UW Medicine is that they are all staffed by UW Medicine faculty physicians and must meet UW Medicine standards for quality patient care, teaching, research and compliance. UW Medicine is a complex organization with an overall mission focused on improving health by its teaching, research and patient care activities.

Corporate Integrity Agreement

Between August 1999 and April 2004, UW Medicine's faculty practice plans (UWP and CUMG) were the subject of Federal criminal and civil investigations into allegations of fraudulent billing of the Medicare program. The investigation was 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. In April 2004, the civil investigation resulted in a \$35 million settlement and a negotiated Corporate Integrity Agreement (CIA) between the Federal government and the practice plans. The CIA establishes minimum standards for the billing compliance programs for each practice plan, and it provides for the imposition of monetary penalties for any violations of its terms.

¹ Some information in this section was taken from the UW Medicine Board Review Committee report "Achieving Excellence in Compliance" issued July 20, 2005

UW Medicine Board Review Committee

In August 2004, the UW Medicine Board, in response to a request from Dean Paul Ramsey and with the endorsement of the UW Board of Regents and President Mark Emmert, announced the formation of a special independent Review Committee. Its goal was to ascertain the "lessons learned" from the billing investigation, determine the adequacy of UW Medicine's Compliance Programs, and make appropriate findings and recommendations.

Between September 2004 and June 2005, the Review Committee undertook an extensive review of documents, conducted interviews, and received briefings to gather information in furtherance of its mission. The Review Committee also commissioned a major consultant report on national best practices in compliance at leading academic medical centers. On June 20, 2005, the Review Committee issued its final Report, entitled "Achieving Excellence in Compliance." The report and supporting appendices are available on the UW Medicine Compliance website (http://www.uwmedicine.org/Global/Compliance/).

On October 18, 2005, Dr. Ramsey responded to the Review Committee with his plans for implementing key recommendations contained in the Report and issued an implementation plan that is being used as the basis for monitoring programmatic and structural changes for UW Medicine compliance (http://www.uwmedicine.org/Global/Compliance/Finalplan.htm).

OVERVIEW AND EXECUTIVE SUMMARY

Purpose of the Annual Report

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

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

Executive Summary

UW Medicine has been actively engaged in enhancing its compliance programs since early 2000. Since the 2004 settlement and negotiation of a CIA with the Federal government and the issuance of the UW Medicine Board Review Committee's report in 2005, UW Medicine has continued to refine, reassess and improve its compliance programs.

Today, UW Medicine devotes approximately 42 FTE and nearly \$4.5 million annually to the support of compliance-specific functions. The organizational structure of compliance at UW Medicine establishes entity-specific accountability. System-wide oversight and coordination occurs through the Associate Vice President for Compliance (AVPC) and is enhanced by

activities of the UW Medicine Board Compliance Committee (UWMB-CC). Additional committees within UW Medicine provide mechanisms for engaging administrative, clinical and operational leaders in compliance initiatives. UW Medicine recognizes the importance of establishing compliance roles and responsibilities, and it is engaged in activities to convey those expectations.

Senior executives, academic/clinical leaders and operational administrators at UW Medicine review compliance issues on a regular basis, identify solutions, minimize barriers, and provide personal support of compliance initiatives.

As do all academic health centers, UW Medicine faces compliance issues in the following areas: clinical billing, information security, faculty effort certification, privacy, and research compliance. These issues have received significant attention in UW Medicine and will continue to be the focus of process improvement projects, expanded education and outreach efforts, enhanced auditing, and continued status reports.

UW MEDICINE COMPLIANCE STRUCTURE AND ORGANIZATION

Evolution of Compliance Programs at UW Medicine

UW Medicine has been actively engaged in enhancing its compliance programs since early 2000. As noted in the UW Medicine Board Review Committee's July 2005 report, "This has included the investment of significant resources, hiring and training new Compliance staff and auditors, revising billing compliance plans and related documents, naming Chief Compliance Officers for each entity, retaining expert consultants to review and assist in refining the compliance process, and other important initiatives."

One of the key recommendations emanating from the July 2005 report was the need for an executive level compliance officer. In September 2005, Dr. Paul Ramsey announced the appointment of Sue Clausen as UW Medicine's first Associate Vice President for Compliance (AVPC) (http://www.uwmedicine.org/Global/Compliance/AVPletter.htm), charging her with responsibility for leadership of UW Medicine's compliance systems and initiatives.

UW Medicine Compliance Infrastructure and Reporting Relationships

The organizational structure of compliance programs in UW Medicine is based on entity-specific accountability. Each entity within UW Medicine has a compliance officer who reports to the senior executive. For example, the compliance officer for the University of Washington Medical Center reports to the Executive Director of UWMC. Each entity compliance officer also has a dotted line relationship to the AVPC. The AVPC reports directly to the CEO of UW Medicine and has a dotted line reporting relationship to the UW President.

² A detailed description of UW Medicine's initiatives up to May 2005 may be found in the UW Medicine Board Review Committee's report "Achieving Excellence in Compliance" in Appendix 5: "Developments in UW Medicine Compliance Program: 1999 – Present" and Appendix 6 (report prepared in May 2005 by UW Medicine at the Committee's request that reviews compliance developments and provides information on funding and personnel). See http://www.uwmedicine.org/Global/Compliance/Appendices.htm

Currently, there are approximately 42 FTEs specifically assigned to UW Medicine compliance functions. The total annual budget for the combined offices is approximately \$4.5 million, including \$3.5 million in salaries and \$1.1 million in supplies/operations/equipment.

UW Medicine Board Compliance Committee (UWMB-CC)

The UWMB-CC was established in 2001 by Dr. Paul Ramsey, then Vice President for Medical Affairs. Although not vested with governance responsibilities, the Committee has a wide scope of advisory responsibilities pertaining to the following areas:

- Strategic planning, program development, organizational structure and resource allocation associated with UW Medicine compliance efforts;
- The role of present and future UW Medicine compliance programs;
- Advocacy and support for UW Medicine compliance efforts;
- Risk assessment; and,
- Analysis of urgent, emergent and on-going compliance issues.

The Committee is currently chaired by Shan Mullin, a member of the UW Medicine Board, and staffed by Sue Clausen, AVPC. Voting members of the Committee include four additional UW Medicine Board members, including the Board Chair and the CEO of UW Medicine, and up to three additional members designated jointly by the UWMB-CC chair and the CEO. The following non-voting individuals also attend Committee meetings on a regular basis:

- Executive Directors of CUMG, HMC, UWMC, UWP and UWPN
- UWP President
- Vice President for Medical Affairs/CFO
- Associate Vice President for Medical Affairs Administration
- School of Medicine Vice Dean for Administration and Finance
- UWP Legal Counsel
- Assistant Attorney General
- Compliance officers for HMC, SCCA, SOM, UWMC, UWP/CUMG and UW Medicine HIPAA

Compliance officers present quarterly and annual reports to the UWMB-CC in addition to updates about the status of their programs, resolution of issues, and information about urgent and emerging issues at each UWMB-CC meeting. The Committee meets at least every other month or more often as necessary. The Committee Charter, current roster and current fiscal year meeting calendar are provided as attachments to this report.

Additional Compliance Committees

Compliance committees serve a valuable purpose in decentralized organizations. They provide a mechanism for engaging administrative, academic and clinical leaders in the analysis and problem-solving process. These venues also enable entities to focus on the regulatory requirements that are specific to each enterprise, which in turn allows for more informed decision making and risk assessment. At UW Medicine, each practice plan and medical center has its own compliance committee. While the specific committee charges vary, all have some level of oversight and/or advisory responsibility. Practice plan committees include the SOM Compliance Director and physicians who work closely with UWP/CUMG compliance and operations staff to evaluate the need for policy clarification, education and implementation

planning for new requirements. Medical center compliance committees include senior administrative and operational leaders, who work closely with compliance staff to identify urgent and emergent issues, monitor progress toward resolution of compliance issues, and communicate requirements to entity staff.

The AVPC also convenes compliance officers from the primary entities (UWMC, HMC, UWP, CUMG, UWPN, SCCA) as well as those from such areas as the General Clinical Research Center, Pharmacy, Laboratory, Hall Health, Patient Financial Services, School of Dentistry and UW Research Compliance. The bi-monthly meetings are used to identify proactively changes in the regulatory environment, assess risks and mitigation strategies, work collaboratively on mutual concerns, identify system-wide needs, and coordinate the handling of urgent/emergent issues that involve multiple entities.

Although not a compliance committee per se, the UW Medicine Finance and Operations Committee includes compliance as a standing agenda item. Convened weekly for two hours by Dr. Ramsey, this group includes the AVPC; the AVPMA/Executive Director of Health Sciences Administration; the VPMA/CFO; Vice Deans for Administration/Finance and Clinical Affairs; Executive Directors and Chief Operating Officers of the medical centers, UWPN and UWP; the School of Medicine CFO; and the Director of UW Medicine News and Community Relations. This group evaluates UW Medicine-wide compliance issues, helps develop and implement system-wide responses to urgent and emergent issues, and oversees the dissemination of new or modified standards and operational safeguards as needed.

The AVPC is a member of the UW Medicine Clinical Management Committee (CMC), a group convened by Dr. Ramsey, in which compliance issues are discussed frequently. The CMC provides an effective venue for disseminating new or modified policies, receiving feedback about the compliance culture, identifying best practices for operationalizing compliance requirements, and identifying risks.

The AVPC also sits on the UW Compliance Committee and serves on its Executive Council. Comprised of UW officials with compliance oversight responsibilities throughout the campus, the Council identifies system-wide risks and mitigation strategies.

UW Medicine Compliance Roles and Responsibilities

A successful compliance program requires clearly defined roles and responsibilities. In the past year, significant effort has made been to identify and communicate the following accountabilities:

- All UW Medicine faculty, staff and trainees are individually responsible for understanding and adhering to UW
 Medicine's policies and procedures, participating in required training, fulfilling recordkeeping requirements,
 reporting compliance concerns, seeking clarification when questions arise, and responding in a timely manner to
 requests for information associated with internal audits or investigations.
- Persons in executive leadership positions are accountable for the successful implementation and sustenance of
 compliance and related operational programs within their specific areas of oversight, and are responsible for
 participating in the development and implementation of UW Medicine-wide systems.

- Persons in management or supervisory positions have additional responsibilities, including communication of
 compliance and operational expectations, ensuring that appropriate training is taken, implementing and
 enforcing policies, and monitoring compliance.
- The Associate Vice President for Compliance (AVPC) develops UW Medicine-wide policies, establishes roles
 and responsibilities, regularly convenes UW Medicine compliance officers to discuss and process shared
 concerns, identifies effective education and outreach strategies, evaluates the effectiveness of auditing and
 monitoring efforts, and coordinates the investigation and resolution of alleged noncompliance.
- Compliance officers at the medical centers, School of Medicine and practice plans monitor developments in the
 regulatory environment, establish entity-specific policies and standards, work closely with operational
 departments to develop procedural safeguards, receive and investigate allegations of noncompliance, develop
 and implement effective auditing programs, and participate in the development and delivery of compliance
 training.

PROCESS FOR MANAGING COMPLIANCE ISSUES

UW Medicine's entities establish annual plans that address known and predicted compliance issues. The activities are planned, deliverables are identified, responsible parties are named, and the plan is monitored for progress.

Responding to urgent and emergent compliance issues in complex organizations requires effective communication. As a result, UW Medicine is engaged in efforts to standardize its process for analyzing issues, engaging accountable parties in the identification and implementation of suitable responses, and providing information to appropriate groups and officials. A more formal process will be finalized during the next year. In the meantime, the following overview describes the general practice in use today:

- Compliance issues are identified in multiple ways, including compliance officer assessments, regulatory changes, cases of noncompliance, internal audits and external reviews, feedback from training sessions, current events and court cases, questions from compliance committee members, etc.
- Compliance officers review these issues with appropriate parties, including legal counsel and external regulatory resources, to assess risk, identify response strategies, and prioritize next steps.
- The committee structures identified previously in this document serve as a venue for raising the issue, finalizing action plans, securing resources as needed, identifying barriers, and reporting progress.
- Often, process improvement projects are generated in response to urgent or emergent compliance issues. UW Medicine has engaged in more than five major projects of this type in the last two years. These projects continue to be the subject of regular updates to the appropriate committees until the project is completed.

UW Medicine's practice ensures that senior executives, academic/clinical leaders and operational administrators are aware of compliance issues and engaged actively in identifying solutions, minimizing barriers, and providing personal support, as appropriate, for compliance initiatives.

SUMMARY OF MAJOR COMPLIANCE ISSUES AND ACTIVITIES

Although each activity in which UW Medicine engages has a compliance or regulatory interface, several areas represent more significant risk and are the subject of enhanced attention.

Professional Fee and Facility Billing

Both medical centers have undergone external reviews of their compliance programs within the last two years. Both programs contain the required elements of an effective compliance program as defined by the US Federal Sentencing Guidelines. Both medical centers recognize the need to expand their auditing and monitoring functions.

The practice plans are entering the third year of their five-year CIA with the Federal government. In each year, the baseline requirements for the CIA have been satisfied completely within the timelines established by the Health and Human Services Office of the Inspector General (OIG). These requirements include annual mandatory training and auditing. A recent site visit from the OIG resulted in a favorable review. Although the CIA requires timely reports to the OIG about any material deficiencies (including substantial overpayments or potential violations of laws governing certain Federal health care programs), the plans have also disclosed non-reportable issues and events, sought guidance about courses of action, and informed the OIG about the status of various activities. This transparency has contributed to a positive relationship between the OIG and the practice plans.

Coders are obtaining certification at both the practice plans and medical centers, and audit results are being used to establish training priorities, identify the need for policy clarifications, and determine repayments in a timely, proactive manner. Repayments and disclosures have been made by both the practice plans and the medical centers, which is an expected and desirable outcome of effective compliance programs. Repayments most frequently occur as a result of routine reconciliations or in response to policy changes. Substantial overpayments are reported to the OIG within timelines established in the CIA; all other repayments are summarized in the CIA annual status report.

Clinical Research Billing

This area has been the focus of many academic health centers since passage of the National Coverage Decision in 2000 which allows certain costs of some clinical research studies to be paid by Medicare. Preliminary work in this area at UW Medicine commenced in 2001. Taskforces were established to identify how best to implement the NCD and prevent billing errors, a Director of Clinical Research Compliance was hired in 2004, and a new office charged with establishing budgets and ensuring appropriate billing was established in 2005. Current work involves creation of hospital-based safeguards and processes for registering subjects, researcher-based requirements for reconciling study charges, development of new internal tools and just-in-time resources, assignment of a medical director to help researchers make coverage decisions, education and outreach, and evaluation of new technology solutions for the charge-capture process.

A special session in August 2006 provided UWMB-CC and UW Medicine Board members with a comprehensive review of the issues, challenges and progress to date in August 2006.

Information Security

UW Medicine shares the same challenges as the UW in this arena. In response to security breaches in early 2006, UW Medicine made changes in its user access systems and is in the process of developing a new strategic plan for information security. As with most compliance areas, current activities focus on the need to modify business practices, create procedural safeguards, enhance technologies, and finance operational improvements.

Effort Certification

The University continued work throughout the year toward refinement and clarification of effort certification policies and procedures. The School of Medicine worked closely with UW officials in the Office of Sponsored Programs, sponsored numerous training sessions, and convened work groups that focused on resolving School of Medicine-specific questions and concerns. Work in this area will continue as national policy is refined, internal operational challenges are addressed, and technology solutions are developed.

HIPAA Privacy

The nature of work at UW Medicine will always keep privacy and confidentiality issues as one of the top five compliance concerns. UW Medicine's privacy program is well defined, but inadvertent distribution of personal health information can and does occur. Compliance staff are focusing their efforts on improving auditing and monitoring mechanisms, and on helping operational units identify and implement necessary changes to business practices.

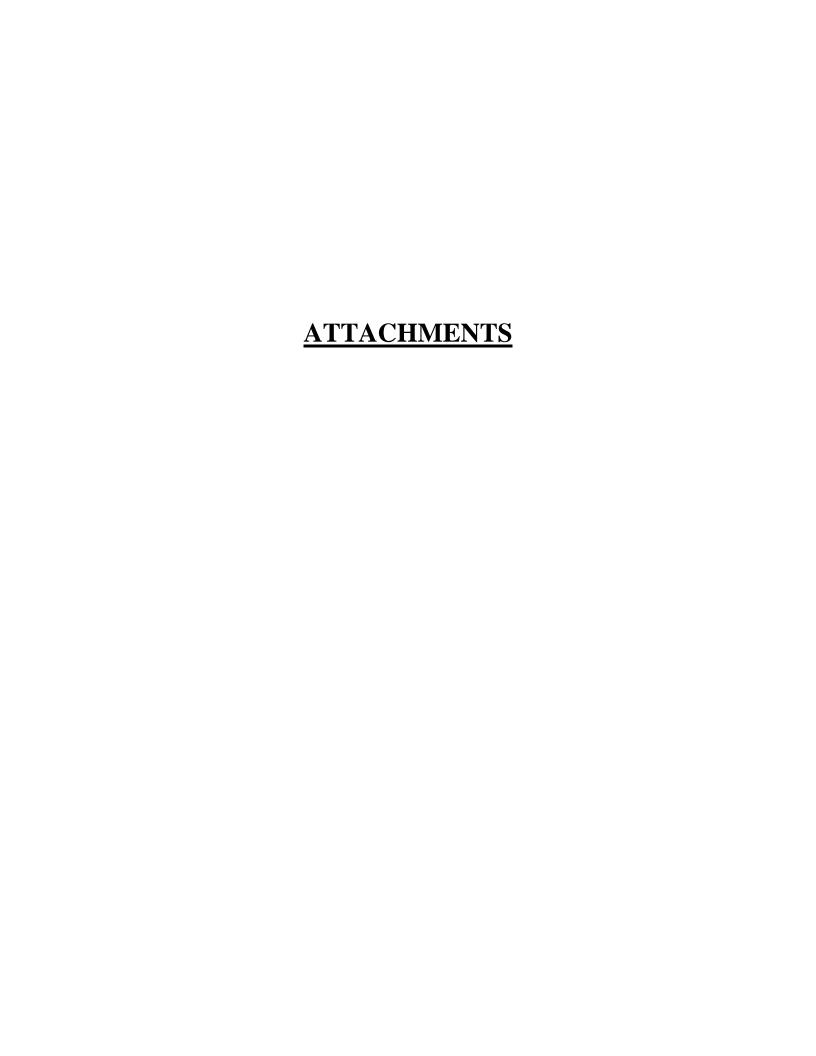
Research Compliance

This category includes such a wide range of issues that it will always be a high priority for UW Medicine compliance. Since responsibility for compliance program development is not directly under UW Medicine control, issues involving human subjects protection, animal care and use, biosafety, radiation safety, environmental safety, grant accounting and reporting, export controls, and conflicts of interest are handled in collaboration with health science officials and UW central offices.

LOOKING FORWARD: PRIORITIES FOR 2007

- Transition the AVPC's current responsibilities for School of Medicine compliance to a separate School of Medicine Compliance Director.
- Building on existing plans established by the practice plans and medical centers, develop a comprehensive UW Medicine compliance plan and risk assessment process.
- Evaluate existing education and outreach programs to improve coordination and delivery, minimize duplication of effort across the entities, enhance curricula, improve access to justin-time tools and resources, and focus on user needs.

- Evaluate existing auditing and monitoring mechanisms to determine where more rigorous programs are needed, to identify resource needs, and to modify organizational accountabilities where needed.
- Maintain the effectiveness of existing programs while continuing to enhance compliance efforts through process improvement projects, collaboration with UW Medicine operational units, and coordination with UW central compliance offices.



UW MEDICINE BOARD UW MEDICINE COMPLIANCE COMMITTEE CHARTER

Revised January 2007

COMMITTEE FUNCTION

The UW Medicine Compliance Committee, hereinafter referred to as the "Committee", is advisory to the Chief Executive Officer of UW Medicine (CEO). There are no governance responsibilities vested in the Committee. The Committee's scope of advisory responsibility pertains to the following areas:

- Strategic planning, program development, organizational structure and resource allocation associated with UW Medicine compliance efforts;
- The role of present and future UW Medicine compliance programs;
- Advocacy and support for UW Medicine compliance efforts;
- Risk assessment; and,
- Analysis of urgent, emergent and on-going compliance issues.

Through its reports to the UW Medicine Board, the Committee provides essential input that supports the Board's advisory and reporting responsibilities to the UW President and Board of Regents.

COMMITTEE MEMBERSHIP & MEETING FREQUENCY

The Committee is chaired by a member of the UW Medicine Board and staffed by the Associate Vice President for UW Medicine Compliance. Voting members of the Committee include:

- Four additional UW Medicine Board members, including the Chair of the UW Medicine Board or designee and the Vice President for Medical Affairs; and
- Up to three additional members designated jointly by the committee chair and the VPMA.

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

- The Executive Directors of CUMG, HMC, UWMC, UWPN and UWP;
- The UWP President:
- The Associate Vice Presidents for Medical Affairs:
- The School of Medicine Vice Dean for Administration and Finance;
- The UWP Legal Counsel;
- A UW Medicine Assistant Attorney General; and,

 The compliance officers for HMC, SCCA, SOM, UWMC, UWP/CUMG and UW Medicine HIPAA.

The Committee meets at least every other month or more often as necessary.

MEETING CONTENT

Five key elements form the basis for the Committee's advisory activities. These include:

- Monthly and quarterly compliance updates from UW Medicine Compliance Officers;
- Quarterly updates on the status of the UWP/CUMG Corporate Integrity Agreement with the federal government;
- The annual UW Medicine risk assessment process;
- The annual report to the UW Board of Regents; and
- The UW Medicine compliance plan (which includes recommendations from the UW Medicine Board Review Committee) and semiannual report.

These regular activities are supplemented with:

- In-service sessions to educate and inform the committee about compliance developments at the university, local, regional and national levels; and
- In-depth discussions about urgent and emergent compliance issues facing UW Medicine.

Through review and discussion of these reports and topics, the Committee provides policy guidance to, and maintains general oversight of the strategic direction of compliance programs at UW Medicine.

MEETING CALENDAR

The meeting calendar (attached) is built around the key elements. Material referenced in the calendar is provided to Committee members one week in advance of the relevant meeting.



UW MEDICINE BOARD

COMPLIANCE COMMITTEE

Fiscal Year 2006-2007 Membership

Members

Stanley Barer Norr

Dan Dubitzky

Gerald Grinstein

Rich Jones

Shan Mullin (Chair)

Paul Ramsey

Orin Smith

Non-Voting Members

Norm Beauchamp

Lisa Brandenburg

John Coulter

Sue Clausen

Rick Deese

Bruce Ferguson

Teresa Gamble

Julie Hamilton

David Jaffe

Ruth Mahan

Richard Meeks

Rick Nielsen

Lori Oliver

Margaret Peyton

Larry Robinson

F. Bruder Stapleton

Lisa Westlund

Jacqueline Zehner

UW Medicine Board Compliance Committee FY 2007 Agenda Calendar

July 2006	August 2006	September 2006*	October 2006	November 2006*	December 2006
UPDATES - CIA - Review Committee Rec's: Workplan - CO Updates	SPECIAL MEETING: CLINICAL RESEARCH BILLING COMPLIANCE	UPDATES - CIA	UPDATES - CIA - Review Committee Rec's: UWP By-laws - Clin Res Billing NEW ITEMS UWP Mgmt Transition 1.5 hrs	UPDATES - CIA - Clin Res Billing: Retreat, Policy Changes, new manual - UWP Mgmt Transition - CO Updates - Review Comm Rec's SCHEDULED REPORTS Quarterly CO Reports NEW ITEMS EH&S Issues	NO MEETING
1.5 hrs	7.1	2 hrs	11 2005	2 hrs	T 20054
January 2007* UPDATES - CIA - Review Committee Rec's - Clin Res Billing - UWP Mgmt Transition - Dental Billing - CO Updates NEW ITEMS - Annual Report to UW BOR - New Professionalism Committee 2 hrs.	February 2007 UPDATES - CIA - Review Committee Rec's - Clin Res Billing - UWP Mgmt Transition - CO Updates SCHEDULED REPORTS - Quarterly CO Reports - Annual Report to UW BOR NEW ITEMS UW Enterprise Risk Management Project: Elizabeth Cherry 2 hrs.	March 2007 NO MEETING (Board Retreat)	April 2007* UPDATES - CIA - Review Committee Rec's - Clin Res Billing - UWP Mgmt Transition - CO Updates - Information Security NEW ITEMS - Industry Relationships - Stark Educational Session	May 2007 UPDATES CIA Review Committee Rec's Clin Res Billing UWP Mgmt Transition CO Updates SCHEDULED REPORTS Quarterly CO Reports NEW ITEMS Human Research Protection Program: Jeff Cheek 2 hrs	UPDATES CIA Review Committee Rec's Clin Res Billing UWP Mgmt Transition CO Updates Professionalism Committee NEW ITEMS 2 hrs.

^{*} Meetings of the Full Board

Compliance Committees_Meetings\UW Med Board Compliance Cmte\Support Materials\Calendars and Timelines\UWMBCC FY07 Agenda Calendar rev. 1_30_07.doc