

University of California Health Science Compliance Program Executive Summary*

1. Introduction

The UC Academic Medical Centers (AMC) continued to encounter a complex regulatory environment. The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) and the Centers for Medicare and Medicaid Services (CMS) added a number of new issues to its regulatory and enforcement foci, as well as implementation of the newly enacted Patient Protection and Affordable Care Act of 2009 (ACA). For a graphic depiction and detailed description of specific enforcement activities of the DHHS refer to Appendices 1 and 2 following this report. The UC Health Sciences Compliance Officers (HSCOs) kept abreast of these new regulatory developments by implementing a number of important enhancements to their specific location ethics and compliance initiatives, partnering with the Office of Ethics, Compliance and Audit Services (ECAS) and the Office of General Counsel (OGC).

The following report highlights and summarizes the key compliance focus areas of the AMC Compliance Programs and describes compliance risk mitigation activities developed and implemented by the HSCOs during calendar year 2010 in response to the new challenges. It is important to note that these increased efforts and risk mitigation activities were conducted in the midst of increased workloads resulting from decreased resources due to budgetary constraints and staff furloughs.

2. Enhanced Governmental Scrutiny

a. Recovery Audit Contractor Audits (RAC)

The Centers for Medicare and Medicaid (CMS) fully implemented its Medicare RAC program. CMS determined that RAC audits are a cost-effective method to identify inaccurate payments with a focus on recovering overpayments. As a consequence, UC AMCs experienced an increasing number of data requests from RAC auditors in the government's attempt to identify improper payments resulting from what the RAC auditors believe to be incorrect payment amounts, medically unnecessary services, incorrectly coded services, and billed duplicate services.

b. Medicaid Integrity Program (MIP) Reviews and Audits

The Deficit Reduction Act (DRA) created the MIP. MIP is the first federal program to review and audit payments made by state Medicaid programs. Under the MIP program, CMS hires Medicaid Integrity Contractors (MICs) to review Medicaid provider billing processes and audit claims to identify overpayments in an effort to combat Medicaid provider fraud, abuse and waste. As a consequence, in 2010, UC AMCs continued to receive requests for data in MIP reviews and audits.

* Calendar Year 2010

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RAC and MIP activities represent a sampling of 2010 enhanced federal and state government oversight of compliance with federal and state healthcare reimbursement rules and regulations, both at the local AMC as well as national level. In addition to the above audit/reviews, UC also experienced other types of claims reviews from CMS contracted carriers including Palmetto for facility-based and professional fee (profee) services and Noridian durable medical equipment (DME) products and services, among other review types established by CMS and other payers. As a consequence, AMC HSCOs had to reduce or defer the number and type of planned work plan audits to adjust for the increased requests from these agencies on their limited resources in order to comply with the mandated short timeframes to submit documentation as requested.

c. Data Privacy and Security

In addition to clinical billing and coding reviews, UC AMCs had to comply with new federal patient and other data privacy and security regulations. For example, HSCOs collaborated with AMC and ECAS leadership to adjust to the new Health Information Technology for Economic and Clinical Health (HITECH) privacy and security provisions of the American Recovery and Reinvestment Act (ARRA) of 2009. This compliance activity was in addition to ongoing efforts to maintain and enhance AMC/Campus compliance with Gramm-Leach-Bliley and the Fair Credit Reporting Act (FCRA) as well as California state privacy rules and regulations.

d. Clinical Research Billing

The rules and regulations governing clinical trials billing are extremely complex. In 2010, AMC clinical billing and compliance departments faced enormous challenges in navigating CMS' Clinical Trial Policy rules and device trial coverage regulations. In working with research compliance program personnel, HSCOs worked to ensure that processes were in place for the AMCs to comply with Medicare coverage rules for qualifying clinical trials, as well as commercial insurance and employer group health plan coverage rules.

3. Response and Prevention

The AMC Reports demonstrate that the existing compliance program infrastructure at each AMC was successful in maintaining, with some adaptation, ongoing compliance activities in accordance with existing rules and regulations, and to implement new initiatives to stay abreast of additional federal and state requirements, even without increasing resources in this economic strained environment.

In response to the stepped-up governmental scrutiny, the AMCs improved their compliance program oversight, adjusted existing or created new policies, improved education and communication outreach, and added additional auditing and monitoring oversight activities to identify and correct deficiencies.

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a. Policy Review and Development

Each AMC either deployed a new policy/procedure or improved upon an existing policy to address the issue of clinical trial billing and payment of medical care costs associated with subject injuries. Existing data privacy and security policies were also adjusted in response to the onerous breach notification requirements as required in the new HITECH provisions of the ACA.

Of note, UCSDHS implemented and UCI developed new conflicts of interest (COI) policies to address potential COI issues related to the delivery of clinical care. Moreover, several campuses have Industry Relations Committees to help oversee implementation of COI policy and related activities.

b. Education and Communication

Each of the five (5) AMC HSCP Annual Reports reflect continued efforts of the HSCOs to update existing staff specific compliance education and training in response to changes and additions to the federal and state reimbursement rules and regulations. Of note:

1. The UC Learning Management System (LMS) is now available for use by AMC personnel, physicians, providers, house staff and other department staff. In addition to the mandated Compliance Briefing for Employees, the LMS training modules implemented this year related to Compliance Program objectives and compliance risk areas include: Conflict of Interest for Health Care Providers; Health Care Vendor Relations Policy; Teaching Physician Rules for Billing; Evaluation/Management Coding (E/M services) for Physician Services; Diagnosis Coding Basics (ICD9 coding) for Hospital Staff; Billing Guidance of Nurse Practitioners (Professional Fee Billing); Annual HIPAA Privacy/Security Training (for the Clinical Enterprise); Research Registration, Admission and the Bulk Account Processes; and Physician Oriented Research Compliance.
2. Each AMC also implemented Responsible Conduct in Research (RCR) training in compliance with the new National Science Foundation (NSF) requirement under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act.
3. Several AMCs revised campus-specific training to accommodate policy changes related to Human Subjects Research, Animal Care and Use, or annual government reimbursement coding updates for specific conditions (Current Procedural Terminology version 4) CPT-4 and (International Classification of Diseases 9th Edition Clinical Modification) ICD-9-CM codes. For example, UCDHS and UCSDHS rolled out vendor relations training for appropriate research personnel in order to provide an update of changes to COI in research policies and procedures. UCI has implemented a general basic training for clinical researchers focused on human subjects research.

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c. Auditing and Monitoring

Substantive auditing and monitoring activities continue to occur in relevant compliance program areas. In 2010, the AMCs conducted compliance risk assessments and incorporated OIG Work Plan focus areas in the development of their annual work plans. In addition, each AMC also proactively conducted reviews in key compliance risk areas in anticipation of increased federal and state oversight activities. For example, clinical trials billing processes were included in auditing and monitoring efforts.

d. Help Lines and Hotlines

AMC employees continue to feel confident in raising potential compliance issues through a variety of available channels. For example, HSCOs have learned about potential issues through compliance help lines, Whistleblower hotlines, and directly from management and staff. With respect to requests for information, staff has asked for guidance on policies, coding and billing issues, protecting patient privacy, among others. With respect to issues that may require investigation, the HSCOs have continued to coordinate investigative efforts with the Locally Designated Official (LDO).

4. Corrective Action

Based on their proactive auditing and monitoring efforts, the AMCs developed and implemented corrective action plans given the trending of identified deficiencies. Corrective action included, for example, education and training, refunds of identified overpayments, expanded reviews, clarification of policies and regulations, assisting with facilitating discussions and identifying remediation for matters with business owners, development of forms and templates, and disciplinary action as applicable to the situation.

HSCOs have assisted with assuring that the appropriate training of personnel occurs in high risk areas, oftentimes conducting the training themselves. ECAS has also worked with the AMCs by providing webinars, workshops or developing reference materials to assist with compliance in these extremely complex arenas.

5. 2011 Work Plans

With respect to 2011 AMC Compliance Work Plan development, the HSCOs uniformly report that they will continue to focus on two high compliance risk areas: billing/coding and research compliance. For example, UCI, UCLA and UCSD are collaborating on the development and implementation of new auditing and monitoring software for physician billing reviews.

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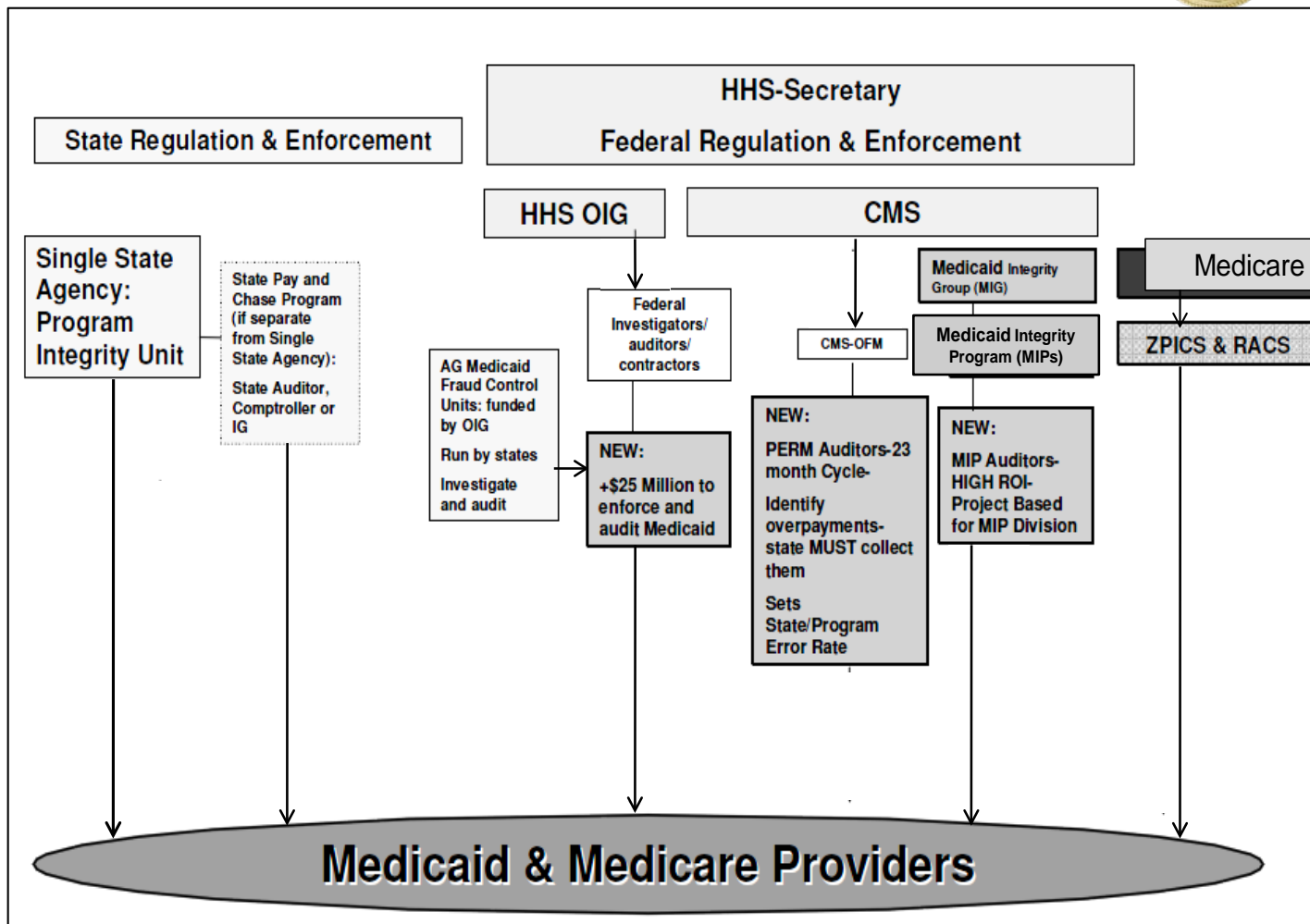
The AMCs also report that they will: (1) continue to use compliance risk assessments to identify focus areas for hospital and provider reviews; (2) monitor trends and outcomes from Medicare Recovery Audit Contractor (RAC) audits and other government audit activities; and (3) provide training to all hospital and professional coders in preparation for ICD-10 implementation and other changes emphasized by our payers through new regulations, guidelines and/or policies.

It is also recognized that with the ACA, there will potentially be a number of compliance-related changes that may impact access to, and delivery of quality patient care – with quality being a key focus of the government’s oversight activities. Additionally, the proposed regulatory changes to the Public Health Services policy on financial conflict of interest is research will have an impact on compliance operations, as will the ongoing scrutiny by Senator Charles (Chuck) Grassley (R-WI) and the Senate Finance Committee surrounding physician/industry relationships and the transparency of reporting to the public the nature and financials of these relationships. UC also has technology challenges around conflicts of interest that will be a focus for not only our HSCP but also our system as a whole, since conflict of interest reporting and management is required in multiple functional areas.

In summary, with the ongoing regulatory scrutiny and additional resource allocation to government and state agencies for detection and prevention of fraud, waste and abuse, as well as the increased focus on quality of care in the delivery of health services, it is a challenge to address all the potential/real areas of ethics and compliance risk. Nevertheless, with appropriate risk prioritization and active engagement of personnel, systems and other resources, we are in a position to address and mitigate our high risk areas.

Appendix 1: HS Compliance Program Summary Reports

Federal and State Enforcement Activities



Appendix 2: HS Compliance Program Summary Reports

CMS Audit Activities Program Description



Recovery Audit Contractors (RAC)

- Established by the Tax Relief and Health Care Act of 2006 (Section 302),
- Outgrowth of a successful demonstration program in California , Florida , New York , Massachusetts , South Carolina and Arizona .
- \$900+ million in overpayments returned to the Medicare Trust Fund between 2005 and 2008
- Approximately \$38 million in underpayments returned to health care providers.
- Includes hospitals, physician practices, nursing homes, home health agencies, durable medical equipment suppliers and any other provider or supplier that bills Medicare Parts A and B.

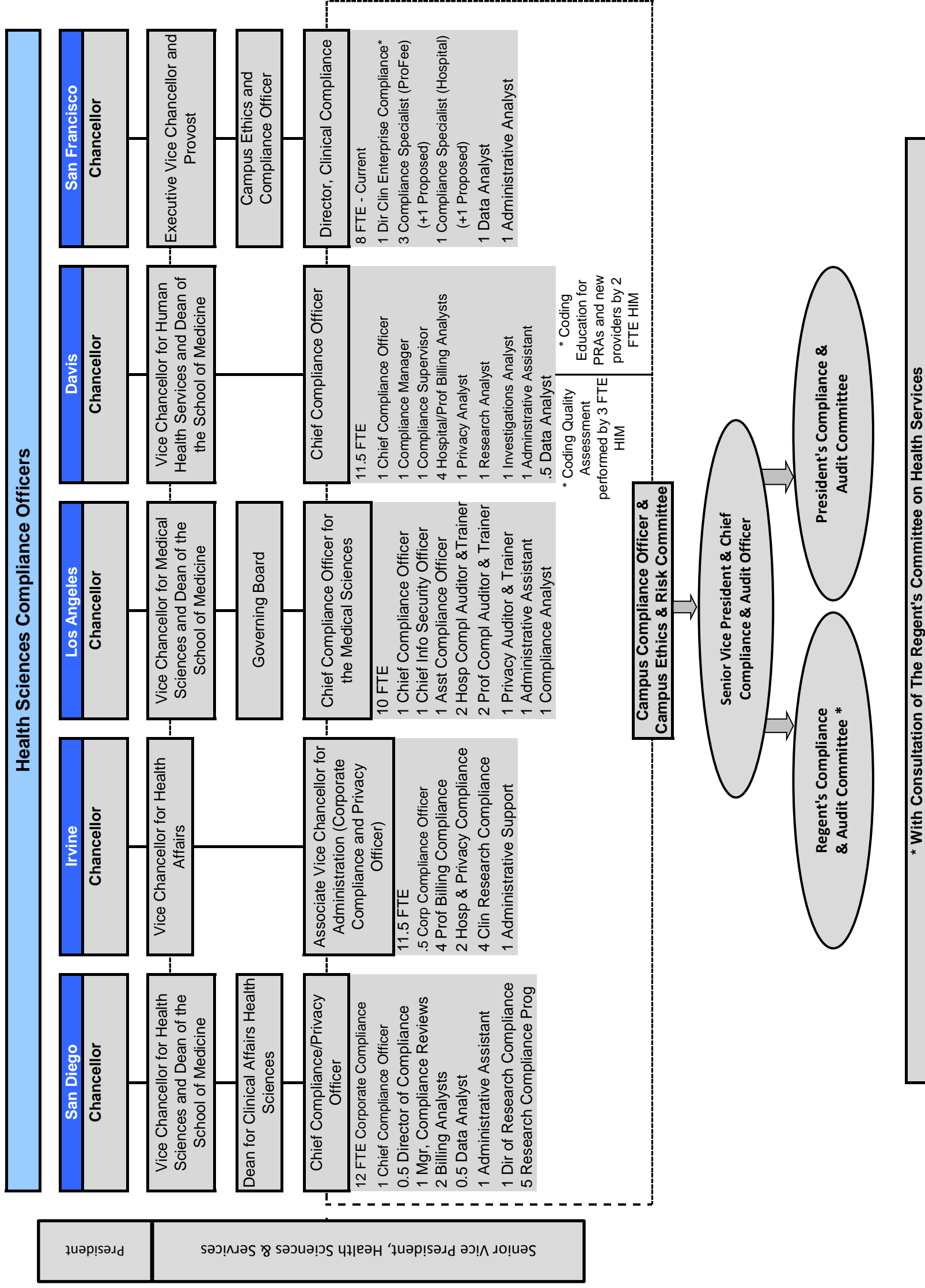
Medicaid Integrity Program (MIP)

- Deficit Reduction Act (DRA) of 2005 created the Medicaid Integrity Program (MIP) under section 1936 of the Social Security Act (the Act).
- 1st comprehensive Federal strategy to prevent and reduce provider fraud, waste, and abuse in the \$300 billion per year Medicaid.
- CMS has two broad responsibilities under the Medicaid Integrity Program:
 - To hire contractors to review Medicaid provider activities, audit claims, identify overpayments, and educate providers and others on Medicaid program integrity issues
 - To provide effective support and assistance to States in their efforts to combat Medicaid provider fraud and abuse

Glossary of Terms

HHS OIG	Department of Health & Human Services Office of Inspector General
CMS	Center for Medicare and Medicaid Services
ZPIC	Zone Program Integrity Contractor
RAC	Recovery Audit Contractor
MIP	Medicaid Integrity Contractor
OFM	Office of Financial Management
PERM	Payment Error Rate Measurement

APPENDIX 3



APPENDIX 4

