

Title: Corporate Integrity Program Policy: Corporate Integrity Program

Document Owner: Ginny Kim (Vice President)

Home Department: Corporate Integrity Program

IMPORTANT NOTICE:

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I. INTRODUCTION

Cedars-Sinai Medical Center and its affiliated organizations are known as the Cedars-Sinai Health System. Examples of affiliated organizations include the Cedars-Sinai Medical Care Foundation, and Cedars-Sinai Accountable Care, L.L.C. For purposes of this program, the various entities are referred to as "Cedars-Sinai." Cedars-Sinai maintains the highest standards of business ethics and uses its best efforts to comply with all federal, state and local laws, regulations, rules, guidelines and ordinances (laws). To ensure that best efforts are taken to comply with the highest standards of business ethics as well as with all laws, Cedars-Sinai has developed a *Corporate Integrity Program* (the "Program").

Among other things, the *Corporate Integrity Program* is intended to ensure that Cedars-Sinai, and its employees, physicians, volunteers, contractors, and agents (CS Staff), would not knowingly violate any laws controlling the conduct of Cedars-Sinai's clinical operations, research activities, academic affairs or community benefit programs. The *Corporate Integrity Program* endeavors to meet this objective through ongoing policy development, general and targeted education and training, continuous monitoring, periodic internal and external audits, and various reporting mechanisms. CS Staff must be familiar with the laws which govern their activities performed on behalf of Cedars-Sinai. As is set forth in more detail in this *Corporate Integrity Program*, that familiarity will be an essential part of every affected CS Staff member's job responsibilities.

This *Corporate Integrity Program* is not, however, intended to cover the operations and management specific to the Cedars-Sinai Accountable Care, L.L.C. ("ACO"). The integrity of ACO-specific operations and management will be addressed through the ACO's own compliance (integrity) policies and procedures. This *Corporate Integrity Program* is intended to address the integrity-related risks associated with the activities of Cedars-Sinai and CS Staff as ACO participants.

All CS Staff will receive on-site education regarding the *Corporate Integrity Program*, and all relevant laws addressed therein. Any employee who has questions or concerns about anything discussed in the *Corporate Integrity Program* should contact Cedars-Sinai's Chief Ethics and Compliance Officer. As is also explained in this Program, a toll-free hotline has been established to provide employees with a confidential way to raise their concerns. Calls will not be traced, and the caller may report all information anonymously if the caller so desires.

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CS Staff are subject to the requirements of the Program. This includes CS Staff who are non-employed physicians under contract with Cedars-Sinai, contractors and agents acting on behalf of any Cedars-Sinai entity, and any others who provide clinical services using the billing or provider number(s) of any Cedars-Sinai entity. Any action taken in violation of the *Corporate Integrity Program* is outside the employee's scope of employment and with regard to other parties under contract or other arrangement will be outside their scope of engagement. Such action could subject the individual to serious sanctions, including termination of employment, liability for breach of contract, civil liability and/or criminal prosecution.

This Program is the current description of Cedars-Sinai's corporate integrity, legal compliance and business ethics programs. This Program description supersedes, as of its effective date, prior years' descriptions of such efforts.

II. CORPORATE INTEGRITY RISKS, STANDARDS, AND POLICIES AND PROCEDURES

A. A Commitment to Corporate Integrity: Code of Conduct for CS Staff

Cedars-Sinai, its governing boards, and its senior management are firmly committed to the highest standards of business ethics and to full compliance with applicable laws. The following Standards of Conduct (Standards) express this commitment.¹ CS Staff are expected to abide by these Standards as a condition of employment, in the case of employees, and as a condition of engagement, in the case of contracted parties.

As a CS Staff member, I will use my best efforts to:

- *Promote and preserve Cedars-Sinai's Organizational Values of **Integrity, Excellence, Teamwork and Collaboration, Respect, Compassion, Innovation, Stewardship, and Diversity**, acknowledging that **Integrity**, as the foundation for the other Organizational Values, requires my ongoing focused attention.*
- *Safeguard the physical security and personal privacy of Cedars-Sinai's patients.*
- *Protect the confidentiality of patient and employee information, as well as Cedars-Sinai's own proprietary information.*

¹ This same commitment is also expressed in HR *Expectation* Policies and Procedures (available in the Policy and Procedure Manager, "PPM"). These Standards of Conduct are supplemental to employment and professional standards contained in other Cedars-Sinai policies and procedures.

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- Avoid all forms of discrimination based on race, color, national origin, sex, age and disability.
- Act in accordance with all Cedars-Sinai's policies and procedures as contained within Cedars-Sinai's Policy and Procedure Manager (PPM), especially those policies and procedures that are elements of the Corporate Integrity Program.
- Comply with all laws, as well as accreditation standards, which apply to Cedars-Sinai's operations and practices, even under circumstances where such compliance may be burdensome and of uncertain value.
- Report any suspected, observed, or known violation of policy, Law, or accreditation standards in accordance with Cedars-Sinai's policies and procedures.
- Disclose all potential conflicts of interests and avoid those conflicts that in the judgment of Cedars-Sinai cannot be managed.
- Accept only those gifts and offers of entertainment, from patients, vendors, or anyone seeking to provide goods or services to Cedars-Sinai, which are allowed under Cedars-Sinai's policies.
- Adhere to all professional standards of conduct and/or codes of ethics that apply to my Cedars-Sinai position and/or responsibilities.

B. Corporate Integrity Risks

In keeping with its commitment to corporate integrity, Cedars-Sinai has developed policies and procedures, monitoring processes, and/or targeted training to address areas of special concern. All Cedars-Sinai policies and procedures currently and from time to time in effect regarding the *Corporate Integrity Program* are hereby incorporated by reference into the *Corporate Integrity Program*. Such policies and procedures may be found in Cedars-Sinai's Policy and Procedure Manager (PPM).

1. OIG Guidance on Potential Corporate Integrity Risks

In its guidance for compliance programs, the Department of Health and Human Services' (HHS') Office of Inspector General (OIG) has identified several risk areas that should be of special concern for healthcare compliance programs.² Accordingly, these risks are

² *OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. 8987 (Feb. 23, 1988), *OIG Supplemental Compliance Program Guidance for Hospitals*, 70 Fed. Reg. 4858 (Jan. 31, 2005) and *OIG Compliance Program for Individual and Small Group Physician Practices*, Notice, 65 Fed. Reg. 59434 (Oct. 5, 2000).

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addressed below, along with the general principles and standards under which Cedars-Sinai intends to address these risk areas.

a. Submission of Accurate Claims And Information

Providers furnishing and submitting claims for items or services provided to Medicare and Medicaid patients are subject to statutory and regulatory obligations, including the obligation to provide items and services that are: (1) medically necessary in the judgment of the treating physician; (2) of a quality that meets professionally recognized standards of health care; and (3) supported by evidence of medical necessity and quality. Any claim submitted for services that are not medically necessary, or which were provided in a substandard manner, or which are not properly documented could give rise to a federal false claim allegation.

The federal Civil Monetary Penalty Law prohibits any person or organization from: (1) presenting or causing to be presented to the federal government any claim for a medical or other item of service that the person knows or should know was not provided as claimed; and (2) engaging in any pattern or practice of presenting a claim for an item or service that is based on a billing-related code that the person knows or should know will result in a greater payment than the applicable code (42 U.S.C. § 1320a-7a(a)(1)(A) and (B)).

The federal False Claims Act (31 U.S.C. § 3729–33) prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval, knowingly making or using or causing to be made or used a false record or statement to have a false or fraudulent claim paid or approved by the government, and knowingly making or using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government. The False Claims Act defines “knowing” and “knowingly” to mean that “a person, with respect to the information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” 31 U.S.C. § 3729(b).

Many other federal laws similarly prohibit fraudulent billing, including statutes governing false statements and representations, wire and mail fraud, and criminal conspiracy. These statutes may apply to private insurance carriers as well as to federal health care programs such as Medicare and Medi-Cal. In addition, California has laws prohibiting false or fraudulent submission of claims to the Medi-Cal program and to private insurance companies.

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In order to minimize the risk that these laws may be violated, even inadvertently, Cedars-Sinai will establish, from time to time, written policies and procedures, monitoring processes, and/or targeted training which reflect and reinforce current federal and state statutes and regulations regarding the development and submission of claims to third party payors. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding submission of accurate claims and information are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are among the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

Cedars-Sinai will submit claims to payors and/or patients ONLY for services:

- That are actually provided or rendered;
- That are provided with the informed consent of the patient or patient's surrogate;
- That are reasonable and medically necessary relative to the patient's current and well-documented medical condition; and
- That have appropriate documentation to support the claims, and only when such documentation is maintained and available for audit and review.

Cedars-Sinai will submit claims for teaching faculty professional services involving residents and fellows ONLY when:

- The services are actually provided or supervised (within applicable regulatory guidelines) by the teaching physician;
- The teaching physician who provides or supervises the provision of services to a patient personally and correctly documents the services that were rendered; in cases where that physician provides or supervises evaluation and management services, the patient's medical record includes appropriate documentation of the applicable key components of the services provided or supervised by the physician (e.g., patient history, physician examination, and medical decision making), as well as documentation to adequately reflect the procedure or portion of the service performed by the physician.

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Cedars-Sinai will also ensure that:

- All services, including physician and other professional services, are reviewed prior to billing (or sampling procedures adopted) to ensure that only accurate and properly documented services are billed to payors and patients;
- All records and medical notes used as the basis for a claim submission are appropriately organized in a legible form so they can be audited and reviewed, consistent with appropriate guidance from Cedars-Sinai's Medical Staff;
- The diagnosis and procedures reported on claims are based on the medical record and other documentation, and the documentation necessary for accurate code assignment is consistently available to coding staff;
- Coding staff have proper qualifications and on-going training to ensure accuracy of coding;
- Any form of "upcoding," meaning the use of a billing code that provides for a higher payment rate than the billing code that accurately reflects the service furnished to the patient, or "DRG creep," meaning the practice of using a DRG code that provides a higher payment rate than the DRG code that accurately reflects the patient's diagnosis and treatment, is strictly prohibited;
- Duplicate billing, meaning submitting more than one claim for the same service or unnecessarily submitting the same claim more than once, is strictly prohibited;
- Any form of "unbundling," or submitting bills in a piecemeal or fragmented fashion for tests or procedures which are required to be billed together, is strictly prohibited;
- Financial incentives intended to cause, or likely to cause, improper billing are strictly prohibited;
- Inpatient and outpatient services are properly distinguished, coded, and billed;
- Computer applications are available and maintained to edit and audit claims data.

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In addition to the general requirement for accurate, well documented claims, the OIG, HHS's Center for Medicare and Medicaid Services (CMS) or other federal and state agencies may, from time to time, identify other billing issues as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

[Also see below Section IX: Special Notice to CS Staff on Identifying and Reporting Healthcare Fraud.]

- b. The Referral Statutes: The Physician Self-Referral Law (the "Stark" Law) and the federal Anti-Kickback Statute

Section 1877 of the Social Security Act, commonly known as the Stark Act (Stark), prohibits physicians from referring Medicare and Medicaid patients to a healthcare provider for certain "designated health services" (DHS), which include inpatient and outpatient hospital services, whenever a physician, or physician's family member, has a financial relationship with that provider. A financial relationship is any ownership interest or compensation arrangement. This general prohibition does not apply, however, wherever the financial relationship satisfies all the elements of one or more of the "exceptions" or "safe harbors" provided for by the Stark Act and its enabling regulations.

Section 1128B(b) of the Social Security Act, commonly known as the Anti-Kickback Statute (AKS) prohibits payment (or offer or solicitation of payment) or remuneration directly or indirectly in any form to any person in order to induce, in part or in whole, that person to refer for, or order or arrange for, goods or services for which payment may be made under a federal health care program. AKS also prohibits any person from offering or transferring remuneration to any person eligible for benefits under Medicare, Medicaid or other federal health care program that such person knows or should know is likely to influence the person to order services from a particular provider. Section 650 of California's Business and Professions Code contains prohibitions similar to the AKS.

Section 650.01 of California's Business and Professions Code, commonly known as the Physician Ownership and Referral Act (PORA) or the Speier Act, contains prohibitions similar to Stark and AKS but applies to referrals of all patients, and not just beneficiaries of federal healthcare programs.

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Cedars-Sinai will establish, from time to time, written policies and procedures, monitoring processes, and/or targeted training which reflect and reinforce current laws regarding physician referrals. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding physician referrals are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **All contracts and other arrangements with referral sources must comply with all applicable laws.**
- **All agreements with physicians who are in a position to make referrals to Cedars-Sinai entities should be approved by legal counsel prior to execution.**
- **All financial arrangements with physicians with admitting, attending, or consulting privileges, or their family members, must meet the requirements of applicable laws for such financial arrangements.**
- **Physicians with privileges at Cedars-Sinai, and CS Staff, should make referrals only on the basis of the best interest of the patient.**
- **No compensation, gift or gratuity of any kind should be provided in exchange for, or to induce, the referral of patients to Cedars-Sinai, and CS Staff should refrain from soliciting, offering or receiving any payment or remuneration of any kind in exchange for referring or recommending the referral of patients to any hospital, physician, medical facility or other provider or supplier.**
- **Any physician receiving a payment of any kind from Cedars-Sinai should submit invoices or time records detailing the time, date, and type of services provided prior to receiving payment.**
- **All payments to physicians or other sources of referrals should be consistent with fair market value and should not take into account the volume or value of referrals which may be made to Cedars-Sinai entities.**
- **Payments should be made for the recruitment of physicians only when necessary to meet the needs of the community served by Cedars-Sinai.**
- **All physician-related advertising and marketing arrangements should be in writing, and payments should be consistent with fair market value and not be based on the volume or value of referrals or any increase in business as a result of marketing efforts.**

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- **No claims should be submitted to any payor for patients who were referred to Cedars-Sinai pursuant to contracts and financial arrangements that were designed to induce such referrals in violation of federal or state physician-self-referral prohibitions or that violate other laws.**

In addition to the general prohibitions and specific "safe harbors" regarding physician referrals, the OIG, the United States Department of Justice (DOJ), or other federal and state agencies may, from time to time, identify other financial arrangements between physicians and hospitals as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

c. Payments to Reduce or Limit Services: Gainsharing Arrangements

Hospitals and physicians have a common professional responsibility to exercise reasonable stewardship over available medical and healthcare resources. This responsibility involves ensuring that those in need of treatment receive all medically necessary treatment. It also involves ensuring that medically unnecessary treatment, as well as unnecessary costs in the delivery of treatment, be avoided especially in those instances where treatment standards and patient conditions are clearest (i.e., instances of "medical waste"). Current federal law limits, however, the ability of hospitals and physicians to form partnerships in order to address medical waste. Specifically, current federal law prohibits so-called "gainsharing" arrangements, wherein cost savings secured by the elimination of medical waste are shared between hospital and physicians, except in a few limited cases. As necessary, Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and/or targeted training to promote compliance with federal laws regarding "gainsharing" arrangements, to include policies and procedures that may be necessary to ensure Cedars-Sinai's participation in any accountable care organization (ACO), including the Cedars-Sinai Accountable Care, L.L.C. meets the requirements for the waiver of gainsharing, as well as AKS and Stark, restrictions in the operation of the ACO.

Cedars-Sinai policies and procedures from time to time in effect regarding these arrangements are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies may be found in PPM. The following are the guiding principles underlying any such policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

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- **Under no circumstances will Cedars-Sinai direct or incentivize the reduction of medically necessary treatment or services.**
- **Any arrangement with physicians that is intended to cause, or may have the effect of causing, a reduction in medically unnecessary treatment, or unnecessary costs in the delivery of treatment, will comply fully with all laws applicable to such arrangements.**

In addition to the general prohibitions and specific "safe harbors" regarding gainsharing arrangements, the OIG, the DOJ, or other federal and state agencies may, from time to time, identify other financial arrangements between physicians and hospitals as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

d. Emergency Medical Treatment and Active Labor Act (EMTALA)

In response to past abuses by a few hospitals wherein patients were denied treatment because of an inability to pay, federal law was enacted that would ensure needed screening and treatment for patients presenting to emergency departments (or their equivalent) with apparent emergency medical conditions or in active labor.

Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and targeted training to promote compliance with EMTALA and its enabling regulations. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding EMTALA are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **All patients presenting to Cedars-Sinai emergency department, labor and delivery department, or to any facility within 250 yards of the Medical Center's inpatient towers, will be provided with all necessary testing and treatment in order to properly assess the patient's condition and to stabilize and treat as necessary.**
- **Cedars-Sinai will accept all transfers from other facilities provided the transfer is for the purpose of accessing a higher level of care, and Cedars-Sinai has both the capacity and capability to provide the higher level of care.**

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- **Cedars-Sinai will transfer patients to other inpatient facilities only if Cedars-Sinai lacks the capacity and/or capability to provide needed treatment, or the patient requests the transfer and a treating physician determines that the patient is stable to transfer.**

In addition to the general requirements regarding individuals presenting themselves for treatment at the Medical Center, the OIG, CMS, or other federal and state agencies may, from time to time, identify certain emergency care and/or transfer practices as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

e. Substandard Care

Substandard care is a compliance risk, as well as issue for quality improvement and peer review processes. Providing substandard care may indicate a failure to satisfy the conditions of participation for federal healthcare programs (e.g., Medicare). Substandard care may also give rise to false claims risks, in so far as providers may only bill for medically necessary treatment and substandard care is not, by definition, medically necessary treatment.

Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and targeted training to avoid substandard care, and the billing for substandard care. Cedars-Sinai policies and procedures currently and from time to time in effect regarding substandard care are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk:

- **Cedars-Sinai will maintain an effective quality improvement process, as well as an effective peer review process, in order to ensure the highest quality of care for its patients.**
- **Any instances of possible substandard care will be addressed in a timely and effective manner.**
- **Cedars-Sinai will meet all the conditions of participation for federal public healthcare programs.**

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- **Cedars-Sinai will avoid billing for services for which there is not adequate proof that the services meet the standard of care and are medically necessary.**

In addition to the general restrictions regarding providing and/or billing for substandard care, the OIG, CMS, or other federal and state agencies may, from time to time, identify certain treatment delivery practices as associated billing, as risks that are currently of focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

f. Relationships with federal Health Care Beneficiaries

Providing free services or gifts to patients who are beneficiaries of federal healthcare programs may create compliance risks for healthcare providers. Such free services or gifts may be taken as inappropriate inducements to seek treatment from one provider instead of another. Cedars-Sinai joins the federal government in its concern that patients select providers on the basis of the quality of care or the availability of insurance coverage, and not for other reasons.

Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and targeted training to promote compliance with federal law regarding relationships with beneficiaries of federal healthcare programs. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding such relations are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **Cedars-Sinai will provide beneficiaries of federal healthcare programs with only those gifts and gratuities permissible under federal law.**
- **Cedars-Sinai will provide waivers of Medicare copayments and deductibles to beneficiaries of federal healthcare programs only on a case-by-case basis based upon an individual patient's ability to pay. Moreover:**
 - **There should be no routine waivers of copayments and deductibles; and**
 - **Waivers of copayments or deductible amounts for beneficiaries of federal public healthcare programs should not take into account the patient's reason for admission, length of stay, or DRG.**

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- **Cedars-Sinai will provide beneficiaries of federal healthcare programs with free transportation only to the extent and in the manner permissible under federal law.**

In addition to the general restrictions regarding possible inducements for accessing services, the OIG, CMS, or other federal and state agencies may, from time to time, identify certain types of gifts and/or free services as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

g. Billing Medicare or Medicaid Substantially in Excess of Usual Charges

Federal law prohibits hospitals from charging the beneficiaries of federal public healthcare programs substantially more for services than what otherwise might be charged to other payors. While there is no requirement that Cedars-Sinai charge all payors the same amount for its services, federal law does provide that charges to federal public healthcare programs for service to beneficiaries be substantially in line with charges to other providers; i.e., that no charges billed to these programs be substantially in excess of usual charges.

Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and targeted training to promote compliance with federal and state law regarding billing in excess of usual charges. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding such charges are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **Cedars-Sinai will bill for services in excess of usual charges only in those instances where unusual circumstances and/or medical complications requiring additional time, effort, or expense clearly warrant the additional charges.**
- **Changes to Cedars-Sinai chargemaster and billing for outlier payments will be fully justified and well documented.**

In addition to the general restrictions regarding billing in excess of usual charges, the OIG, CMS, or other federal and state agencies may, from time to time, identify certain types

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of charges as risks that are currently of focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

h. Research: Institutional Review Board (IRB) and Grants Administration

Cedars-Sinai has established and maintains a *Research Integrity Program* for the express purpose of addressing and managing specific risks in the areas of IRB administration and research grants management. Cedars-Sinai's *Research Integrity Program* is hereby incorporated by reference into this *Corporate Integrity Program* and will be available through research administration as well as in PPM.

There are, however, certain research-related activities that currently carry significant compliance risks and therefore warrant additional attention in the *Corporate Integrity Program*. These include: conflicts of interests; time and effort reporting; allocating charges to grants; clinical trial billing; and reporting funding support from non-governmental sources.

Cedars-Sinai has established and will establish, from time to time, policies and procedures, monitoring processes, and targeted training to promote compliance with federal requirements for grants administration. Cedars-Sinai's policies and procedures currently and from time to time in effect regarding grants administration are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies may be found in PPM, along with the *Research Integrity Program*. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **Cedars-Sinai will create and maintain effective, compliant processes for the disclosing and managing of outside financial interests that may create conflicts of interests for those conducting human subject and other forms of sponsored research. (Also see below "Industry Relations as a Potential Corporate Integrity Risk".)**
- **Cedars-Sinai will create and maintain effective and accurate processes for the capture, documentation, and certification of time and effort.**
- **Cedars-Sinai will maintain proper accounting and audit processes to ensure research-related costs are correctly charged to grants or other funding sources as appropriate.**

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- Cedars-Sinai will maintain adequate processes and procedures for ensuring that third-party payors, to include federal healthcare programs, are billed only for those services provided in conjunction with human subject research that qualify as standard of care.
- Cedars-Sinai will satisfy all information and disclosure requirements in federal grant applications and in periodic reporting required by federal grant awards.

In addition to the general requirements regarding IRB and research grant administration, the OIG, CMS, the National Institutes of Health (NIH), the federal Food and Drug Administration (FDA), or other federal and state agencies may, from time to time, identify certain types of research issues as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

2. Accountable Care Organization Participation As a Potential Corporate Integrity Risk

Cedars-Sinai Accountable Care, L.L.C. (the ACO), is a California limited liability company that has been formed to participate in the Medicare Shared Savings Program and other governmental and commercial health care programs. The sole member of the ACO is Cedars-Sinai Medical Care Foundation.

Even though the ACO is considered a component of the Cedars-Sinai Health System, the ACO will implement and maintain its own compliance program, which is intended to ensure that the ACO and its participants and agents would not violate any laws governing the conduct of the ACO's business and/or operations. This compliance program endeavors to meet this objective through ongoing policy development, annual and targeted education and training, continuous monitoring, and various reporting mechanisms.

The ACO will be entering into various agreements with health care providers and suppliers (the ACO "Participants") who will all agree to comply with the ACO's compliance program. Cedars-Sinai Medical Center, Cedars-Sinai Medical Care Foundation, and certain CS Staff will themselves function as ACO Participants. In addition to cooperating with and assisting the ACO compliance program, Cedars-Sinai's *Corporate Integrity Program* and the Chief Ethics and Compliance Officer (chief compliance (integrity) officer) will be responsible for ensuring that CS Staff, as well as various Cedars-Sinai operations, in their capacity as ACO

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Participants, are firmly committed to the highest standards of business ethics and to full compliance with ACO-applicable laws, and as such agree to use their best efforts to:

- **Promote and preserve the ACO's Organizational Values: Integrity, Excellence, Teamwork and Collaboration, Respect, Compassion, Innovation, Stewardship, and Diversity.**
- **Safeguard the physical security and privacy of all patient and employee information maintained by the ACO.**
- **Protect the confidentiality of all ACO proprietary information.**
- **Adhere to all ACO policies and procedures.**
- **Adhere to federal and state laws and regulations that apply to ACO operations and practices.**
- **Immediately report any suspected, observed or known violation of policy, regulation, or law specific to ACO operations to the ACO compliance officer.**
- **Promptly disclose all potential conflicts of interests relative to the ACO's own operations, and avoid those ACO-related conflicts that, in the judgment of the ACO, cannot be managed.**
- **Adhere to all applicable professional standards of conduct.**

In addition to the risks associated with various waivers of federal laws and regulations associated with the operations of an ACO, the OIG, CMS, or other federal and state agencies may, from time to time, identify certain types of ACO practices that are currently of focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices, relative to such risks associated with ACO participation, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

3. HIPAA Privacy as a Potential Corporate Integrity Risk

Various federal and state laws, regulations, rules and guidelines govern the use, disclosure and protection of health information. These include certain provisions of the Health Insurance Portability and Accountability Act (HIPAA), certain provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the Confidentiality of Medical Information Act (CMIA), California Health and Safety Code § 1280.15, and any other patient privacy-related laws, regulations, rules and guidelines that currently are and may be enacted or amended from time to time (Privacy laws).

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Cedars-Sinai is dedicated to safeguarding the privacy of Cedars-Sinai patients and protecting the confidentiality of patient information. For this purpose, Cedars-Sinai will establish and maintain a *Patient Privacy Protection Program* for the express purpose of addressing and managing specific risks regarding the use and disclosure of confidential patient information. Cedars-Sinai's *Patient Privacy Protection Program* is hereby incorporated by reference into this *Corporate Integrity Program* and will be available through the Chief Privacy Officer (CPO) as well as in PPM.

In order to minimize the risk that patient privacy may be violated, even inadvertently, Cedars-Sinai will also establish, from time to time, written policies and procedures, monitoring processes, and/or training that reflect and reinforce current federal and state statutes and regulations regarding the use and disclosure of confidential patient information, protection of confidential patient information, and patient privacy rights. Cedars-Sinai policies and procedures currently and from time to time in effect regarding the use and disclosure of confidential patient information, protection of confidential patient information, and patient privacy rights are hereby incorporated by reference into this *Corporate Integrity Program*. Cedars-Sinai Medical Care Foundation may also, from time to time, develop and implement policies and procedures regarding the protection of patient privacy specific to the office and clinic practices managed through the Foundation. All such policies and procedures are hereby incorporated by reference into this *Corporate Integrity Program*, and will be contained within PPM. The following are among the guiding principles underlying the *Corporate Integrity Program*, the *Patient Privacy Protection Program*, and related policies and procedures, as well as monitoring processes for and training on this corporate integrity risk area:

- **Cedars-Sinai will use or disclose confidential patient information ONLY as permitted or required by law, or pursuant to valid written patient authorization.**
 - **Common permitted uses and disclosures that do not require patient authorization are for the purposes of treatment, payment, and health care operations.**
 - **Confidential patient information may also be used without the patient's authorization for, among other purposes, uses and disclosures required by law; public health activities; reporting requirements such as abuse reporting; health oversight activities; judicial and administrative proceedings; law enforcement; organ donation; and workers' compensation.**
 - **Cedars-Sinai will take reasonable steps to limit the use or disclosure of, and requests for, confidential patient information to the minimum necessary to**

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- accomplish the intended purpose. The minimum necessary standard does not apply to uses and disclosures for treatment purposes, to the patient, made pursuant to patient authorization, or when otherwise required by law.
- Use or disclosure of confidential patient information by a CS Staff member in a manner that is not permitted by law is a violation of Cedars-Sinai policy that is subject to disciplinary action.
 - Cedars-Sinai will put in place reasonable and appropriate administrative, technical, and physical safeguards to protect against any uses or disclosures not permitted by law, as well as to limit incidental uses and disclosures that may be secondary to a permissible use or disclosure.
 - Cedars-Sinai will respect, and establish policies and procedures to allow individuals to exercise, individual rights regarding confidential patient information as required by Law.
 - Cedars-Sinai will establish, and make publicly available, a Notice of Privacy Practices, as required by the HIPAA Privacy Rule, to inform individuals of how their protected health information (PHI) may be used and disclosed, and of the individual's rights and Cedars-Sinai's legal duties with respect to PHI.
 - Cedars-Sinai will establish processes to review suspected violations of patient privacy and confidentiality that may be identified through a report, complaint, auditing or monitoring efforts, or other means. If it is determined that a violation of the Privacy laws or Cedars-Sinai policies or procedures has occurred, Cedars-Sinai will take appropriate corrective action and, if applicable, report the violation in accordance with breach notification laws and regulations.

In addition to the general requirements regarding the use and disclosure of confidential patient information, protection of confidential patient information, and patient privacy rights, the HHS Office for Civil Rights or other federal and state agencies may, from time to time, identify certain types of patient privacy issues as risks requiring focused concern. Cedars-Sinai will annually evaluate its own clinical, administrative, operational, and business practices relative to such risks, in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

4. HIPAA Security as a Potential Corporate Integrity Risk

Cedars-Sinai's electronic information and the systems that are associated with its production, storage, processing, and display are assets that are essential to the mission of the organization. These assets include all information that is not generally available to or known by the public, and patient protected health information (PHI) that is governed by federal and

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state statutes. It also may include information that Cedars-Sinai develops, purchases, licenses, or receives from other entities (including vendors, providers, and patients).

Information security refers to safeguarding information and information systems from damage, loss, unauthorized access or unauthorized modification. All types of information, including, but not limited to, patient data, payroll records, personnel files, research data, passwords and access codes, will be maintained and safeguarded to prevent unauthorized disclosures. Such disclosures may occur as the result of stolen computer disks and media, malfunctioning computers, hackers, and human error.

The *Cedars-Sinai Information Security Program* is based on the ISO 17799 Security Standards. However, specific aspects of *Cedars-Sinai Information Security Program* are driven by "Security Standards for the Protection of Electronic Protected Health Information (E PHI)", 45 CFR Part 160 and Part 164, Subparts A and C, commonly known as the "Security Rule," adopted to implement provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Cedars-Sinai will establish, from time to time, written policies and procedures, monitoring processes, and/or targeted training which reflect and reinforce federal and state statutes and regulations regarding protection of electronic health information to supplement policies and procedures that reflect best practices for safeguarding electronic information and information systems. Cedars-Sinai policies and procedures currently and from time to time in effect regarding information security are hereby incorporated by reference into this *Corporate Integrity Program*. Such policies and procedures may be found in PPM. The following are guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **Cedars-Sinai will assign a classification to all information and develop information security policies consistent with the classification. These policies will define standards for the lifecycle (creation, storage, use, and destruction) of all Cedars-Sinai information.**
- **Unless the information is intended for general public use, all information access, use, and disclosure are restricted in accordance with a legitimate need to know or requirement to perform one's normal job function. Additionally, such information will not be inappropriately accessed, shared, or used for any purpose other than its intended use.**

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- A key guiding principle is individual accountability for access to and use of Cedars-Sinai information and its information systems. Each workforce member is issued unique access credentials that will not be shared with others. Any deviations from this guiding principle (e.g., due to operational requirements) must be justified, approved, and documented.
- All of Cedars-Sinai's information systems, including computers, communications systems, magnetic media, e-mail, voice mail, Intranet, and internet access systems, are Cedars-Sinai's property and generally must be used only for legitimate business activities and for the benefit of Cedars-Sinai, and not for personal gain. Limited personal use is allowed as long as such use does not interfere with normal business operations.
- Cedars-Sinai reserves the right periodically to access, read, monitor, inspect and disclose the contents of, postings to and downloads from all of Cedars-Sinai's information systems to the full extent permitted by applicable law, at any time without notice.
- All workforce members are expected to comply with acceptable use standards as detailed in PPM. These standards include limitations on access to inappropriate materials on the internet, respect for intellectual property rights, and inappropriate behavior.
- Cedars-Sinai will maintain and monitor its information systems so as to maintain their confidentiality, integrity and availability of information in accordance with laws, Regulations and Policies.

In addition to the general requirements detailed by the ISO 17799 standards, Cedars-Sinai will periodically evaluate its policies and procedures to ensure compliance with requirements from the OIG, CMS, or other federal and state agencies as they are produced. This will supplement a periodic review of administrative, operational, and business practices in conjunction with the creation of the annual Corporate Integrity Monitoring Work Plan.

5. Public Civil Rights Compliance as a Potential Corporate Integrity Risk

It is the policy of the Cedars-Sinai to ensure compliance with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, Section 1557 of the Patient Protection and Affordable Care Act of 2010, and other related statutes, regulations, executive orders, and directives (collectively, "Public Civil Rights Laws") to the end that no person shall, on the

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grounds of race, color, national origin, disability, age, sex, or other personal characteristic be excluded, denied benefits to, or otherwise discriminated against.

Cedars-Sinai strictly forbids and will not tolerate actions that intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by the Public Civil Rights Laws, or because he/she has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing related to the enforcement of the Public Civil Rights Laws.

In order to minimize the risk of such discrimination, Cedars-Sinai will establish and maintain *Title VI* and *Public Civil Rights Compliance Programs*, tied to and administered through the *Corporate Integrity Program*. Cedars-Sinai will also establish, from time to time, written policies and procedures, monitoring processes, and/or training that reflect and reinforce the Public Civil Rights Laws. Cedars-Sinai policies and procedures currently and from time to time in effect regarding non-discrimination requirements are hereby incorporated by reference into this *Corporate Integrity Program*. All such policies and procedures are hereby incorporated by reference into this *Corporate Integrity Program*, and will be contained within PPM. The following are among the guiding principles underlying the *Corporate Integrity Program*, the *Title VI* and *Public Civil Rights Compliance Programs*, and related policies and procedures, as well as monitoring processes for and training on this corporate integrity risk area:

- **That no person shall on the grounds of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or be otherwise subject to discrimination under any program or activity conducted by Cedars-Sinai regardless of whether those programs and activities are federally funded or not.**
- **That each Cedars-Sinai program, activity, and facility will be conducted and/or operated in compliance with non-discriminatory requirements under all Public Civil Rights Laws; and that Cedars-Sinai will promptly take any measure necessary to effectuate this non-discrimination requirement.**
- **These non-discrimination requirements are binding not only on Cedars-Sinai, but also on any of its recipients, sub-recipients, contractors, subcontractors, transferees, successors in interest, and other participants.**
- **Cedars-Sinai will affirmatively ensure that disadvantaged business enterprises will be afforded full opportunity to submit bids and proposals in response to all**

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invitations and will not be discriminated against on the grounds of race, color, national origin, or sex in consideration for an award.

6. Industry Relations as a Potential Corporate Integrity Risk

Collaborations between Cedars-Sinai, to include individual CS Staff members, and life sciences companies (Industry) are vital to Cedars-Sinai's mission as an academic medical center. Such collaborations bring needed resources into Cedars-Sinai's efforts to advance patient care services, conduct cutting-edge biomedical research, and enhance the education and training of CS Staff. They are also essential to ensure that the scientific advancements achieved by CS Staff find widespread use to the benefit of patients and communities. However, such collaborations may also create for Cedars-Sinai reputational and other risks, if not based on principles that ensure that the collaborations are properly oriented and founded. In this regard, Cedars-Sinai recognizes and endorses the work of the Healthcare Leadership Council's *National Dialogue for Healthcare Innovation* (NDHI) whose consensus statement sets out the following principles for collaborations between academic medicine and Industry:

- **The benefit of patients:** Collaborations at any level, from the research lab to the doctor's office, must aim to benefit patients and put patients' interests first.
- **The autonomy of healthcare professionals:** Healthcare professionals and scientists must be free to assess independently multiple sources of information and treat each patient in a manner consistent with the patient's needs and best medical practice. This is vital to preserve the public's trust in the innovation process and in our healthcare system.
- **Transparency:** Patients and all those involved in healthcare should have reasonable access to relevant and meaningful information about how academic institutions, researchers, healthcare professionals, and medical products companies engage in collaborative relationships. Transparency builds trust between patients and the healthcare professionals who serve them.
- **Accountability:** All participants across healthcare must be responsible for their actions. External regulation is important here, but internal self-regulation with recurrent training and communication is essential to this effort.

Cedars-Sinai will establish, from time to time, policies and procedures, monitoring processes, and targeted training to promote collaborations with Industry based upon these principles. Cedars-Sinai policies and procedures currently and from time to time in effect

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regarding Industry collaborations are hereby incorporated by reference into this *Corporate Integrity Program*. Also incorporated by reference into this *Corporate Integrity Program* are those policies and procedures that address potential conflicts of interest and potential conflicts of commitment that may arise in CS Staff's financial relationships and professional activities with Industry. These may also include policies and procedures addressing Cedars-Sinai own potential (institutional) conflicts of interests. Such policies may be found in PPM. The following are the guiding principles underlying those policies and procedures, as well as monitoring processes for and targeted training on this corporate integrity risk area:

- **Financial interests and/or extramural professional activities with Industry will be disclosed to and tracked by management staff charged with responsibility for overseeing Cedars-Sinai's industry relations.**
- **Full transparency is the standard for those Industry-related financial interests and/or extramural professional activities mostly like to give rise to potential conflicts of interest and potential conflicts of commitment.**
- **Potential conflicts of interest and potential conflicts of commitment are actively managed to resolve, or at least mitigate to the extent possible, the potential conflicts.**
- **Medical-legal consulting, to include but not limited to expert witness services, is subject to the same requirements for disclosures and management as are financial interests and extramural professional activities with Industry.**

7. Other Potential Corporate Integrity Risks

As a general matter, the scope of responsibility for Cedars-Sinai's *Corporate Integrity Program* will be the types of risks and/or issues that may be identified in the OIG's Annual Work Plan, as well as any risk areas identified in federal and state guidance or regulations covering compliance programs for hospitals, physician practices, biomedical research (federally-funded or otherwise), and/or accountable care organization. From time to time, Cedars-Sinai's President and Chief Executive Officer, in consultation with Cedars-Sinai's Board of Directors, may assign the *Corporate Integrity Program* responsibility for risks and/or tasks not otherwise of the type addressed in the OIG's Annual Work Plan or in federal and state guidance on compliance programs. Those risks and/or tasks will also be subject to the oversight described below.

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III. STRUCTURE AND STAFFING OF CORPORATE INTEGRITY PROGRAM**A. Organizational Structure and Placement of Staff With Corporate Integrity-Related Responsibilities****1. Chief Compliance (Integrity) Officer, President and Chief Executive Officer, and Board Of Directors Audit Committee**

Cedars-Sinai will appoint a chief compliance (integrity) officer who will be responsible for the Corporate Integrity Program, and all its component parts, for Cedars-Sinai and all its affiliated entities (except where provided otherwise in the Corporate Integrity Program). The chief compliance (integrity) officer will be a Cedars-Sinai executive with direct access to Cedars-Sinai's President and Chief Executive Officer and, where appropriate, Cedars-Sinai's Medical Care Foundation President and Chief Executive Officer for purposes of reporting on all corporate integrity issues and program matters. The President and Chief Executive Officer, or his or her designee, is responsible to Cedars-Sinai's Board of Directors for administratively supervising the work of the chief compliance (integrity) officer. Under the direction and authority of Cedars-Sinai's President and Chief Executive Officer, the chief compliance (integrity) officer also serves as Cedars-Sinai's public civil rights compliance officer.

Cedars-Sinai Board of Directors is responsible for assuring that Cedars-Sinai implements and maintains an effective corporate integrity program. The Cedars-Sinai Board of Directors, through its Audit Committee, oversees Cedars-Sinai's corporate integrity efforts, receives reports on a regular basis from Cedars-Sinai's President and Chief Executive Officer and/or chief compliance (integrity) officer, concerning implementation and maintenance of the *Corporate Integrity Program*, and takes whatever actions are appropriate and necessary to ensure that Cedars-Sinai conducts its activities in compliance with all applicable laws and the highest standards of business ethics. Minutes of Board meetings are maintained reflecting the reports made to the Board regarding the *Corporate Integrity Program* and the Board's decisions on any corporate integrity issues raised.

2. Management's Responsibility for Corporate Integrity Risks

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In order to maximize efficiency and ensure local management ownership for the monitoring and management of corporate integrity-related risks, the *Corporate Integrity Program* is decentralized in its staffing structure. Executive staff overseeing operations in which corporate integrity-related risk may arise are expected to create, maintain, and appropriately staff corporate integrity functions within their respective areas of responsibility. For example, executive staff overseeing billing (for hospital and/or professional services) will be expected to create, maintain, and appropriately staff a corporate integrity function within those billing services; just as executive staff overseeing research (human subject, animal, and/or bench-science) will be expected to create, maintain, and appropriately staff a research integrity function within the research enterprise. The President and Chief Executive Officer, in consultation with the chief compliance (integrity) officer, will be responsible for designating those members of the executive staff responsible for creating, maintaining, and appropriately staffing, within their respective areas of responsibility, corporate integrity functions.

3. Chief Privacy Officer and Chief Security Officer

Cedars-Sinai will designate and maintain a Chief Privacy Officer (CPO) and assign to the CPO responsibility for implementing and maintaining a *Patient Privacy Protection Program* that meets both federal and state requirements regarding the uses and disclosures of protected health information (PHI). Cedars-Sinai will also designate a Chief Security Officer (CSO) and assign to the CSO responsibility for implementing and maintaining an information technology (IT) security program that meets both federal and state requirements for the security and protection of electronic protected health information (ePHI). The CPO will have a reporting relationship with the chief compliance (integrity) officer in a form to be determined by Cedars-Sinai's President and Chief Executive Officer, in consultation with the chief compliance (integrity) officer. The CSO will also have a reporting relationship with the chief compliance (integrity) officer in a form to be determined by Cedars-Sinai's President and Chief Executive Officer, in consultation with the chief compliance (integrity) officer and the executive responsible for Cedars-Sinai IT services. Finally, Cedars-Sinai Medical Care Foundation may, from time to time, and upon the endorsement of the CPO, appoint a Privacy Officer to manage privacy related policies and procedures within the office practices and clinics managed by the Foundation. The Foundation's Privacy Officer will have a reporting relationship with the CPO in a form to be determined by the Foundation's President and Chief Executive Officer and in consultation with the chief compliance (integrity) officer.

4. Chief Compliance (Integrity) Officer's and Cedars-Sinai's ACO Compliance Officer's Cooperative Roles

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Cedars-Sinai's ACO is required, under federal law, to designate and maintain an ACO compliance officer and assign to the ACO compliance officer responsibility for implementing and maintaining a compliance (Corporate Integrity) program that meets all federal requirements for ACO compliance programs. The ACO compliance officer will have a reporting relationship with the chief compliance (integrity) officer in a form to be determined by Cedars-Sinai's President and Chief Executive Officer, in consultation with the chief compliance (integrity) officer and with the approval of the ACO's Board of Managers. The purpose of this reporting relationship is for the chief compliance (integrity) officer to provide support, guidance, and any necessary assistance to the ACO's compliance officer in the latter's implementation and maintenance of the ACO compliance (Corporate Integrity) program.

5. Chief Compliance (Integrity) Officer's and General Counsel's Cooperative Roles

Cedars-Sinai's Legal Affairs Department supports the role of the chief compliance (integrity) officer through legal opinions and counsel. Cedars-Sinai's General Counsel and/or Legal Affairs Department will be directly available to the chief compliance (integrity) officer in order to provide any legal opinions and/or counsel that the chief compliance (integrity) officer may need in carrying out his or her responsibilities. In internal reviews of or investigations into practices relating to corporate integrity risks, such as those described above, the President and Chief Executive Officer may direct either the chief compliance (integrity) officer or General Counsel to lead the review or investigation. In cases where the Legal Affairs Department leads a review or investigation into corporate integrity-related risks, the chief compliance (integrity) officer may be informed of the investigation and asked to participate as an assistant to the General Counsel in the discretion of the General Counsel. In cases where the chief compliance (integrity) officer leads the review or investigation, the General Counsel or a member of the General Counsel's staff may serve as counsel to the chief compliance (integrity) officer for the investigation. When the Legal Affairs Department conducts internal reviews or investigations or asks the chief compliance (integrity) officer to assist the Legal Affairs Department in such activity, the work product of that activity is intended to be that of the Legal Affairs Department. Reviews or investigations conducted solely by the chief compliance (integrity) officer are intended to be operational in nature and the work product is **not** intended to be attorney work product for purposes of privilege. For additional information on corporate integrity-related investigations see below "*Corrective Action - Violations and Investigations.*"

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B. Specific Responsibilities of the Chief Compliance (Integrity) Officer

The chief compliance (integrity) officer's specific responsibilities include the following:

- Provide executive leadership on all matters relating to corporate integrity risks;
- Oversee the implementation and maintenance of the *Corporate Integrity Program* as described herein;
- Report on a regularly scheduled basis to the President and Chief Executive Officer for the following purposes:
 - To advise on the effective implementation of corporate integrity-related functions by Cedars-Sinai executives whose areas of responsibility contain corporate integrity risks.
 - To provide guidance on the handling of any federal or state investigation or audit relating to corporate integrity risks.
 - To inform on legal and regulatory developments affecting the *Corporate Integrity Program*.
 - To report on any special programs, projects, or initiatives assigned to the chief compliance (integrity) officer by the President and Chief Executive Officer;
- Report on a regular basis to the Audit Committee of the Board, on the progress of the *Corporate Integrity Program*, to include participating in the Audit Committee's executive sessions;
- Create, maintain, and chair a Corporate Integrity Committee comprised of senior staff members, to include staff with corporate integrity responsibilities;
- Develop and implement an annual Corporate Integrity Monitoring function, devoted to tracking corporate integrity risks requiring focused attention;
- Recommend, review and revise, as needed, the *Corporate Integrity Program*, as well as all policies and procedures relating to the *Corporate Integrity Program* in light of changes in the needs of Cedars-Sinai, and in the applicable laws;
- Develop, coordinate, and participate in a multifaceted educational and training program that focuses on the elements of the *Corporate Integrity Program*, in order to ensure that CS Staff are knowledgeable of, and act in compliance with all applicable laws and with the general standards of business ethics;
- Ensure that independent contractors and agents who furnish services to Cedars-Sinai are aware of the *Corporate Integrity Program*;

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- **Ensure that all employees, medical staff members, research personnel, and vendors are screened for excluded provider and/or debarred individuals (or entities) status prior to employment, credentialing, engagement, or provision of services, and regularly thereafter;**
- **Be involved with the development of internal and/or external audit plans that Cedars-Sinai may, from time to time, implement;**
- **Investigate matters related to corporate integrity risks, at the direction of the General Counsel, as may be determined by the President and Chief Executive Officer;**
- **Ensure compliance with policies and/or program initiatives that encourage managers and staff to report suspected non-compliance with applicable laws and/or Cedars-Sinai's policies and procedures without fear of retaliation; and**
- **Implement and maintain Title VI and Public Civil Rights Compliance Programs that satisfy requirements under the Public Civil Rights Laws.**

Subject to applicable legal restrictions the chief compliance (integrity) officer has the authority to access and review all documents and other information that are relevant to the *Corporate Integrity Program*, including, but not limited to patient records, billing records, public relations and marketing records, fundraising records, and all contracts and other written agreements with CS Staff, contracted parties, and other third parties, to include third-party payors. Requests for information and/or records by the chief compliance (integrity) officer will be complied with promptly by CS Staff receiving such requests.

C. Corporate Integrity Committee

Cedars-Sinai has established a Corporate Integrity Committee (CIC) to advise the chief compliance (integrity) officer and assist in the implementation of the *Corporate Integrity Program*. The CIC operates under a charter approved by the President and Chief Executive Officer. The charter specifies the CIC's responsibilities, as well as its membership. The CIC Charter is hereby incorporated into the *Corporate Integrity Program* and is available in PPM.

Principal among its responsibilities is an annual Corporate Integrity Monitoring Plan (Monitoring Plan). The Monitoring Plan identifies specific integrity risks selected for focused attention during each fiscal year. The Monitoring Plan then calls for reports from management staff whose responsibilities include the area in which the integrity risk exists. The CIC then determines whether management's handling of the risk is (i) adequate requiring no additional

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follow-up, (ii) is currently adequate but follow-up continues to be needed by the CIC, or (iii) is inadequate requiring immediate corrective action.

The CIC may also, from time to time, commission and charter subcommittees to address programmatic and risk-related matters requiring ongoing attention. Among these is a subcommittee on HIPAA privacy and security matters and a subcommittee on staff training and education. The chief compliance (integrity) officer approves the charters for subcommittees. Subcommittee charters are herein incorporated into the *Corporate Integrity Program* and are available in PPM.

CIC minutes, to include reports on Monitoring Plan focused risks, are provided to the President and Chief Executive Officer and Chair of the Audit Committee for their review and comment.

IV. TRAINING AND EDUCATION

As part of the *Corporate Integrity Program*, Cedars-Sinai requires CS Staff to attend specific training on a periodic basis, including appropriate training regarding applicable laws, the policies and procedures set forth in the *Corporate Integrity Program*, and in business ethics. The training sessions emphasize Cedars-Sinai's commitment to compliance with all applicable laws as well as the general standards of business ethics. New employees are targeted for training early in their employment.

These training programs include, but are not limited to, sessions highlighting the corporate integrity risks of the type highlighted above. All formal training undertaken as part of the *Corporate Integrity Program* is documented by responsible management staff. A variety of teaching methods are employed, such as interactive training, so that all affected CS Staff are knowledgeable of the required standards of conduct, as well as the policies and procedures for alerting senior management to integrity-related problems and concerns.

The chief compliance (integrity) officer, in consultation with the CIC and its subcommittee on training, will periodically develop, implement, and monitor training requirements for CS Staff, as well as for other individuals in regards to whom Cedars-Sinai has a regulatory or similar responsibility for compliance training. The chief compliance (integrity) officer, in consultation with respective executive overseeing corporate integrity functions will also develop, implement, and monitor, as needed, training targeted at specific integrity risks. Attendance and participation in targeted training programs may also affect a CS Staff member's annual performance

POLICY



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Document Owner: Ginny Kim (Vice President)

Home Department: Corporate Integrity Program

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evaluation. Cedars-Sinai's compliance training will meet all applicable regulatory requirements in terms of timing, frequency, and content.

The above corporate integrity training is in addition to any periodic professional education courses that may be required by statute and regulation for certain personnel. Cedars-Sinai expects that CS Staff will comply with such education requirements, and the failure to do so may result in some form of adverse employment action.

V. LINES OF COMMUNICATION

A. Access to the Chief Compliance (integrity) Officer

Cedars-Sinai recognizes that clear and open lines of communication between the chief compliance (integrity) officer and CS Staff are important to the successful implementation of the *Corporate Integrity Program*. To that end, written confidentiality and non-retaliation policies and procedures will be established, from time to time, to encourage communication and the reporting of incidents of potential non-compliance with the *Corporate Integrity Program*. Any CS Staff member may contact the chief compliance (integrity) officer or any member of the CIC at any time to report concerns or to seek clarification on matters relating to the *Corporate Integrity Program*.

Information about the *Corporate Integrity Program*, its policies and procedures, and department contacts can be found on the Cedars-Sinai intranet; to include the current locations of the Program's offices and the office of the chief compliance (integrity) officer. The Program's and chief compliance (integrity) officer's phone and email contact information are also available on Cedars-Sinai intranet website.

B. Hotline And Post Office Address

Cedars-Sinai has established the following toll-free integrity hotline and *Corporate Integrity Program* post office address, so that employees have every opportunity to report concerns or possible wrongdoing regarding corporate integrity issues:

Hotline Telephone Number: 1-800-233-2775 (1-800-CEDARS5)

Post Office Address: Corporate Integrity Program
Cedars-Sinai Medical Center

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8700 Beverly Boulevard
Los Angeles, California 90048

Calls to the hotline will be treated confidentially, and will not be traced. If the caller desires, the caller need not provide his or her name. Similarly, written communications to the *Corporate Integrity Program* post office address will be handled confidentially, and the author need not provide his or her name.

Communications via the hotline, or post office address will be treated as privileged to the extent permitted by applicable law; however, it is possible that at some point the identity of a person making a report may become known, or that governmental authorities or a court may compel disclosure of the reporting person.

Matters reported through the hotline or post office address that suggest violations of policies or procedures, or regulations or statutes, will be documented and investigated promptly to determine their veracity. A log is maintained by the chief compliance (integrity) officer that records such calls or communications, including the nature of any investigation and its results. A summary of such information is reported periodically by the chief compliance (integrity) officer to the Corporate Integrity Committee, the President and Chief Executive Officer, and the Audit Committee.

It is Cedars-Sinai's policy to prohibit any retaliatory action against a CS Staff member for making a hotline call or written report regarding any integrity-related risk. However, CS Staff may not use the hotline or post office box in an effort to insulate themselves from the consequences of their own wrongdoing or misconduct. It will be considered a mitigating factor that a CS Staff member makes a forthright disclosure of an error made by that CS Staff member. In no event will the sanction be increased because a CS Staff member has chosen to report improper conduct committed by that same CS Staff member.

Nothing contained in this *Corporate Integrity Program* should be interpreted to mean that CS Staff are prevented or discouraged from reporting concerns or possible wrongdoing to the government or to any other responsible agency. CS Staff making such reports are protected from retaliation, just like CS Staff members who internally make such reports.

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VI. ENFORCING STANDARDS, POLICIES AND PROCEDURES

A. Discipline Policy And Actions

Cedars-Sinai will establish, from time to time, policies and procedures to ensure timely, consistent, and effective disciplinary action for CS Staff who have failed to comply with applicable laws, CSHS policies and procedures, and/or the general standards of business ethics.

The guiding principles underlying these disciplinary policies and procedures are the following:

- **Intentional or reckless noncompliance should subject transgressors to significant sanctions, which could range from permanent written warnings to suspension, to privilege revocation where applicable (subject to any applicable peer review procedures), and to termination;**
- **Negligent noncompliance should also result in similarly appropriate sanctions;**
- **Disciplinary action should also be taken where a responsible CS Staff member fails to detect a violation and that failure is attributable to his or her negligence or reckless conduct;**
- **Disciplinary action must always be taken on a fair and equitable basis;**
- **All levels of CS Staff are subject to the same disciplinary action for the commission of similar offenses;**
- **In determining disciplinary actions, consideration will be given to the systems and processes that contributed to the identified problem.**

B. New CS Staff Members

For all CS Staff members who have discretionary authority to make decisions that may involve compliance with the law or who have responsibility for any *Corporate Integrity Program* function, Cedars-Sinai conducts appropriate background investigation, including a reference check, as part of every such employment application. The employment application specifically requires the applicant to disclose any criminal conviction or action to exclude that individual from participation in any federal healthcare program. It is Cedars-

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Sinai's policy not to employ individuals who have been convicted of a criminal offense related to health care, or who are listed by a federal agency as debarred, excluded or otherwise ineligible for participation in federal health care programs. In addition, pending the resolution of any criminal charges or proposed debarment or exclusion of a current employee, that CS Staff member will be removed from direct responsibility for or involvement in any federal health care program.

Further, the execution of contracts with companies that have been convicted, in a court of law, of a criminal offense related to health care within the past 10 years, or that are currently listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federal health care programs, is prohibited. With regard to either current employees or independent contractors, if the resolution of any matter under investigation by federal or state authorities results in conviction, debarment or exclusion, it is Cedars-Sinai's policy to terminate its employment or other contract arrangement with the individual or contractor involved.

C. Corporate Integrity as an Element of Performance

The promotion of, and adherence to, the elements of this *Corporate Integrity Program* is a factor in evaluating the performance of Cedars-Sinai's management staff members and other employees. Management staff members will be periodically trained regarding the *Corporate Integrity Program*, and new compliance policies and procedures that are established. In particular, all management staff members are required to comply with the following:

- **Discuss with all supervised personnel, to include all contractors and agents, the corporate integrity risks set forth in this *Corporate Integrity Program* which are applicable to their function;**
- **Inform all supervised personnel that strict compliance with this *Corporate Integrity Program Plan* is a condition of continued employment; and**
- **Disclose to all supervised personnel that disciplinary action will be taken, up to and including termination or revocation of employment, for violation of this *Corporate Integrity Program*.**

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Management staff members will be sanctioned for failure to adequately instruct their subordinates, or for failing to detect noncompliance with applicable components of the *Corporate Integrity Program*, where reasonable diligence on the part of the management staff member would have led to the discovery of a problem or violation and provided Cedars-Sinai with the opportunity to take corrective action earlier.

VII. MONITORING

In addition to the annual Corporate Integrity Monitoring Plan, overseen by the CIC and separate from Cedars-Sinai Audit Plan conducted by Internal Audit, the chief compliance (integrity) officer may, from time to time, employ the services of auditors who have expertise in federal and state health care statutes, regulations and federal health care program requirements. These audits may focus on specific programs, departments, service lines, and/or institutes, including external relationships with third-party contractors, with particular attention to those programs, departments, service lines, and/or institutes with substantive exposure to government enforcement actions. Such *Corporate Integrity Program* audits are designed to address, among other possibilities, compliance with laws governing kickback arrangements, physician self-referrals, coding, claim development and submission, reimbursement, cost reporting, and research. In addition, the audits may also inquire into compliance with specific rules and policies that have been the focus of particular attention on the part of the Medicare contractors and law enforcement agencies, as evidenced by fraud alerts, federal audits and evaluations, and law enforcement initiatives.

The chief compliance (integrity) officer determines the appropriate follow-up to *Corporate Integrity Program* audits to include whether the findings of any such *Corporate Integrity Program* audits warrant reporting to the President and Chief Executive Officer, and/or the Audit Committee of Cedars-Sinai Board of Directors.

VIII. CORRECTIVE ACTION

A. Violations and Investigations

Violations of the *Corporate Integrity Program*, failures to comply with applicable federal or state law, and other types of misconduct threaten Cedars-Sinai's status as a reliable, honest and trustworthy provider capable of participating in federal health care programs. Detected but uncorrected misconduct can seriously endanger Cedars-Sinai's mission, reputation, tax-exempt status and participation in federal health care programs. Consequently, upon reports or

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reasonable indications of suspected noncompliance, timely, consistent, and effective steps to investigate the conduct in question will be initiated to determine whether a material violation of applicable law or the requirements of the *Corporate Integrity Program* has occurred. If such a violation has occurred, prompt steps will be taken to correct the problem. Appropriate reporting to external agencies shall be made as required by law. The specific steps that are appropriate in a given case will be determined after consultation with legal counsel.

Depending upon the nature of the alleged violations, the internal investigation could include interviews with relevant staff and a review of relevant documents. Outside legal counsel, auditors, or health care experts may also be engaged to assist in an investigation where such assistance is deemed appropriate. Complete records of all investigations will be maintained, which contain documentation of the alleged violations, a description of the investigative process, copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation, e.g., any disciplinary action taken, and the corrective action implemented. While any action taken as the result of an investigation will necessarily vary depending upon the situation, Cedars-Sinai intends to strive for consistency by utilizing sound practices and disciplinary protocols. Further, after a reasonable period, the chief compliance (integrity) officer will review the circumstances that formed the basis for the investigation to determine whether similar problems may occur elsewhere in the organization.

If an investigation of an alleged violation is undertaken and the chief compliance (integrity) officer and/or General Counsel believes the integrity of the investigation may be at stake because of the presence of specific CS Staff members under investigation, the chief compliance (integrity) officer and/or General Counsel may recommend to the President and Chief Executive Officer that those subjects be removed from their current work activity until the investigation is completed. In addition, where necessary the chief compliance (integrity) officer and/or General Counsel will take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation. If it is determined that disciplinary action is warranted, it will be prompt and imposed in accordance with the written standards of disciplinary action. As a part of the investigation, a review of systems and processes that may have contributed to the violation will be conducted so that changes can be made to prevent such occurrences in the future.

B. Reporting

If the chief compliance (integrity) officer discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct violates criminal, civil or

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administrative law, then the existence of the misconduct will be promptly reported to the President and Chief Executive Officer for investigation. If the misconduct involves a member of Cedars-Sinai executive staff, the existence of the misconduct will also be reported to the Audit Committee of Cedars-Sinai Board of Directors. All such misconduct which is confirmed to be violative of laws shall be reported to the appropriate governmental authority as required by law. Additionally, compliance concerns and suspected or actual violations related to the Medicare program shall be reported to applicable health plans, as required.

IX. SPECIAL NOTICE TO CS STAFF ON IDENTIFYING AND REPORTING HEALTHCARE FRAUD

A. Introduction

This is a special notice that Cedars-Sinai is required, under law, to provide to CS staff members. Federal and state regulatory agencies have an important interest in detecting and eliminating health care fraud. That effort is enhanced when health care workers understand what constitutes health care fraud and how they can report the fraud.

Cedars-Sinai has a robust *Corporate Integrity Program* that is designed to prevent violations of applicable law and to provide employees with a means of reporting concerns. This notice supplements the *Cedars-Sinai Corporate Integrity Program*.

Cedars-Sinai joins with federal and state authorities in a concern over the detection and prevention of healthcare fraud. Fraud and abuse laws prohibit anyone from knowingly and willfully offering, paying, soliciting or receiving any money, gifts, kickbacks, rebates or any other type of value, remuneration or service in return for the referral of patients or to induce the purchase, lease or ordering of any item, good or service for which payment may be made by the federal or state government. Examples of fraud and abuse can include: (i) payment of an incentive each time a patient is referred to a health care provider; (ii) provision or receipt of free or significantly discounted hospital inpatient/outpatient services, billing, nursing care or rent (this would not include negotiated managed care contracts, discounts disclosed in the claim, or pursuant to charity care and financial assistance accommodations); (iii) payment for services in excess of their fair market value; and (iv) forgiveness of indebtedness absent a charitable or risk management purpose.

In addition, Cedars-Sinai strives to maintain honesty and accurate records in compliance with all state and federal False Claims Acts. The False Claims Acts are an important part of preventing and detecting fraud, waste, and abuse in federal and state health care programs

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because they provide governmental agencies with the authority to investigate and prosecute fraudulent activities. The state and federal False Claims laws described below summarize some of the major laws that provide liability for false claims and statements. This summary is not intended to identify all applicable laws, but rather to outline some of the major statutory provisions.

B. Federal False Claims Act

A health care provider can be liable under the federal False Claims Act (FCA) if the provider improperly receives money from the federal government or avoids payment to the federal government. The FCA prohibits many activities, but is often used as an enforcement tool to prevent Medicare/Medi-Cal fraud. The FCA prohibits, among other things, *knowingly* filing a false or fraudulent claim for payment to Medicare, Medi-Cal or another federally funded health care program, or using a false record or statement in order to obtain payment from one or more of these programs, as well as making or using a false record or statement to get a false claim paid or approved by the government. "Knowingly," as used in the FCA, means having actual knowledge that the claim is false, or acting with ignorance or reckless disregard as to whether a claim is true or false. A false claim can include any of the following actions, all of which are prohibited by the Medical Center and the terms of its *Corporate Integrity Program*:

- **Billing for supplies or services not delivered or delivered in less than promised amounts.**
- **Misrepresenting or overcharging for products or services actually provided.**
- **Double billing for services rendered (this would not include follow-up bills or bills used in the course of obtaining payment for services).**
- **Falsely certifying that services were medically necessary.**
- **Falsely certifying that an individual meets the Medicare or Medi-Cal requirements for certain services.**
- **Improperly billing procedures such as "upcoding" (changing a procedure code in order to obtain higher reimbursement for the procedure actually performed), or "unbundling" (dividing a procedure or service into two or more parts for the purpose of obtaining higher reimbursement).**
- **Offering money, gifts, or other items of value to a person/entity in order to receive that person's/entity's business.**

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- **Accepting money, gifts, or other items of value from a private party (except in accordance with Cedars-Sinai's policies and procedures on gifts).**
- **Underpaying money owed to the government.**

The U. S. Attorney General is the agency that initiates most civil actions under the FCA, but anyone who comes forward with information regarding false claims is authorized to file an FCA case in federal court and sue, on behalf of the government, those persons/entities involved in the fraud. These are called "qui tam" lawsuits. A person who brings a "qui tam" lawsuit is called a "relator/whistleblower." Once a lawsuit is filed by a relator/whistleblower, the government then decides whether to join with the relator/whistleblower in prosecuting the case. If the case is successful, a relator/whistleblower may share in the recovery amount. The amount of the relator's/whistleblower's share in the recovery depends on multiple factors.

C. California False Claim laws

The California false claims act covers similar types of activities as described under the FCA, but this law applies to false claims that are submitted to the state, city, city/county or any other political subdivision of the state. Violations of the California false claims act are usually initiated by the Attorney General, but like the FCA, individual "qui tam" relators/whistleblowers can bring civil actions in the name of the state and if successful, can receive a percentage of the proceeds of the action or settlement, plus reasonable expenses, costs and attorneys' fees.

The California Penal Code contains laws that make it a misdemeanor or felony, depending on the amount of the fraud, for knowingly preparing or using any writing with the intent to use it in support of a false or fraudulent claim, as well as knowingly making any false or fraudulent claim for health care benefits. Penalties under the Penal code include jail time, fines and prison.

D. Policy Against Retaliation

CS Staff members who observe activities or behavior that may violate the law in some manner and who report their observations either to management or to governmental agencies are provided protection from retaliation by their employers under certain laws and under Cedars-Sinai policy. For example, if an individual files a qui tam lawsuit under the FCA, he/she is entitled to recover damages if he/she is discharged, demoted, suspended, or discriminated against by his/her employer in retaliation for filing the false claims case. In order to recover damages for retaliation by an employer, the courts generally require the following:

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- **The employee must have been involved in an activity protected by the FCA in furtherance of a qui tam suit;**
- **The employer must have known of the employee's protected activity; and**
- **The employer must have retaliated or discriminated against the employee because of those actions.**

If a court determines that a relator/whistleblower was terminated or otherwise retaliated against for filing a qui tam lawsuit, the employee is entitled to reinstatement at the same level, and two times the back pay owed, plus interest, litigation costs and reasonable attorneys' fees and compensation for any "special damages" sustained as a result of the discrimination.

While there are many state laws that prohibit retaliation, both the California Government and Labor Codes generally prohibit employers from retaliating against employees who disclose information to a government or law enforcement agency where the employee has reason to believe that information discloses a violation of state or federal law or regulation or is in furtherance of a false claims action.

Consistent with these laws, Cedars-Sinai prohibits the discharge, threatening, harassing, demotion, suspension or other discrimination or retaliation against any employee for:

- **Disclosing information to a member of management, human resources, the Chief Ethics and Compliance Officer or any government or law enforcement agency, that the employee reasonably believes discloses a violation or failure to comply with state or federal laws, rules or regulations;**
- **Acting as a relator/whistleblower;**
- **Initiating, assisting or cooperating with a Cedars-Sinai or, government or law enforcement investigation or proceeding relating to the care, services or conditions, or operations of Cedars-Sinai; or**
- **Refusing to engage in conduct that would violate or fail to comply with state or federal laws, rules or regulations.**

Employees are protected from retaliation, even if they engaged in this legally protected conduct at a previous employer.

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All concerns regarding retaliation should be immediately reported by Cedars-Sinai employees to one of the following:

- **Manager, director, or other individual in their line management;**
- **Director of Human Resources Compliance;**
- **Chief Compliance (Integrity) Officer; or**
- **Corporate Integrity 'hotline' or post office address (both of which can be used for anonymous reporting).**

As stated above, employees who engage in the protected activities described in this policy are protected from retaliation based upon those activities. However, employees should not expect to use the complaint procedure set forth in this policy as a means of avoiding discipline for matters that are unrelated to any protected activity.

E. Corporate Integrity Hotline and Attorney General Hotline

Cedars-Sinai encourages CS Staff to use its Corporate Integrity hotline (800-233-2775), which allows anonymous reporting of suspected unlawful and fraudulent activity. Employees may also report suspected unlawful activity and/or retaliation against them for legally protected conduct to any governmental agency, including the California Attorney General's Whistleblower Hotline at 1 (800) 952-5225. [Also see *Reporting of Compliance Concerns* and *Non-Retaliation Policy*, which can be found in PPM.]

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X. RECORD KEEPING

All records related to compliance with the *Corporate Integrity Program* will be maintained for ten (10) years. This includes documentation of required trainings, as well as investigations and reporting of violations of the *Corporate Integrity Program*, failures to comply with applicable federal or state law, and other types of misconduct.

XI. APPROVALS, EFFECTIVE DATE, AND ENDORSEMENTS

Program Author: Ginny Kim
Vice President, Corporate Integrity Program

Program Approval: Thomas M. Priselac
CSHS President and Chief Executive Officer

Board of Directors

Program Effective Date: **July 1, 2013**