



Health Science Compliance Program

Responsible Officer:	SVP - Chief Compliance & Audit Officer
Responsible Office:	EC - Ethics, Compliance & Audit Services
Issuance Date:	6/12/2013
Effective Date:	6/12/2013
Scope:	This policy governs the oversight and management of all University of California Health Science Compliance Program activities.

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I. POLICY SUMMARY

This Health Sciences Compliance Program (HSCP) Policy provides guidance for the development, implementation and evaluation of all Health Science Compliance Program activities at University of California (University) Academic Medical Centers and related Health Science functions. This policy is based upon the United States Sentencing Commission’s (USSC) Seven Elements of an Effective Compliance Program (Section XIII of the Federal Sentencing Guidelines) as recommended by the Centers for Medicare and Medicaid (CMS) Services and its Office of Inspector General (OIG) for compliance program structure. It is the responsibility of each Health Science responsible party to comply with the HSCP in an effort to detect, deter, and prevent instances of potential fraud, waste and abuse.

II. DEFINITIONS

Responsible Parties: Defined as all Health Science personnel, vendors, contractors and other representatives of the University. For the purpose of this policy, University personnel includes all administrative management and staff, faculty, physicians, graduate health profession students and other health care personnel, including non-salaried faculty and volunteers at the Health Sciences campuses, their Medical Centers, clinics and respective Health Science professional schools which are responsible for:

- 1) Direct provision of patient care services;
- 2) Provision of clinical support services including administrative or patient care services;
- 3) Ensuring that members of the Health Sciences Clinical Enterprise carry out their individual and corporate responsibilities in a legal manner, consistent with federal, state and local laws and regulations. This group includes campus and Office of the President leadership responsible for the above activities.

Independence

To permit rendering of impartial and unbiased judgment essential to the proper conduct of the HSCP, the Health Sciences Compliance Officer (HSCO) and staff shall be independent of the activities they review. In performing the compliance function, the HSCO cannot have any direct responsibility for or authority over, any of the activities reviewed. Therefore, the HSCP review and evaluation process does not in any way relieve other persons in the organization of the responsibilities assigned to them.

Campus Ethics and Compliance Risk Committee (CECRC)

Per the Regentally-approved Ethics and Compliance Program Plan, each campus and Lawrence Berkeley National Laboratory (LBNL), Agriculture and Natural Resources (ANR) and the Office of the President (UCOP) are required to have a senior level committee that will provide compliance oversight to their location and will be advisory to the Senior Vice President - Chief Compliance and Audit Officer (CCAO). The CECRC will be comprised of senior campus leadership responsible for various areas of campus compliance risks, academic leadership, and one or more members of the Office of Ethics, Compliance and Audit Services. The CECRC will be co-chaired by the Executive Vice Chancellor / Provost and the designated Chief Ethics and Compliance Officer (CECO).

The CECRC is charged with the following responsibilities, including but not limited to: 1) responsibility and support for the overall compliance program including implementation, performance metrics and ongoing programmatic processes; 2) developing risk assessment tools for campus/location use in identifying and mitigating high risk compliance areas; 3) advising on the need for campus-specific guidance documents, education materials, and training courses, 4) monitoring the compliance environment as it relates to specific risk areas and recommending compliance policies and best practices for systemwide implementation; and 5) reporting compliance risk areas of high priority and proposed risk mitigation activities to the President's Compliance and Audit Committee (PCAC), both on an ad hoc basis and through formal quarterly and annual campus compliance reports.

Locally Designated Official (LDO)

The person designated by each campus, LBNL, ANR and UCOP as the official with primary responsibility to receive reports of allegations of suspected improper governmental activities.

III. POLICY TEXT

The Board of Regents adopted a resolution in July 2008 directing the CCAO to develop and oversee a comprehensive Ethics and Compliance Program (ECP) that spans all University locations, including those with Health Science (HS) functions. The ECP effectively incorporates the HSCP approved by the Regents in 2000, and which has been in effect since that date at each University with a HS function.

A. Objectives of the Health Science Compliance Programs

Each University HSCP shall be designed to:

1. Detect, deter, resolve and prevent potential violations of University policies and other applicable governmental rules and regulations.
2. Promote a culture of compliance with applicable governmental rules, regulations, professional standards of practice, and other standards (e.g., accreditation agencies).
3. Reinforce the University's mission by providing quality patient care services and receiving appropriate reimbursement based on accurate clinical documentation, coding and billing, and patient and clinical research services.
4. Establish and maintain a culture of collaboration with appropriate HS operational departments to continually review and improve operational processes involved in the efficient and effective delivery and payment for patient care services.
5. Provide overall guidance and direction to applicable University responsible parties to act in a legal manner, consistent with all applicable standards and regulations related to the provision of and claim for reimbursement for all health-related services.
6. Establish, review, revise, and communicate applicable policies that facilitate education of all responsible parties and promote the importance of compliance to applicable laws and regulations.
7. Encourage all employees and other responsible parties to report all suspected or known improper governmental activities (IGAs) under the

provisions of the [Policy on Reporting and Investigating Allegations of Suspected Improper Governmental Activities](#).

8. Establish and maintain mechanisms for responsible parties to raise questions and concerns about potential compliance issues without fear of retaliation, and to ensure that those concerns are appropriately addressed, according to the [Policy for Protection of Whistleblowers from Retaliation and Guidelines for Reviewing Retaliation Complaints](#).
9. Report, disclose, trend, and follow up as appropriate, on potential violations or inappropriate interpretation of University compliance-related policies, compliance standards, laws, or regulations as identified.

B. Health Sciences Compliance Officer Role and Reporting Structure

1. Each HS Campus shall appoint a high level HSCO to implement the HSCP.
2. The HSCO shall have overall responsibility for maintaining and enhancing campus-specific HSCP activities which are under the management control of the HSCO, to include identifying, intervening, and responding to potential compliance issues and assuring the effective operations of the HSCP.
 - a. Health science business areas **not** under the operational management of the HSCO shall be responsible for specific, periodic reporting of their compliance related issues to the CECRC.
3. The HSCO shall have a direct reporting relationship to senior level HS leadership, for example, the Medical Center Chief Executive Officer (CEO) or the Dean of Health Sciences, as determined by each location that allows for autonomy and independence in the HSCP's operations. In addition, the HSCO shall have a matrixed reporting relationship to the independent systemwide CCAO who has a direct reporting relationship to the Board of Regents Compliance and Audit Committee Chairperson and the University President.
 - a. The HSCO has full and free access to all University records, personnel and vendors.
4. Each HSCP shall maintain a current position description accurately detailing the roles and specific responsibilities of the HSCO. Qualifications and competencies shall be established for this position based upon the size, scope and complexity of the HSCP and be reflective of industry requirements for a health care compliance officer.

C. Health Sciences Compliance Program Office Structure and Budget

1. In collaboration with HS leadership and the CCAO, each HSCO shall develop a program structure that incorporates the compliance plan (CP) requirements listed herein for each HSCP office.
2. Each HSCO shall be responsible for the collaborative development and implementation of an approved budget that is commensurate with the scope of the HSCP and related activities needed to mitigate compliance risks.

D. Health Science Compliance Program Committee(s)

1. Each HSCP shall have a designated Compliance Committee (CC) that provides oversight to the development, implementation and evaluation of the campus-specific HSCP adhering to systemwide HSCP policies and related guidance.
 - a. If not a member of the CECRC, the HSCO and/or chair of designated committee shall periodically report to the CECRC on key compliance activities and areas of concern as discussed at the CC.
 - b. The CC membership shall include, but not be limited to, representation from senior level academic medical center, professional school and faculty practice plan staff to facilitate discussions on key compliance risks and plans for mitigation.
 - c. The *HSCP Annual Work Plan and Annual Report* shall be presented to the CC for review and approval on an annual basis, prior to submission to the CECRC and Ethics and Compliance Services (ECS) for inclusion in systemwide documents.
 - i. The HSCP Annual Work Plan shall be developed in conjunction with the campus annual compliance workplan and submitted to the CECRC for approval and submission to the ECS for integration into the systemwide Annual Plan which is approved by the Regents.
 - ii. The Annual Report shall be developed on an annual basis in conjunction with the campus annual report and then submitted to the CECRC for approval and integration, as appropriate, into the systemwide Annual Report to the Regents.

2. Each HSCO may establish function-specific committees, which may include, but not be limited to, Professional Fee Compliance Committee, Medical Billing Advisory Committee, Health Information Portability and Accountability Act (HIPAA) Privacy and Security Committee, to assist in the oversight and management of compliance activities related to those specific areas.
 - a. Each subordinate committee or workgroup shall have a direct reporting relationship to the HSCC wherein summary reports of plans and activities are reported.

E. Health Sciences Code of Conduct

1. The University [Statement of Ethical Values and Standards of Ethical Conduct](#) is the systemwide code of conduct and all campus, location or function specific codes of conduct shall be aligned to the Regents' approved statement, as noted above.

F. Health Sciences Compliance Program Policies and Procedures

1. Each HSCP shall establish a mechanism to develop, approve, implement and evaluate compliance-specific policies and procedures as mandated by federal, state or local regulations, University policy, or campus directive to provide guidance for the HSCP's daily operations. The policies are to be reviewed and updated periodically, at time frames mandated by campus policy or by systemwide directive in the absence of a campus policy.
2. Each HSCO shall develop and implement location-specific policies, procedures or other protocols that are an integral element of the campus-specific HSCP and operationalize the governmental rules and regulations and/or other University systemwide or campus-specific policies adhering to systemwide and industry best practices including, at a minimum, the following list of high compliance risk areas :
 - a. Coding and Billing Accuracy
 - i. Inpatient Services
 - ii. Outpatient Hospital Based Services
 - iii. Professional Services
 - iv. Post Acute Services
 - b. Conflict of Interest
 - c. Conflict Resolution
 - d. Contract Management

- e. HIPAA Privacy and Security
- f. Repayment/Refund of Third Party Reimbursement
- g. Responding to Government Investigations
- h. Screening of Employees (LEIE – List of Excluded Individuals/ Entities)
- i. Vendor Relations

G. Reporting Concerns

1. The opportunity to ask questions, clarify expectations, and raise concerns in a non-threatening environment is the cornerstone of an effective compliance program. Each HSCP shall support open discussion of ethical and legal questions surrounding potential compliance issues and will not tolerate retaliation against any individual who, in good faith, raises questions or reports suspected violations.
2. All University responsible parties are expected to report potential issues, concerns or suspected violations related to the ECP which includes the HSCP. The mechanism for reporting includes a direct report to a supervisor, legal staff, human resources, the HSCO, the systemwide CCAO, or to the University confidential hotline ([Whistleblower Hotline](#)).
3. In collaboration with the campus/location Locally Designated Official (LDO) or other campus designee, each HSCO is responsible for ensuring education is provided to HS responsible parties on how to raise compliance concerns.

H. Education and Training

1. Education is an integral part of an effective compliance program and consists of two primary types of compliance education.
 - a. **General Compliance Training** consists of presenting and reinforcing general knowledge of the compliance program, such as commitment of the organization to ethical and compliant behavior as promulgated through the *Statement of Ethical Values and Standards of Ethical Conduct*, the HSCP structure, presence of the HSCO, the confidential hotline and the [Policy for Protection of Whistleblowers from Retaliation and Procedures for Reviewing Retaliation Complaints](#).
 - i. General Compliance Training shall be periodically presented to all HS staff at the direction HS leadership, but not less than mandated by CCAO from a systemwide perspective.

- b. **Specific/Relevant Employee Compliance Training** is training specific to the job responsibilities of an employee that has an impact on applicable governmental regulations and/or University Policy.
 - i. General Compliance Training can be incorporated into specific training at the discretion of the HS function, and if approved by the HSCO, can meet the general training requirement from the System or campus level.
- 2. It shall be the responsibility of the HSCO to assure that processes are in place, and are periodically evaluated, for the effective and timely training and orientation of all relevant staff on areas of high compliance risk, e.g., clinical documentation to support reimbursement and data privacy and security concerns.
 - a. Staff shall be trained at time of hire, and periodically thereafter, as noted above in paragraph H.1.a.i.
- 3. An annual education workplan based upon identified industry concerns, the OIG's annual workplan and model guidance, and locally identified issues shall be developed by the HSCO in conjunction with the development of the Annual Work Plan and presented to the HSCC for approval.

I. Exclusion Screening

- 1. The HSCO shall be responsible for ensuring that processes are in place to screen all responsible parties against the List of Excluded Individuals and Entities.
 - a. This screening is completed at time of hire and periodically thereafter, but no less frequently than on a monthly basis.
 - b. All responsible parties will be educated as to their responsibility to report any change in their exclusion status to their employer as soon as they have been officially notified.
- 2. When a responsible party has been identified as excluded from government programs, the HS function shall ensure that timely reimbursement is completed to the government program wherein reimbursement was received for the services provided by the excluded individual during the period of exclusion.
 - a. As noted in Section III.F, each HSCP shall have a process in place for the timely repayment of funds received in error, or that did not comply with reimbursement criteria.

J. Auditing and Monitoring

1. No effective compliance program is viable without a comprehensive focus on assuring compliance with applicable governmental rules, regulations and specific University policies surrounding regulatory areas. The HSCO will collaborate with other campus leadership and the CCAO to assure that processes are in place to meet the regulatory requirements that govern the delivery of services provided by University employees.
2. In addition to ongoing monitoring of key high risk compliance areas, such as hospital and professional fee billing, each HSCP shall develop and report to the CCAO on an annual basis, outlining a comprehensive audit and monitoring workplan that focuses on identified areas of risk, such as a risk assessment, industry literature, the OIG work plan, or another identified source.
 - a. The plan shall be developed with input from and approval of the HSCC.
 - b. The systemwide CCAO reserves the right to establish systemwide Health Science metrics that may include an audit element, based upon identification of a potential systemwide compliance risk.
3. All audit and monitoring activities conducted by the HSCP shall be governed by appropriate industry-accepted methodologies for the sampling and selection of claims to review and criteria for review.
 - a. Each HSCP shall have written guidance (e.g., policy, procedure, or instructions) on the implementation techniques for their specific activities.
4. Audit and monitoring reports are to be generated, shared with appropriate University personnel, and management plans developed and formalized that effectively monitor the mitigation of the identified risk. These plans or summaries of observations and recommendations shall be reported through the appropriate campus compliance structure to the CCAO.

K. Enforcement

1. The University reserves the right to take disciplinary action or cause disciplinary action to occur against anyone who fails to comply with elements of the HSCP, as per University Policy.
2. The HSCO, in collaboration with Academic Personnel or Human Resources staff as applicable, shall evaluate violations of the HSCP and refer cases for potential disciplinary action in accordance with University Policy or other governing statements.

NOTE: No action will be taken on the right of a provider to see a patient without the prior approval of the Dean and/or the Medical Staff; however, suspension of billing privileges shall occur at the discretion of the HSCO.

L. Response and Prevention

1. The HSCO shall ensure that procedures are in place, as noted in Section F, to assist staff in the event of a government or other agency investigation. At a minimum, in the event of an external investigation, staff should be educated or directed to request assistance from Campus or Medical Center Legal Counsel. In the absence or unavailability of Campus Counsel, the Office of General Counsel shall be notified and assistance requested.
2. Of note, no employee shall:
 - a. Destroy or alter documents in anticipation of a government request, as per appropriate systemwide or campus specific record retention protocols;
 - b. Lie or make misleading statements to government investigators;
 - c. Pressure or advise anyone to hide information or provide false or misleading information.

IV. COMPLIANCE / RESPONSIBILITIES

The CCAO may periodically conduct audit(s) of the HSCP to determine compliance with this policy, specific compliance risk areas, and/or the intent of the USSC guidance on effective compliance programs.

V. PROCEDURES

Each Chancellor of a health-science campus shall ensure that a functioning HSCP is established on campus, adhering to the guidance outlined above.

VI. RELATED INFORMATION

[Statement of Ethical Values and Standards of Ethical Conduct](#)

[University Ethics and Compliance Program](#)

[Employee - Vendor Relations Policy](#)

VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

This policy was developed in 2000.
Reviewed and revised – 2012

IX. APPENDIX – LIST OF ACRONYMS

Acronym	Definition
ANR	Agriculture and Natural Resources
CC	Compliance Committee (specific to Health Sciences)
CCAO	Senior Vice President and Chief Compliance and Audit Officer
CP	Compliance Plan (Workplan)
CECO	Campus Ethics and Compliance Officer
CECRC	Campus Ethics and Compliance Risk Committee
CEO	Chief Executive Officer
CMS	Centers for Medicare and Medicaid Services
ECP	Ethics and Compliance Program
HIPAA	Health Insurance Portability and Accountability Act of 1996
HS	Health Sciences
HSCO	Health Sciences Compliance Officer
HSCP	Health Sciences Compliance Program
IGA	Improper Governmental Activity
LBNL	Lawrence Berkeley National Laboratory
LDO	Locally Designated Official
LEIE	List of Excluded Individuals and Entities (compiled by the Office of Inspector General, Department of Health and Human Services) http://oig.hhs.gov/exclusions/
OIG	Office of Inspector General
PCAC	President’s Compliance and Audit Committee
UCOP	University of California Office of the President
University or UC	University of California
USSC	United States Sentencing Commission