UNIVERSITY OF CALIFORNIA
HEALTH SCIENCES CORPORATE COMPLIANCE
ANNUAL REPORT TO THE BOARD OF REGENTS
July 1, 2002 – June 30, 2003

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SECTION A
PURPOSE: THE ANNUAL REPORT PROCESS

The purpose of the Health Sciences Corporate Compliance Annual Report (Report) Process is to:

1. Meet the requirements of the University’s Health Sciences Clinical Enterprise Corporate Compliance Program (Compliance Program) that:
   a. Each Campus Corporate Compliance Committee provide an annual report to its respective Chancellor and to the Office of the President; and
   b. The Systemwide Compliance Committee use this information as the basis for a system Annual Report to the Board of Regents;
2. Demonstrate ongoing commitment to promoting and enhancing compliance at all levels of the University’s health sciences clinical enterprise; and
3. Provide a mechanism for the Board of Regents to review and oversee the University’s Compliance Program.

SECTION B

In the spring of 1996, the Office of the Inspector General (OIG), Department of Health and Human Services (DHHS), notified the University’s academic medical centers of the OIG’s intent to conduct a review of the Medicare billing practices of the University’s physicians to determine whether Medicare reimbursements for physician services provided to Medicare beneficiaries were reasonable, allowable and documented in accordance with Medicare regulations. This nationwide initiative by DHHS/OIG to audit physician professional fee billings at teaching institutions became known as the Physicians at Teaching Hospitals (PATH) Audit.

Systemwide Compliance Committee Established in 1996. In preparation for these federal initiatives, the leadership of the University’s five academic health centers (AHCs) and the Board of Regents, in consultation with the Office of the General Counsel, established the University-wide Corporate Compliance Committee (Systemwide Compliance Committee), and charged the Systemwide
Compliance Committee with responsibility for providing a University-wide coordinated effort to respond to the federal auditors and to DHHS/OIG.

Currently, the Systemwide Compliance Committee includes Office of the President representatives: John Lundberg, University of California Deputy General Counsel, Patrick Reed, University Auditor, and Dr. Maria Faer, HIPAA Privacy Officer and Director of Health Sciences Corporate Compliance. Campus Compliance Officers include: Dr. Jeremiah Tilles and Jim Herron, UC Irvine (UCI); Harry Cordon, UC San Francisco (UCSF); Dr. Rory Jaffe, UC Davis (UCD); Dr. Charles Mittman, UCSD; and Dr. Michael McCoy, UC Los Angeles (UCLA). Dr. Faer serves as Chair of the Committee. Attachment A includes a full list of all members of the Systemwide Compliance Committee and the HIPAA Privacy Liaisons as of July 1, 2003.

**Systemwide Compliance Committee Charge.** Since 1996, the charge from the Board of Regents to the Systemwide Compliance Committee has been to:

1. Provide a forum for discussion and analysis of ongoing issues related to achieving compliance with new federal and state regulations;
2. Develop standards for achieving financial, legal and ethical compliance; and
3. Establish guidelines for determining when it is necessary to take appropriate action and report simple overpayments, systemic financial problems and material deficiencies.

**Compliance Program Objectives.** To meet this responsibility, the Systemwide Compliance Committee and local Compliance Committees have established, along with the executive management team at each campus, the following Compliance Program’s objectives:

1. Maintain and enhance quality of care;
2. Demonstrate sincere, ongoing efforts to comply with all applicable laws;
3. Revise and clarify current policies and procedures in order to enhance compliance;
4. Enhance communications with governmental entities with respect to compliance activities;
5. Empower all responsible parties to prevent, detect, respond to, report and resolve conduct that does not conform to applicable laws, regulations and the University’s Code of Conduct;
6. Provide compliance education;
7. Respond to employees’ questions and concerns;
8. Act on recommendations from staff and management;
9. Provide for controls to prevent and reduce errors and identify wrongdoing;
10. Work with campus academic and administrative leadership to implement remedial actions and take appropriate corrective and disciplinary actions; and
11. Cause reports of possible compliance wrongdoing by administration, faculty or staff to be investigated in accordance with University policy.

**Systemwide Compliance Committee Initiatives.** To implement these objectives, the Systemwide Committee has provided compliance leadership in the following areas:

1. Developed a systemwide response to the DHHS/OIG PATH Audit (1996 – 2001), including system policy, audit and technical support to the University’s legal team and development of the strategic response to the OIG’s proposed Institutional Compliance Agreement. The Compliance Committee’s efforts contributed to the University’s successful resolution of the PATH Audit in February 2001 without litigation, double or treble damages, an OIG imposed
Institutional Compliance Agreement or any suggestion of fraud and abuse on the part of the University’s physicians;
2. Developed the University’s Professional Fee Billing Guidelines (September 1997) in response to new regulations established by the federal government to guide the Medicare billing practices of teaching physicians;
3. Developed the Corporate Compliance Code of Conduct (August 2000) in response to the Department of Health and Human Services/Office of the Inspector General’s Compliance Program Guidelines for Hospitals that strongly encouraged all corporations in the health care industry to implement effective corporate compliance programs; and
4. Developed the HIPAA Privacy Rule Systemwide Standards and Implementation Policies (April 2003) to provide for the University’s compliance with the organizational and administrative requirements regarding the privacy and security of an individual’s protected health information.

The University Health Sciences Clinical Enterprise Code of Conduct Standards currently include:

1. Quality of Care
2. Medical Necessity
3. Coding, Billing and Patient Accounts
4. Cost Reports
5. Personal and Confidential Information
6. Creation and Retention of Patient and Institutional Records
7. Government Investigation Policy
8. Preventing Improper Referrals or Kickbacks
9. Adherence to Antitrust Regulations
10. Avoiding Conflicts of Interests
11. Patient’s Freedom of Choice
12. External Relations
13. Fair Treatment of Employees.

Section C of this report reviews the elements of the campus Compliance Programs. Section D provides recommendations for the Systemwide Compliance Committee FY 2004 activities. Section F summarizes the University’s HIPAA Privacy Rule compliance activities.

For Fiscal Year 2003, the Systemwide Compliance Committee and campus Compliance Committees continued their efforts on the following initiatives:

1. Professional Fee Billing Compliance Program;
2. Hospital Compliance Program;
3. Clinical Laboratory Compliance and sharing of best practices;
4. Clinical Research Compliance and sharing of best practices;
5. Sharing of Compliance Best Practices;
6. Home Health/Hospice Compliance;
7. Health Plan Compliance;
8. Dentistry Compliance; and
9. Willed Body Program (policy review and development).
SECTION C
SYSTEMWIDE COMPLIANCE COMMITTEE REVIEW OF FY 2003 CAMPUS REPORTS

The Systemwide Compliance Committee recommended that, at a minimum, each campus Compliance Committee would include the following review elements in the campus FY 2003 Annual Report, which was submitted in September 2003. As a part of the review, each member of the Systemwide Compliance Committee assessed whether those elements were adequately addressed by the annual report in order to provide assurance that local efforts were appropriate.

FY 2003 Annual Report Elements

1. Description of the Compliance Organization and Reporting Structure, including the scope of compliance program activities, risk assessment process, annual planning process and FY 2004 workplan;
2. Summary of any significant updates to the Compliance policies and procedures;
3. Description of training conducted during the reporting period;
4. Narrative summary of the calls to the compliance hot or help lines and the action taken to resolve any compliance issues;
5. Narrative summary of enforcement and discipline activities, including individuals identified on the federal “exclusion list” and a description of any action taken;
6. Summary of any external reviews conducted by outside governmental agencies;
7. Other compliance activities, initiatives or potential risk areas for consideration by the Systemwide Compliance Committee; and
8. The Compliance Officer’s Certification to the campus Chancellor and Senior Vice President Mullinix of the Annual Report contents.

Review Summary: The campus Compliance Committee’s Annual Reports demonstrate that all campuses have implemented compliance programs that include all of the OIG’s recommended elements of an effective compliance program although the method of addressing these elements may vary by campus due to differences in clinical enterprise activities (e.g., not all campuses have home health programs), allocation of resources (e.g., one campus may allocate more resources to training of new providers while another may provide additional training for coders), and risks identified through the local risk analysis process. Variability and flexibility in local programs are acceptable and appropriate, so long as each campus can demonstrate that the process achieves the required outcomes. For example, Compliance Committee membership varies, but all campus Compliance Committees include a depth and breadth of expertise and leadership. Local flexibility also provides for the development of shared best practices that enhances the strength and viability of the overall compliance program and for the identification of issues that need to be addressed by all campuses. For example, three campuses currently have developed Clinical Research Compliance programs and, as a result of these local efforts, the Systemwide Compliance Committee has identified clinical research compliance as the priority initiative for the current fiscal year. The Systemwide Compliance Committee has also concluded that the overall compliance program has now reached a point of development (since 2000 when the University’s Code of Conduct was distributed) that would warrant the development and implementation of certain minimum compliance or audit review standards to guide local decision making, provide for comparability and further reduce risks.
The following sections summarize the review of the compliance elements of the campus compliance programs.

Compliance Element: Organization and Scope of the Compliance Committee and Compliance Program Workplan

All campus Compliance Programs have well-established organizational structures with the Compliance Officer reporting directly to the executive leadership. All Compliance Committees include members from other divisions or departments within the organization in order to provide a cross-division, integrated approach to compliance. Likewise, the Compliance Officer and/or Compliance Manager participate on a number of leadership and decision-making committees within the organization. The campuses include within the scope of their activities Hospital System or Facility Compliance, Professional Fee Billing Compliance, Laboratory Services Compliance and HIPAA Privacy Rule Compliance. Health systems with specialized activities (e.g., home health, dentistry school), may integrate these in their scope of effort.

At each campus, the Compliance Committee reviews and approves the annual compliance workplan that has been developed through a process that, at a minimum, considers the following risk assessment factors: consultations with management personnel; results from Hot Line or Help Line inquiries; published Office of the Inspector General initiatives; benchmarking with published standards; corrective action plans associated with prior reviews; issues identified through the ongoing claims review process; physician profiling results; risk assessment survey tools; and potential problems discussed at System Compliance Meetings.

The scope of workplan issues identified by the Annual Reports include (note: these are not listed in order of priority or risk):

1. Ongoing hospital billing activities, including Medicare cost outliers, one-day stays, documentation and coding review program and policy;
2. Pharmacy compliance;
3. Willed Body Program compliance;
4. Outpatient coding and charge entry;
5. Non-physician provider services;
6. Clinical laboratory compliance, and, specifically, training on medical necessity and coding;
7. Clinical research activities, and, specifically, clinical trial research billing;
8. New billing vendors and new coders; and
9. School of Medicine physician contracts.

At the Office of the President, the Director of Corporate Compliance also reports to the executive leadership of the University, Senior Vice President of Business and Finance, with the responsibility to report at least on an annual basis to the Board of Regents regarding the activities of the campus and system Compliance Committees and to chair all activities of the Systemwide Compliance Committee. Currently, within the Office of the President there is informal communication by the Director of Corporate Compliance as needed with other divisions, and the University Auditor and Deputy General Counsel serve as members of the Systemwide Compliance Committee. Although there is currently no Office of the President Compliance Committee that mirrors the cross-divisional activities of the campuses, the cross-campus collaborative effort of the HIPAA Taskforce provides a
cost-effective model for achieving compliance with broad-reaching, complex and sometimes confusing regulations.

As a part of its overall assessment of issues that could pose a risk to all campuses, the Systemwide Compliance Committee also reviews the OIG Workplan, campus Annual Reports, and recommendations brought to the Systemwide Compliance Committee. The Systemwide Compliance Committee has identified a number of recommendations that that should be addressed by the Systemwide Compliance Committee in its FY 2004 Workplan.

Compliance Element: Compliance Program Code of Conduct, Policies and Procedures

All campuses review, update and amend existing policies as necessary to respond to the dynamic regulatory and compliance environment. For example, some local compliance policies include the addition of a Clinical Research Compliance Policy. All campuses developed local HIPAA Privacy Rule policies and revised existing policies to respond to the requirements of the Privacy Rule. The Systemwide HIPAA Taskforce, a part of the overall systemwide compliance activities, developed a 100-page document entitled *University of California Systemwide HIPAA Standards and Implementation Policies* that has been used by all HIPAA-covered entities in the development of local policies and procedures. This document is currently under review by the Academic Senate and modification by the Taskforce to provide additional guidance in response to operational issues identified by members of the Taskforce since the compliance date of April 2003.

Compliance Element: Training Program

The Compliance Programs include active training and retraining activities, but the training objectives and target audience may vary by campus in order to respond to local needs and provide program flexibility. For example, some campuses may target new employees while another may provide additional training for departmental managers. All campuses emphasize coding staff training to improve coding knowledge and expertise and provide training sessions for residents on the basics of good documentation. A number of the Compliance Officer or Managers hold national certifications in health care compliance; Compliance Managers and Specialists at several campuses have credentials as professional coders. Educational methodologies vary by campus, and all campuses have developed tools for facilitating training and documentation. For example, several campuses have developed specialty-specific templates for documentation training and designed pocketsize laminated cards as documentation aides.

All campuses allocated resources in FY 2003 to provide workforce training as required by the HIPAA Privacy Rule. The systemwide HIPAA Taskforce assisted in those training activities by developing training modules in a number of areas, including: HIPAA 101, Provider, Research, External Relations, Health Plans/HR, and Data Steward.

All campuses have shared their HIPAA training materials with teaching affiliates as a way of achieving common practices among providers and academic programs.

Compliance Element: Confidential Communication Mechanisms and Awareness Process

All campus Compliance Program have established several communication avenues, including at a minimum, a confidential compliance line for reporting alleged erroneous or fraudulent conduct, and
all Compliance Programs include procedures for either responding to those reports or redirecting the caller to another division within the organization (e.g., human resources). The Compliance Officers and staff have developed a clear “open door” policy. Over the last year, the campuses reported an increase in direct communications or notifications to the Compliance Office or members of the compliance team. All campuses have established some type of “help line” that enables employees to seek help in carrying out their billing, coding or documentation activities and newsletters or other periodic health system communications to update employees on compliance issues.

**Compliance Element: Compliance Reviews and Audit Activities**

All campus Professional Fee Billing and Hospital Compliance Programs include routine reviews, targeted reviews based on potential risk areas (e.g., new provider reviews) and focused reviews that address specific elements of documentation and/or billing that appear to present compliance issues requiring more intense audit and investigation. Again, issues identified in the OIG Workplan or by a Compliance Committee member may also initiate a specific review. The objective of all audits and reviews is to evaluate compliance with carrier guidelines; the adequacy of medical record documentation; the appropriateness of codes; and compliance with University policies and procedures. Issues targeted for review and the methodology for carrying out those reviews vary significantly by campus.

In order to enhance consistency and assess the rigor of the program, the Systemwide Compliance Committee identified a working group (Compliance Director Faer, University Auditor Reed, Deputy General Counsel Lundberg, UCD Compliance Officer Jaffe, and UCSF Compliance Officer Cordon) to develop a draft minimum audit and compliance standard for review by the Compliance Committee.

Several campuses have expanded the reviews to include issues other than professional fee or hospital billing and claims. These campuses have implemented research billing and clinical lab reviews that provide examples of best practices.

**Compliance Element: Corrective, Enforcement and Discipline Activities, Investigations, Exclusion of Individuals Identified on the Federal “Exclusion List”**

An effective compliance program must also include clearly articulated and fairly implemented consequences when individuals fail to comply with the University’s standards, policies and procedures. At all campuses, the Compliance Committee works within existing University policy to determine the action that should be taken for corrective, disciplinary or enforcement purposes. Employment actions are at the discretion of the employee’s manager. To date, remediation has consisted primarily of additional training of individuals and/or departments, but actions taken in response to problems may also include development and dissemination of new policies, clarification of regulations and policies through a variety of communication strategies, modification to systems, repayment of overpayment or reporting of systemic problems, and direct disciplinary action of employees up to and including dismissal.

Each campus has implemented a process for carrying out investigations or expanded reviews of compliance issues that have been identified through a variety of sources, including the confidential communication line, direct contacts to the Compliance Office, meetings, educational programs, complaints, physicians’ profiles and departmental reviews. In anticipation of the April 14, 2003 implementation date for the HIPAA Privacy Rule, Compliance and HIPAA Privacy Officers
implemented a proactive strategy to respond to privacy or security breaches where protected health information was inappropriately accessed. The University’s HIPAA basic training module emphasizes that under no circumstances should health information be accessed unless it is required or permitted by law or directly authorized by the individual.

Major External Audits

Campus compliance programs help coordinate external audits by payers and health plans of billing, utilization review, clinical quality improvement, credentialing, and graduate training program functions. Upon the conclusion of external audits, the Compliance Office works with the auditing entity to evaluate, address and resolve issues identified and to repay any overpayments and carryout corrective actions to prevent future occurrences.

SECTION D
RECOMMENDATIONS

1. Evaluating Compliance Effectiveness: Effort and Outcome. Since the mid 1990’s, regulatory enforcement officials, compliance officers and committees, and the executive leadership of organizations that have compliance programs have struggled with how to evaluate the effectiveness of a compliance program and the organization’s compliance efforts. “Due to the relative infancy of such programs, there is scant data of measurable and objective criteria on which to build an evaluation process,” 1 The Health Care Compliance Association recommends that effort and outcome are two dimensions of compliance. Measurement of outcomes include: improved coding and documentation; decline in claim denial rates; fewer instances where employees do not receive the required training; improved risk assessment tools; and, prompt action by the organization when errors do occur.2

Bringing about change in an academic health center environment requires a collegial process; the system and campus Corporate Compliance Committees continue to enhance compliance by building on campus and individual expertise; developing local and system standards and guidelines; and sharing best-practices. The University’s campus Compliance Offices and Committees have expended considerable time and resources on compliance, with the most notable being the personal and professional effort of the compliance teams at each of the campuses.

Recommendation: Overall, the annual reports demonstrate positive outcomes on those identified measures, but the Systemwide Compliance Committee should implement more consistent reporting criteria to provide for the identification and development of effectiveness measures.

2. Minimum Audit and Compliance Monitoring Standard. All campus Compliance Committees have established a regular schedule for auditing divisions and departments but monitoring criteria and the reporting of those reviews vary by campus.

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Recommendation: The Systemwide Compliance Committee should develop a minimum audit or compliance standard(s) for the review and documentation of compliance audits or reviews. In the development of that standard, the Systemwide Compliance Committee should consider a number of factors, including appropriate criteria for: 1) determining who should be notified in the event there are major, significant or adverse findings; 2) developing written correction plans; 3) assessing whether Compliance Offices are appropriately staffed, trained, have access to those records necessary to conduct the work and sufficiently independent of the units monitored; and 4) identifying sufficient data to conduct trend analyses that would assess improvement in the organization’s understanding of and compliance with program requirements.

3. Corrective and Remedial Actions. All Campus Code of Conducts clearly state the individual’s responsibility to comply, and they provide a discussion of policies and procedures in place for enforcement and discipline. A challenge in implementing remedial or corrective procedures is the differing ability to impose remedial and corrective actions on staff and faculty and on tenured faculty and clinical faculty and the variability in applying these standards.

Recommendation: The Systemwide Compliance Committee should develop recommendations for presentation to the Chair of the Academic Council so that the University can continue to develop strategies for addressing this issue.

4. Initiatives Identified for Review and Consideration by the Systemwide Compliance Committee: Clinical Research Compliance, Laboratory Compliance, Willed Body Program Policies. In reviewing the campus compliance workplans and initiatives currently implemented or under consideration by the campuses, the Systemwide Compliance Committee has identified clinical research compliance, clinical laboratory compliance, and the willed body program policies as compliance activities that should be assessed by the Systemwide Compliance Committee for possible action by all campuses and the system in order to enhance overall compliance with federal and state regulations and reduce risks to the University.

Recommendation: For FY 2004, The Systemwide Compliance Committee, in consultation with other units with the Office of the President and campus leadership regarding the appropriate level of compliance program responsibility, should amend the systemwide Code of Conduct to include a Clinical Research Compliance Standard. The Committee should also review the campus Laboratory Compliance Programs and local policies to determine if a Laboratory Compliance Standard should be included in the systemwide Code of Conduct. The Committee should review Willed Body Program policies currently under revision at some campuses to determine if it is appropriate to recommend a set of systemwide guidelines.

SECTION E
UNIVERSITY INTERNAL AUDIT ROLE

The University’s Internal Audit Program has played a role in the assessment of the overall Corporate Compliance Program. Under a coordinated program, each Health Sciences Campus Internal Audit Department has conducted a review of the structure, scope and implementation of the Campus
Professional Fee Compliance Program and reviewed the Annual Report to the Office of the President. Each Health Science Campus Internal Audit Department has provided a report to the Office of the University Auditor based on their review. The Office of the University Auditor has reviewed the Campus Internal Audit Department Reports, and the Health Sciences Clinical Enterprise Corporate Compliance Annual campus report, and issued a report to the Senior Vice President of Business and Finance (Attachment B). Each campus’s and University Auditor’s reports conclude that the Corporate Compliance Program is being carried out in accordance with the University’s approved program and federal guidelines where applicable.

SECTION F
HIPAA PRIVACY RULE HIGHLIGHTS

In November 2000 the Systemwide Compliance Committee recommended that the Systemwide Compliance Committee take a lead role in developing and implementing a work-plan and strategy for providing compliance with the privacy and security regulations mandated by the Health Insurance Portability and Accountability Act of 1996: The Privacy Rule (HIPAA Privacy Rule). In response, the Medical Center CEOs and School of Medicine Deans appointed individuals from each of their academic health centers to the University’s HIPAA Taskforce (HIPAA Taskforce) and charged the group with developing a work-plan(s) for achieving campus and system compliance prior to the HIPAA Privacy Rule effective date of April 2003.

Membership has grown from approximately 20 members to over 100 persons from all ten University of California campuses, the Office of the President and the Federal Department of Energy Labs, because it was soon determined that the scope and applicability of HIPAA goes well beyond the academic health centers to cover other University functions, including: the Student Health Centers at all nine campuses, some Athletic Departments, Federal Department of Energy Labs onsite clinics, and the University’s self-funded health plans.

In May 2002, the Board of Regents, at the recommendation of the HIPAA Taskforce, designated all HIPAA-covered entities within the University’s “hybrid-covered entity” as a “Single Health Care Component (SHCC)” in order to:

1. Reduce costs of compliance by standardizing the University’s approach and creating, where appropriate, a single set of policies, procedures and practices and sharing of resources;
2. Reduce the University’s business and audit risks by providing consistency of approach, shared best practices and uniform application of the “reasonable and appropriate” principles for HIPAA compliance;
3. Enhance compliance by demonstrating commitment and leadership across the organization and providing support at all levels for the cultural change necessary to manage privacy and security; and
4. Minimize disruption to the care, research and teaching missions of the University and build patient confidence and loyalty.

From May 2002 through the end of the Fiscal Year 2003, the System Corporate Compliance Committee/HIPAA Taskforce, in close consultation with their counterparts at the campuses, guided the development and implementation of the mandated administrative and organizational requirements of the HIPAA Privacy Rule. In May 2003, Senior Vice President Joseph Mullinix and HIPAA Privacy Officer Maria Faer reported to the Board of Regents that the University’s HIPAA Taskforce
and SHCC had met the administrative and organizational requirements of the Privacy Rule, and due to the efforts of the HIPAA Taskforce, had significantly reduced the University’s costs of compliance.

The HIPAA Taskforce continues to meet on a regular basis to respond to ongoing operational and compliance issues that have arisen since April 14, 2003, the compliance date and to provide guidance and share best practices. The HIPAA Security Rule goes into effect April 2005, and the academic health center CIOs, in consultation with the Office of Business and Finance/Information Resources and Communication, have recommended that the HIPAA Taskforce take a leadership role in developing a workplan for the Security Rule modeled on the systemwide process for the Privacy Rule. The process is underway as of October 2003.

One of the more unexpected, ongoing outcomes of the HIPAA compliance activities has been the number of HIPAA and state law research compliance questions that have arisen regarding the use and disclosure of patient information for research activities. The HIPAA Taskforce, in consultation with the Offices of Research and Research Administration, has worked closely with the Institutional Review Board (IRB) Directors and Contracts and Grants Officers to develop policies to address those research compliance issues.

For reporting purposes, the HIPAA-covered entities at the Office of the President, five academic health centers, the nine Student Health Centers, ten Chancellors’ offices, the University’s self-funded health plans and the federal laboratories were asked to provide data regarding the frequency and estimated cost of handling requests by patients to account for disclosures; provide access to or copies of health information; amend health records; and restrict the use or disclosure of information. HIPAA campus Privacy Officers and Liaisons were also asked to describe ongoing operational issues and other outcomes of the HIPAA compliance activities.

The University HIPAA covered entities reported that for the time period of April 14, 2003 (HIPAA compliance date) to June 30, 2003, there were a total of:

1. Over 700 requests for copies of medical records or other records containing PHI, but in many instances this volume was anticipated and not due to HIPAA because individuals have been able to request copies or have access to records prior to HIPAA under state law;
2. Less than 25 total requests for restrictions on the use and disclosure of PHI;
3. Less than 10 requests for an accounting of disclosures, although the costs of creating and maintaining databases to account for disclosures is one of the more costly and challenging documentation requirements under the Privacy Rule;
4. Less than 15 requests for amendments of the medical record or other records; however, although the number is small, the process of amending a medical record can be complex, lengthy and costly because of the need to verify that the requested amendment is accurate and appropriate; and
5. Less than 30 total complaint or reports of alleged violations to either the campuses or systemwide HIPAA hotline.

The Privacy Officers and Liaisons also provided a list of issues still being addressed. Predominantly, these are:
1. Requests for access to records by outside entities for activities that were previously allowed but now, under HIPAA, require patient authorization or that certain requirements be met;
2. Amendment requests, although small in number, are usually complex and require considerable amount of resources to reply because requests are for amendments to multiple documents, many of which are not documents maintained by a University facility;
3. Refusals by large vendor or national associations to sign the University’s business associate agreement, thus requiring lengthy negotiations in order to comply with the business associate mandates of the law;
4. Disclosure tracking database is the major operational issue and expense for a number of the University’s covered entities. The resources include: staff time to enter disclosures; staff education regarding the requirement to enter the database; programmer time to develop online Disclosure Tracking Database; ongoing database maintenance and operational costs;
5. Costs of accounting for routine disclosures required by law—e.g., cancer registry, public health reporting, etc;
6. For some of the smaller covered entities that are not large health care providers, identifying which members of the workforce are covered by the law and the documentation of that training has been an operational cost and challenge because of the decentralized activities at many campuses. Also, for the Student Health Services, the need to purchase a larger system in order to provide for centralized record keeping has added costs;
7. Training of clinical faculty regarding the University’s HIPAA policies is a challenge because many faculty have attended or received HIPAA information from outside entities who do not understand the complexity of complying with HIPAA in an academic setting nor the requirements;
8. Implementation of a Research Authorization that complies with HIPAA and state law, responds to requests of sponsors and is at an 8th grade level;
9. Need to development guidelines for teaching activities involving entities such as visiting faculty, students and volunteers; and
10. Changing the culture within research/academic institutions to address management of access, use, disclosure and security (physical and electronic) of databases containing protected health information to promote respect for the confidentiality of health information.