TULANE UNIVERSITY MEDICAL GROUP

INTERIM HEALTH CARE COMPLIANCE POLICY

AUGUST 22, 2007
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HEALTH CARE COMPLIANCE POLICY MANUAL

PART I - CODE OF CONDUCT

Patient care services provided by the clinical faculty and other providers employed by the clinical departments of the Tulane University (the “University”) School of Medicine are delivered through, and billed by, the Tulane University Medical Group (“TUMG”). It is TUMG’s policy to provide services and conduct its operations in compliance with all state and federal laws and consistent with the highest standards of business and professional ethics and to carry out our activities with honesty, integrity, and diligence. TUMG recognizes that its physicians and other clinicians provide services in a highly regulated health care environment and that TUMG, as a faculty group practice, has a special responsibility to teach and train new physicians who understand the legal responsibilities of physicians in connection with the delivery of high quality care.

To assist with its compliance effort, TUMG has established this Code of Conduct and Interim Health Care Compliance Policy Manual (the “Policy Manual”) to provide TUMG physicians, clinicians and staff with an overview of the Compliance Program. This Code of Conduct and Policy Manual applies to all members of the TUMG community including the TUMG governing board, physicians, other clinicians, administrative and support staff as well as volunteers, contractors, vendors and agents.

TUMG’s continued ability to operate and fulfill its various missions depends upon each physician and staff member’s dedication to compliance. It is the obligation of every member of the TUMG community to help TUMG maintain its high standards of professional practice by reporting any actual, apparent or potential violation of law, regulation or policy.

The Policy Manual includes an overview of health care compliance policies to which all TUMG physicians, clinicians and staff, vendors, contractors and agents are expected to adhere. The Policy Manual is intended to supplement and not supersede existing University compliance policies including, without limitation, University conflicts of interest, harassment and fraud in research policies. TUMG physicians and clinicians also are expected to adhere to compliance initiatives established by Tulane University Hospital and Clinic (“TUHC”) and other affiliated teaching hospitals, as well as by certain community hospitals and health care facilities where they hold medical staff privileges or to which they provide administrative or clinical services.

PART II - THE TUMG COMPLIANCE PROGRAM

1. Clinical Compliance Operations Committee (“Clinical Compliance Committee”)

The Clinical Compliance Committee has direct responsibility for implementing and overseeing the annual TUMG Compliance Workplan. The Clinical Compliance Committee is chaired by the TUMG Compliance Officer. The Clinical Compliance Committee is one of three compliance operations committees that report to the University Compliance Steering Committee.
which, in turn, reports through the Chief Financial Officer to the University President and the University Audit Committee of the Board of Trustees. The Clinical Compliance Committee also reports to the TUMG Governing Board. An attorney from the Office of the General Counsel assigned to the Health Sciences Center serves as counsel to the Clinical Compliance Committee. The Clinical Compliance Committee consists of both a physician leadership group and a working group whose representatives include the TUMG Medical Director, the HIPAA Privacy Officer, the HIPAA Security Officer, and business office representatives. See Appendix 1 for a description of the University compliance program structure. See Appendix 2 for a list of key compliance contacts.

In addition to its general oversight responsibilities, the Clinical Compliance Committee's areas of responsibility include HIPAA compliance, anti-kickback and Stark issues, physician billing, industry relationships, physician/hospital financial arrangements, and physician outreach arrangements. The Clinical Compliance Committee's charge includes the development of compliance policies, education and training, the identification of internal audit priorities and risk areas based on the annual HHS OIG Work Plan, and making recommendations for an annual compliance plan. The Clinical Compliance Committee oversees responses to external billing audits. The Clinical Compliance Committee also coordinates implementation of the TUMG Compliance Plan at the TUMG departmental level, including physician training, by working with TUMG departmental liaisons. The Clinical Compliance Committee provides regular reports of its activities to the Steering Committee and to the TUMG Governing Board. In addition, the Clinical Compliance Committee maintains and monitors the compliance hotline described in Section 2 below. Finally, the Clinical Compliance Committee monitors and reviews the annual physician compliance credits program administered by TUMG.

http://www.tulane.edu/%7Econtract/index.html

2. Reporting Suspected Compliance Problems/Protection of Whistleblowers

TUMG engages in specific compliance efforts to detect and prevent regulatory noncompliance. Despite the best efforts of each individual associated with TUMG to comply with TUMG policies and applicable laws, inevitably there will be questions about the propriety of certain conduct or practices. Accordingly, TUMG makes it a part of the duty of all TUMG physicians, clinicians and staff to notify it of any actual, apparent, or potential compliance violations. Any good-faith report of a suspected compliance violation may be made without fear of retaliation. Reports may be made anonymously, and all persons making such reports are assured that they will be treated with appropriate confidentiality. Reports will be shared only on a bona fide need-to-know basis.

A reporting system exists at TUMG that allows any member of the TUMG community to ask a question about a compliance issue or to report a good-faith suspicion of a compliance violation to one’s supervisor, program director, or department chair, and/or to the Compliance Officer, the Office of the General Counsel, the Compliance Inquiry Line “hotline” at (504) 862-8698. In addition, information on the hotline and reporting any potential improprieties can be found at http://www.tulane.edu/%7Eaudit/hotline.shtml.
Retaliation against any TUMG physician, clinician or staff member making a good-faith report of suspicion of noncompliance to TUMG, or cooperating in the investigation of such reports, is prohibited. The federal and state laws contain protections for “whistleblowers” who alert the appropriate governmental authority of a violation of the false claims acts. Under these laws, any person with actual knowledge of an allegedly false claim, including employees, agents and contractors, may, under certain conditions, become a whistleblower under these statutes and is free to notify the appropriate state or federal governmental authorities if he/she does not believe that TUMG is responding appropriately when notified about potential violations. TUMG is prohibited from taking adverse or retaliatory action against a whistleblower who in good faith notifies the appropriate governmental authority of an alleged violation. Whistleblowers may also be entitled to relief, including employment reinstatement, back pay, and other compensation arising from retaliatory conduct against him or her.

Any TUMG physician, clinician or staff member who feels that he or she is being retaliated against, demoted, suspended, threatened or harassed by TUMG for reporting a suspected violation should contact the Compliance Officer immediately, and any TUMG physician, clinician or staff member who commits or condones any form of retaliation will be subject to sanctions. However, any TUMG physician, clinician or staff member who intentionally and maliciously misuses the reporting system to make false allegations against any person will be subject to disciplinary actions.

3. **Background Checks**

TUMG does not knowingly employ, engage or delegate authority to individuals who have criminal propensities or who are listed by a federal agency as debarred, suspended or otherwise ineligible to participate in federal programs. Accordingly, the University and TUMG conducts background checks on the status of current and potential staff, consultants, and contractors.

4. **Corrective Action**

In the event of non-compliant behavior by a TUMG physician or staff member, the Clinical Compliance Committee will recommend an individual remediation program to correct the problem. If noncompliant behavior continues after completion of the remediation program, the Clinical Compliance Committee will recommend sanctions to the TUMG Governing Board and the University Compliance Steering Committee.

5. **Compliance Review**

5.01. **Internal Review**

The Compliance Officer, in consultation with the Clinical Compliance Committee and The Office of the General Counsel, will periodically review TUMG’s compliance with state and federal regulatory requirements and TUMG policies and procedures. The Compliance Officer will report any significant findings to the Clinical Compliance Committee, the TUMG Governing Board and University Compliance Steering Committee. TUMG also routinely reviews financial relationships between TUMG and its members, vendors, contractors, or agents.
5.02. External Review

TUMG will consider retaining independent audits of selected areas of compliance. Any such audit will be performed as an adjunct to legal advice and will be maintained in a confidential manner.

PART III - SELECTED RISK AREAS

Please direct any compliance questions or concerns regarding the following matters to the Compliance Officer, members of the Clinical Compliance Operations Committee or the General Counsel's Office. To the extent possible, questions concerning the propriety of a course of action or the correct application of a stated policy should be communicated promptly to one’s supervisor before taking additional action.

Penalties for failure to comply with certain of the laws mentioned below include civil monetary penalties, criminal penalties and suspension from participation in Medicare, Medicaid, or other federal health care programs.

1. Coding, Billing and Claims

When claiming payment for professional services, TUMG physicians, clinicians and staff have an obligation to patients, third party payors including managed care plans, and the state and federal governments, to exercise diligence, care, and integrity. TUMG is committed to maintaining the accuracy of every claim it processes and submits. All of the data elements that must be included in submissions for reimbursement from Medicare, Medicaid, and other federal health care programs must be accurate. In addition, TUMG must comply with federal and state antitrust laws when negotiating payment rates with third party payors.

Federal law defines a “false claim” as knowingly presenting false or fraudulent claims for payment or making or using a false record or statement to receive payment for a claim. “Knowingly” under this law includes acting with deliberate ignorance or reckless disregard for the truth or falsity of the information in the claim. Louisiana law defines a “false or fraudulent claim” as a claim that a health care provider (or his agent) submits knowing the claim to be false, fictitious, untrue, or misleading in regard to any material information. Examples of false claims include:

- Billing for services not rendered
- Falsifying certificates of medical necessity
- Falsifying medical records
- Filing duplicate claims
- “Upcoding” to more complex procedures than were actually performed
- Falsely indicating that a particular health care professional attended a procedure
• Unbundling groups of tests or procedures
• Billing for services that are provided on the basis of a prohibited referral
• Billing excessive charges
• Failure to designate site of service

2. Reasonable and Necessary Services

Medicare and other government health benefit programs condition payment for many services on the treating physician’s certification that he or she has reviewed the patient’s condition and has determined that the service is reasonable and necessary. Medicare primarily relies on the professional judgment of the treating physician, so it is important that physicians provide complete and accurate information on any certifications they sign. Physician certification is obtained through a variety of forms, including prescriptions, orders, and Certificates of Medical Necessity (“CMNs”). By signing a CMN, a physician makes several representations, including: (1) he or she is the patient’s treating physician; (2) the entire CMN was completed prior to the physician’s signature; and (3) information relating to whether the service is reasonable and necessary is true, accurate, and complete to the best of the physician’s knowledge. Physicians who sign CMNs either knowing they are false or disregarding whether they are true or false may be subjecting themselves and/or TUMG to criminal, civil and administrative penalties. Activities such as signing blank CMNs, signing a CMN without seeing the patient, or signing a CMN for a service that the physician knows is not reasonable and necessary are not permitted.

3. Record-Keeping and Retention

TUMG maintains and retains numerous different types of records concerning nearly every aspect of TUMG’s operations. Particularly important is the proper maintenance of records concerning patient treatment. Proper record-keeping is necessary not only to comply with state and federal law and to permit proper reimbursement of services, but also to ensure proper medical treatment for patients of TUMG in the future.

Each TUMG physician and clinician must comply with the following Louisiana rules related to record-keeping in order to maintain and renew his or her license to practice medicine. Each physician must maintain patient records in their original form for a period of six years from the date of last treatment. And each physician must document, as appropriate, the evaluation and treatment of the patient. For TUMG operated clinics or programs, TUMG must maintain patient records in their original form for a period of six years from the date of last treatment. Medicare, Medicaid and third party payors may impose longer record retention requirements as a condition of physician participation.

4. Documentation

A key factor in accurate billing is the proper (i.e., accurate and complete) documentation of medical records. In general, all TUMG medical records must document the medical necessity of services rendered. Specifically, TUMG medical records must meet the following criteria:
• Record is complete and legible;

• Record documents each patient encounter, including: the reason for the encounter; any relevant history; physical examination findings; prior diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; date; and legible identity of the observer;

• Record includes a statement of the rationale for ordering diagnostic and other ancillary services, unless such rationale easily can be inferred by an independent reviewer or third party with appropriate medical training;

• Record identifies appropriate health risk factors, the patient’s progress, his or her response to, and any changes in, treatment, and any revision in diagnosis; and

• Record supports CPT and ICD 9 CM codes used for claims submission.

TUMG physicians or staff who become aware of any billing problems should report the matter to their supervisor or the Compliance Officer immediately.

5. Patient Referrals/Payments, Discounts and Gifts

5.01. Patient Referrals

TUMG’s policy with respect to patient referrals is that patients, or their legal representatives, are free to select their health care providers and suppliers subject to the requirements of their health insurance plans. The choice of a provider, diagnostic facility, or supplier should be made by the patient, with guidance from his or her physician as to which providers are qualified and medically appropriate.

TUMG recognizes that TUMG physicians may have financial relationships with health care entities that may be in a position to generate referrals to TUMG. These financial relationships may include compensation for administrative or management services, income guarantees, loans of certain types, or free or subsidized administrative services. In some cases, a physician may have invested as a part-owner in a piece of diagnostic equipment or a health care facility. These sorts of financial relationships raise issues under federal and state laws, including the physician self-referral laws and anti-kickback laws.

Due to the complexities involved, all compensation arrangements with outside entities must be reviewed and approved in accordance with the TUMG contracting guidelines for professional services. [http://www.tulane.edu/~contract/HIPAAccm.html](http://www.tulane.edu/~contract/HIPAAccm.html)

5.02. Prohibition Against Payment for Referrals

Federal law makes it illegal for TUMG to provide or accept “remuneration” (in other words, anything of value) in exchange for referrals of patients covered by federal health care programs, which include Medicare and Medicaid. Federal and state fraud and abuse laws prohibit TUMG and its representatives from knowingly and willfully soliciting, receiving,
offering or paying, any remuneration, directly or indirectly, in return for the referral of patients or other business that may be reimbursed by a third party payor. The law also bars paying or receiving remuneration in return for purchasing, leasing, ordering, arranging for, or recommending purchasing, leasing, or ordering of any goods, facilities, services, or items for which payment may be made under Medicare or Medicaid.

5.03. Entertainment and Gifts

(a) Persons in a Referral Relationship

TUMG physicians, clinicians and staff may not receive any gift under circumstances that could be reasonably interpreted as having been given to influence decisions or actions. The principle underlying this policy is that decisions or actions of health care providers should not be influenced by gifts or entertainment.

Whenever TUMG physicians, clinicians and staff are not sure whether a gift is prohibited by this policy, the gift must be discussed with the Department Chair, Compliance Officer or the Office of the General Counsel prior to its being given or upon its receipt.

(b) Gifts/Grants from Pharmaceutical Companies

The Office of the Inspector General (“OIG”) has specifically cautioned against programs under which drug manufacturers offer grants to physicians for studies of prescription products when the studies are of questionable scientific value and require little or no scientific pursuit. Payments may generally be considered improper if the payment is made to persons in a position to generate business for the donor company, related to the volume of business generated, is more than nominal in value and/or exceeds the fair market value of any legitimate service provided to the donor company, or is unrelated to any service at all other than the referral of patients.

6. Confidentiality

TUMG physicians, clinicians and staff possess and have access to sensitive, privileged information about patients and their care. Patients properly expect that this information will be kept confidential. Federal and state laws impose a variety of obligations on TUMG and its personnel to protect the privacy of patient information. TUMG takes very seriously any violation of a patient’s confidentiality. Discussing a patient’s medical condition, or providing any information about patients to anyone other than TUMG personnel who need the information or other authorized persons who need the information will have serious consequences for an employee. TUMG physicians, clinicians and staff should not discuss patients with anyone outside TUMG including their families.

TUMG is the owner of the medical record, which documents a patient’s condition and the services received by the patient from TUMG physicians, in private office settings. Medical records for TUMG services in facilities where TUMG physicians see patients, such as TUHC are maintained in accordance with the policies and procedures of those facilities. Medical records are strictly confidential, which means that they may not be released by TUMG to outside parties except with the consent of the patient or in other limited circumstances. Medical records should not be physically removed, altered, or destroyed. Employees who have access to medical
records must take pains to preserve their confidentiality and integrity, and no employee is permitted access to the medical record of any patient without a legitimate, TUMG-related reason for so doing. Any unauthorized release of or access to medical records should be reported to a supervisor.

In addition, the Health Insurance Portability and Accountability Act ("HIPAA"), as amended from time to time, imposes standards for privacy and security of patient information, and uses and disclosures of patient information including electronic information transfers. TUMG is committed to maintaining the privacy and integrity of patient information and complying with all of the regulatory requirements imposed by HIPAA. The University has a separate HIPAA Compliance Program with which TUMG physicians, clinicians and staff are responsible for complying. [http://www.tulane.edu/~contract/HIPAA/HIPAA_training](http://www.tulane.edu/~contract/HIPAA/HIPAA_training)

7. Investments in Health Care Entities

Joint ventures between TUMG physicians and other health care providers, or an investment by a TUMG physician in another health care entity may give rise to a financial relationship implicating the Stark and anti-kickback statutes discussed above. When physicians invest in health care entities to which they can direct business, there is a concern that the physician-investor’s clinical judgment will be improperly affected by his or her wish to increase the return on his or her investment. In addition, if you have any questions related to Stark or the anti-kickback statutes, you should contact The Office of the General Counsel.

8. Maintaining Tax-Exempt Status

As part of the University, TUMG benefits from the University’s tax exemption under section 501(c)(3) of the Internal Revenue Code. That is, TUMG is exempt from paying federal income tax on most of its revenue. As an exempt organization, TUMG is permitted to accept tax-deductible charitable contributions. Loss of TUMG’s exempt status would result in substantial penalties, interest, and the inability to receive tax-deductible charitable contributions.

TUMG is dedicated to its charitable purposes and therefore all contracts and agreements must be negotiated at arm’s length. Compensation provided to health professionals for recruitment, retention, employment, and personal services must be reasonable in the context of the services provided and the need for them. Reasonableness must be analyzed based on overall compensation and benefits. Areas of particular concern are below-market rents, compensation tied to TUMG or department revenues, income guarantees (especially where there is no obligation to repay), below-market loans, and loan guarantees.

9. Conflicts of Interest

TUMG physicians, clinicians and staff are subject to the Conflict of Interest Policies of the University which may be found in the Faculty and Staff Handbooks. [http://www.tulane.edu/~fachand/Conflict_of%20_Interest.htm](http://www.tulane.edu/~fachand/Conflict_of%20_Interest.htm)

10. Controlled Substances
Certain licensed practitioners employed by TUMG are registered to purchase, acquire, and dispense narcotics and other controlled substances. Improper use of these substances is illegal and extremely dangerous. TUMG requires that its physicians, clinicians and staff comply with the federal and state laws regulating controlled substances.

Access to controlled substances is limited to persons who are properly licensed and who have express authority to handle them. No health care practitioner may dispense controlled substances except in conformity with state and federal laws and the terms of the practitioner’s license. Unauthorized manufacture, distribution, use, or possession of controlled substances by TUMG physicians, clinicians and staff is strictly prohibited. Any TUMG physician, clinician or staff member who knows of unauthorized handling of controlled substances should provide the information immediately to his or her supervisor or the Compliance Officer.

PART IV - INDEPENDENT CONTRACTORS & VENDORS

TUMG purchases goods and services from many consultants, independent contractors, and vendors. TUMG’s policy is that all contractors and vendors who provide items or services to TUMG must comply with all applicable laws and TUMG policies. Each consultant, vendor, contractor, or other agent furnishing items or services worth at least $5,000 per year should be given a copy of this Policy Manual and should provide a written certification included in Appendix 4 that he or she is aware of and will comply with TUMG’s health care compliance policies and procedures. Contractors should bring any questions or concerns about TUMG or their own operations to the Compliance Officer or the Office of the General Counsel.

PART V - RESPONSE TO INVESTIGATIONS

State and federal agencies have broad legal authority to investigate TUMG and to review its records. TUMG will comply with subpoenas and cooperate with governmental investigations to the full extent required by law. The Office of the General Counsel, in consultation with the Compliance Officer, is responsible for coordinating TUMG’s response to investigations and the release of any information.

If a TUMG department, physician, clinician or staff member receives an investigative demand, subpoena, or search warrant involving TUMG, it should be brought immediately to the Compliance Officer or the Office of the General Counsel. Do not release or copy any documents without authorization from the Compliance Officer or the Office of the General Counsel. If an investigator, agent, or government auditor comes to TUMG, contact the Compliance Officer immediately. Ask the investigator to wait until the Compliance Officer or his designee arrives before reviewing any documents or conducting any interviews. The Compliance Officer, his designee, or the Office of the General Counsel is responsible for assisting with any interviews, and TUMG will provide counsel to employees, where appropriate. If a TUMG physician or staff member is approached by government investigators and agents, he or she has the right to insist on being interviewed only at TUMG, during business hours and with counsel present.

In the event of an investigation, TUMG physicians, clinicians and staff are not permitted to alter, remove, or destroy documents or records of TUMG. This includes email, paper, tape, computer and other electronic records.
PART VI - APPENDICES

1. University Compliance Program Structure
2. List of Key Compliance Contacts
3. Employee Verification Certificate
4. Contractor/Vendor Verification Certificate
Appendix 1 - University Compliance Program Structure

Compliance Program: Organizational Chart

Audit Committee ➔ CFO ➔ President

Meeting Quarterly

Composition:
- Interim Sr. VP Health Sciences Center/Assoc. Sr. VP HSC (Co-Chair)
- Dean SOM
- Dean SPHTM
- Director of Primate Center

University Compliance Steering Committee

Legal Advisor: General Counsel

Compliance Operations Committees

- Clinical: Chair (TUMG Compliance Officer)
  - Legal Advisor (HSC Staff Attorney)
  - Responsible for: Billing, HIPAA, Fed Programs (Stark/F&A), Hospital Compliance Coordination, Training

- Research: Chair (Research Compliance Officer)
  - Legal Advisor (HSC Staff Attorney)
  - Responsible for: Biosafety, USA PATRIOT Act, IRB, SOM IACUC, Primate Center IACUC, Grants & Contracts, Training, other HSC research centers (e.g., Gene Therapy)

- Teaching & Administration: Chair (Associate Dean/GME)
  - Legal Advisor (HSC Staff Attorney)
  - Responsible for: Accreditation Programs, Willed Body, CME, Policy & Training not Related to Clinical or Research Matters

Reporting Relationships

- Conflict of Interest Committee
- Office of Environmental Health and Safety
- TUMG Executive Committees
- Research Council

At least one SOM Liaison per Department

SPHTM Liaisons:
- To be Determined

Primate Center Liaisons:
- Associate Director of Admin. and Operations
- Member of the Primate Center Executive Committee
Appendix 2

List of Key Compliance Contacts

Chair of University Steering Committee: Laura Levy, Ph.D. 988-3291
Compliance Officer Edwin Dennard, M.D. 988-4700
Research Compliance Officer Brian Weimer 988-1147
HIPAA Privacy Officer Glenda Folse 988-7739
HIPAA Security Officer Leo Tran 988-8514
Counsel to Clinical Compliance Committee Sarah Gorham Hunter 988-5297
General Counsel Victoria Johnson 865-5783
Appendix 3

EMPLOYEE CERTIFICATION AND AGREEMENT OF COMPLIANCE

I certify that I have read today The Tulane University Medical Group ("TUMG") Health Care Compliance Policy Manual and fully understand the requirements set forth in that document. I agree specifically to act in accordance with the policies of TUMG set forth in that document, and I understand that I will be subject to disciplinary action, including possible termination, if I violate those policies or fail to report material violations of these policies consistent with the procedures and standards set forth in the Policy Manual.

Signed: ____________________________________________

Print Name: _________________________________________

Date: _______________________________________________
CONTRACTOR CERTIFICATION AND AGREEMENT OF COMPLIANCE

I hereby certify that I am a duly authorized officer of the consultant, independent contractor, vendor, or other agent named below (“Contractor”). On behalf of Contractor and its officers, directors, employees, and agents, I certify that I have received and read the Health Care Compliance Policy Manual (the “Policy Manual”) of the Tulane University Medical Group (“TUMG”) and fully understand the requirements set forth in that document. I certify that Contractor shall act in full accordance with all rules and policies of TUMG.

These rules and policies include TUMG’s commitment to comply with all applicable federal and state laws, and TUMG’s commitment to conduct its business in compliance with the highest ethical standards. To this end, Contractor expressly agrees that the Policy Manual shall be incorporated within and made a part of Contractor’s agreement with TUMG and shall survive termination of that agreement for any reason. Any failure of Contractor to comply with the rules and policies set forth in the Policy Manual, or to report violations of these rules and policies, may result in immediate termination by TUMG of its agreement with Contractor.

Name of Contractor ________________________________
Signed: __________________________________________
Date: ____________________________________________