

VANDERBILT UNIVERSITY

Legal Compliance and Integrity Plan
Policy Guide
for
Vanderbilt University Medical Center
and
Vanderbilt Affiliated Health Care Organizations

This Legal Compliance and Integrity Plan Policy Guide complements, but does not replace or supersede other policy statements published elsewhere, such as in the Faculty Manual, Staff Handbook, Medical Staff Bylaws and Hospital Policy Manual.

**Vanderbilt University Medical Center
and
Vanderbilt Affiliated Health Care Organizations**

**Legal Compliance Plan
Policy Guide**

General Policy

It is the policy of Vanderbilt University, the Vanderbilt University Medical Center, the Vanderbilt Medical Group, and the health care related entities affiliated with the Vanderbilt University Medical Center (collectively referred to hereafter as "VUMC"), to provide health care and health care-related services in compliance with all state, local and federal laws governing its operations and consistent with the highest standards of business and professional ethics. This policy is a solemn commitment made by the trustees, officers, faculty and staff of Vanderbilt University to the patients and community served by VUMC and to those government agencies that regulate VUMC.

In order for VUMC's compliance policies to be applied consistently, VUMC has established a legal and regulatory Legal Compliance and Integrity Plan (ACompliance Plan@). The Compliance Plan program is directed by a Medical Center Compliance Committee (the "Committee"), chaired by the Vice Chancellor for Health Affairs, and a Medical Center Compliance Officer (the ACompliance Officer@), who is appointed by the Vice Chancellor for Health Affairs, who are charged with reviewing and enforcing VUMC's compliance policies and addressing specific compliance situations that may arise. In carrying out their duties and

responsibilities, the Committee and Compliance Officer will be expected to consult with and seek the advice and counsel of the University's Office of General Counsel, other legal counsel as may be engaged by the Office of General Counsel, and other offices of the University as may be necessary or appropriate, such as the Office of Internal Audit.

All VUMC faculty and staff, as well as those professionals who enjoy professional staff privileges or deliver care to VUMC's patients, must carry out their duties for VUMC in accordance with this policy. Any violation of applicable law or VUMC's Compliance Plan, or deviation from appropriate ethical standards, may subject a staff member or independent professional to disciplinary action, which may include oral or written warning, disciplinary probation, suspension, reduction in salary, demotion, dismissal from employment, or revocation of privileges. These disciplinary actions also may apply to a supervisor who directs or approves the person's improper actions, or is aware of those actions but does not act appropriately to correct them; or who otherwise fails to exercise appropriate supervision.

This Guide sets forth VUMC's policy statements in a number of specific areas with which all faculty, staff and professionals with privileges must comply. If a question arises as to whether any action complies with VUMC policies or applicable law, a staff member should present that question to that staff member's supervisor, or, if appropriate, directly to the Compliance Officer, the Compliance hotline, or to a member of the Committee.

If, at any time, any staff member or professional staff member becomes aware of any apparent violation of VUMC's Compliance Plan or policies, he or she **must** report it to his or her

supervisor (in the case of a staff member) or to the Compliance Officer or Compliance hotline.

All persons making such reports are assured that such reports will be treated as confidential; such reports will be shared with others only on a bona fide need-to-know basis. VUMC will take no adverse action against persons making such reports in good faith, whether or not the report ultimately proves to be well-founded. If a staff member or professional staff member does not report conduct that violates VUMC's Compliance Plan or policies, that staff member or professional staff member may be subject to disciplinary action, up to and including termination of employment or revocation of privileges.

The laws discussed in this Policy Guide are complex and many of the concepts must be analyzed in a fact specific manner. In addition, this Guide deals only generally with some of the more important legal principles. Their mention is not intended to present an exclusive list of applicable laws or regulations which apply to VUMC or to minimize the importance of other applicable laws, professional standards, or ethical principles that may be covered by other VUMC policies, such as those found in the Faculty Manual, Staff Handbook, Hospital Policy Manual and Medical Staff Bylaws. Where appropriate, reference has been made to specific policies that are currently in place at VUMC and that are an integral part of VUMC's Compliance Plan. Periodically, and otherwise as necessary, VUMC will update this Guide to address new risk areas and changes of law, regulations and Compliance Program requirements. Any person who is in doubt as to the propriety of a course of action or concerned about the

applicability of a stated policy must promptly communicate with his or her supervisor, or with the Compliance Officer or Compliance hotline, before taking action.

Payments, Discounts, and Gifts

VUMC participates in a variety of federal and state health care programs, including the Medicare program, a federal program that provides health insurance to the aged and disabled, and the TennCare and Medicaid programs, federal/state programs that provide health care coverage to low-income persons and, in the case of TennCare, persons who are determined to be uninsured or uninsurable. Federal law makes it illegal for VUMC or anyone acting on behalf of VUMC to provide or accept "remuneration" in exchange for referrals of patients covered by Medicare, TennCare, Medicaid or other federal health care programs, such as, CHAMPUS and the Railroad Retirement Board. The law also prohibits the payment or receipt of such remuneration in return for directly purchasing, leasing, ordering, or recommending the purchase, lease, or ordering of any goods, facilities, services, or items covered under the benefits of Medicare, TennCare or Medicaid.

Similar state regulations have been adopted in regard to the TennCare program. Tennessee regulations prohibit a provider from offering or receiving remuneration in any form related to the volume or value of referrals made or received from or to another provider. In addition, managed care organizations and providers are prohibited from soliciting TennCare enrollees by any method offering as enticements other goods and services (free or otherwise) for the opportunity of providing enrollees with TennCare covered services that are not medically necessary and/or that over-utilize the TennCare program, unless specifically waived by TennCare.

"Fraud and abuse" laws are designed to prevent fraud in health care programs and abuse of the public funds supporting the programs. VUMC is committed to abiding by the fraud and abuse laws and avoiding any practice that may be interpreted as abusive. Administrative and other staff in VUMC departments that enter into personal services arrangements, including, but not limited to, Hospital and Clinic Administration, Financial Management, Pathology, Pharmacy, and Vanderbilt Home Health Care, are expected to be vigilant in identifying potential fraud and abuse violations and bringing them to the attention of the Compliance Officer or any member of the Compliance Committee.

(a) Anti-Kickback Laws

Federal and state anti-kickback laws are broadly written to prohibit VUMC and its representatives from knowingly and willfully offering, paying, asking, or receiving any money or other benefit, directly or indirectly, in return for referrals, purchases, leases, or orders and impose criminal sanctions for violations of these laws. The anti-kickback laws must be considered whenever something of value is offered, given or received by VUMC or its representatives or affiliates, that is in any way connected to patient services, or any program funded in whole or in part by any federal, state or local governmental agency. This is particularly true when the arrangement could result in either an over-utilization or under-utilization of services or a reduction in patient choice. Even if only one purpose of a payment is to influence referrals, the payment may be unlawful.

There are many transactions that may violate the anti-kickback rules. For example, no one acting on behalf of VUMC may offer gifts, loans, rebates, services, or payment of any kind to a physician who refers patients to VUMC, or to a patient, without consulting the Compliance Officer. The Compliance Officer should review any discounts offered to VUMC by suppliers and vendors, as well as discounts offered by VUMC to third party payers. In general, patient deductibles and copayments must be collected in accordance with VUMC policy and may not be waived without the prior authorization of the Director of the Hospital, and should be reported to the Compliance Officer. Rentals of space and equipment must be at fair market value, without regard to the volume or value of referrals that may be received by VUMC. Fair market value should be determined through an independent assessment and appropriately documented.

Payments based on a percentage of revenue should be avoided in many circumstances. Any questions about these agreements should be directed to the Compliance Officer. Joint ventures with physicians or other health care providers, or investments in other health care entities, should be reported to the Office of General Counsel.

The U.S. Department of Health and Human Services (USDHHS) has described a number of payment practices that will not be subject to criminal prosecution under the anti-kickback laws. These so-called "safe harbors" are intended to help providers protect against abusive payment practices while permitting legitimate ones. If an arrangement fits within a safe harbor, it will not create a risk of criminal penalties and exclusion from the Medicare, Medicaid, TennCare, or other federal/state programs regulated by USDHHS. However, the failure to

satisfy every element of a safe harbor does not in itself make an arrangement illegal. Analysis of a payment practice under the anti-kickback laws and the safe harbors is complex and depends upon the specific facts and circumstances of each case. Staff members of VUMC should not make unilateral judgments on the availability of a safe harbor for a payment practice, investment, discount, or other arrangement. These situations must be brought to the attention of the Compliance Officer for review with legal counsel.

Violation of the anti-kickback laws is a felony under federal law, punishable by a \$25,000 fine, imprisonment for up to five years, or both. Violation of the anti-kickback law could also mean that VUMC and/or a physician is excluded from participating in the Medicare, TennCare and Medicaid programs.

(b) Entertainment and Gifts

VUMC recognizes that business dealings may include a shared meal or other similar social occasions, which may be proper business expenses and activities. More extensive entertainment, however, only rarely will be consistent with VUMC policy and should be reviewed and approved in advance by a supervisor. Questions regarding the appropriateness of a specific activity may also be directed to the Compliance Officer. VUMC staff members may not receive any gift under circumstances that could be construed as an improper attempt to influence VUMC's decisions or actions. When a staff member receives a gift that reasonably appears to violate this policy, the gift should be returned to the donor and reported to the Compliance Officer. Gifts may be received by VUMC staff members when they are of such nominal or

limited value that they could not reasonably be perceived as an attempt to affect the judgment of the recipient. For example, token promotional gratuities from suppliers, such as advertising novelties marked with the donor's name, are not prohibited under this policy.

Staff and faculty are also reminded of the conflict of interest policies enumerated in the **Staff Handbook** and the **Faculty Manual** as they apply to the receipt of gifts while acting on behalf of the University, including VUMC.

Whenever a staff member or a professional is not sure whether a payment, discount or gift constitutes remuneration that is prohibited by this policy, the remuneration (or offer of remuneration) must be reported promptly to his or her supervisor. The staff member or professional may also report to the Compliance Officer. A conflict of interest, real or perceived, should be directed to the person designated in the **Faculty Manual** or **Staff Handbook** or reported to the Compliance hotline.

Billing and Claims

When submitting claims for payment for VUMC services, VUMC has an obligation to its patients, third-party payers, and the state and federal governments to exercise diligence, care, and integrity. We all must recognize that the right to bill the Medicare, TennCare, Medicaid and other federal and state programs, conferred through the award of a provider or supplier number, carries a responsibility that may not be abused. VUMC is committed to maintaining the accuracy of every claim it processes and submits. Many individuals throughout VUMC have responsibility for entering charges, diagnoses and procedure codes. Each of these individuals is expected to monitor compliance with applicable billing rules and established coding guidelines. Any false, inaccurate, or questionable claims should be reported immediately to a supervisor or to the Compliance Officer or Compliance hotline.

False billing is a serious offense. Medicare, TennCare and Medicaid rules prohibit knowingly and willfully making, using or causing to be made or used any false statement or representation of a material fact in an application for benefits or payment. Furthermore, federal and state laws provide that it is also unlawful to conceal or fail to disclose the occurrence of an event affecting a health care provider's right to payment with the intent to secure payment that is not due. Examples of false claims include:

- X Claiming reimbursement for services that have not been rendered
- X Filing duplicate claims
- X "Upcoding" to more complex procedures

- X Including inappropriate or inaccurate costs on VUMC cost reports
- X Falsely indicating that a particular health care professional attended a procedure
- X Billing for a length of stay beyond what is medically necessary
- X Billing for services or items that are not medically necessary
- X Failing to provide medically necessary services or items
- X Billing excessive charges.

Legislation enacted in 1996 extends the reach of federal criminal penalties to false claims submitted not only to Medicare, TennCare and Medicaid, but to any health care benefit program, including commercial third-party payers. VUMC staff members and agents who prepare or submit claims should be on alert for these and other errors. It is important to remember that outside consultants only advise VUMC. The final decision on billing questions rests with VUMC.

The Tennessee Medicaid False Claims Act, which applies to the TennCare program, states that it is criminal theft for any person to make or present any claim knowing such claim to be false, fictitious, or fraudulent.

VUMC carefully follows the Medicare rules on assignment and reassignment of billing rights. If there is any question whether VUMC may bill for a particular service, either on behalf of a physician or on its own behalf, the question should be directed to the Compliance Officer for review. VUMC staff members should not submit claims for other entities or claims prepared by other entities unless such arrangement has been approved by both the head of the department and

the Compliance Officer. Special care should be taken in reviewing these claims, and VUMC personnel should request documentation from outside entities if necessary to verify the accuracy of the claims.

A health care provider or supplier who violates the false claims rules is guilty of a felony, and may be subject to criminal fines of up to \$25,000 per offense, imprisonment for up to ten years, or both. Other persons guilty of false claims may face fines of up to \$10,000 per offense, imprisonment for up to one year, or both. In addition to the criminal penalties, the Federal False Claims Act and the Civil Monetary Penalties Statute permit substantial civil monetary penalties against any person who submits false claims. These Acts also provide for a penalty of triple damages as well as fines up to \$11,000 for each false claim submitted. An individual health care provider (as well as VUMC) may be excluded from participating in the Medicare, TennCare and Medicaid programs for submitting false claims. As mentioned above, state statutes impose criminal penalties for false and deceitful conduct in connection with billing.

Numerous other federal and state laws prohibit false statements or inadequate disclosure to the government and mandate exclusion from the Medicare, TennCare and Medicaid programs upon conviction. For instance, neither VUMC nor its agents are permitted to make, or induce others to make, false statements in connection with VUMC's Medicare certification. Persons doing so are guilty of a felony and may be subject to fines of up to \$25,000 and imprisonment for up to five years. VUMC and/or individual health care providers will be excluded from the Medicare, TennCare and Medicaid programs for at least five years if convicted of a Medicare- or

Medicaid-related crime or any crime relating to patient abuse. Medicare, TennCare and Medicaid exclusion may result if VUMC or a provider is convicted of fraud, theft, embezzlement, or other financial misconduct in connection with any government-financed program.

It is illegal to make any false statement to the federal government, including statements on Medicare, TennCare or Medicaid claim forms. It is illegal to use the U.S. mail in a scheme to defraud the government. Any agreement between two or more people to submit false claims may be prosecuted as a conspiracy to defraud the government if any of these people perform any act to effect the object of the conspiracy.

It is also illegal under state criminal law to present a false or fraudulent claim for the payment of any benefit under any insurance policy, including commercial insurance policies.

VUMC promotes full compliance with each of the relevant laws by maintaining a strict policy of ethics, integrity, and accuracy in all its financial dealings. Each staff member and professional who is involved in submitting charges, preparing claims, billing, and documenting services is expected to maintain the highest standards of personal, professional, and institutional responsibility.

Patient Referrals

Patient referrals are important to the delivery of appropriate health care services. Patients are admitted, or referred, to VUMC by their physicians. Patients leaving VUMC may be referred to other facilities, such as skilled nursing or rehabilitation facilities. Patients may also need durable medical equipment, home care, pharmaceuticals, oxygen, and other services, and may be referred to qualified suppliers of these items and services. VUMC's policy 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 health care provider, a diagnostic facility, or a supplier should be made by the patient, with guidance from his or her physician as to which providers are qualified and medically appropriate.

Physicians and other health care providers may have financial relationships with VUMC or its affiliates. These 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.

A federal law known as the "Stark law" applies to any physician who has, or whose immediate family member has, a "financial relationship" with an entity such as VUMC, and prohibits referrals by that physician to VUMC for the provision of certain designated health services that are reimbursed by Medicare, TennCare and Medicaid. If a financial relationship exists, referrals are prohibited unless a specific exception is met. VUMC requires that each

financial relationship with a referring physician or his or her family member fit within one of the exceptions to the Stark law. Under the University's conflict of interest policy, set forth in the **Faculty Manual**, each faculty member is responsible for reporting to his or her dean and department chair any potential conflicts of interest, including financial relationships that may affect the faculty member's duties to the University. Responsibility for evaluating financial relationships with physicians lies with the Vice Chancellor for Health Affairs, the department chair and the Compliance Officer, in consultation with legal counsel.

The Stark law applies to a variety of services, including:

- X clinical laboratory;
- X physical therapy;
- X occupational therapy;
- X radiology (including MRI, CT, ultrasound, and mammography);
- X durable medical equipment and supplies;
- X parenteral and enteral nutrients equipment and supplies;
- X prosthetics and orthotics;
- X home health services;
- X outpatient prescription drugs;
- X inpatient and outpatient VUMC services;
- X radiation therapy services and supplies.

The exceptions under the Stark law are complex, and several general rules must be followed. Both leases for physician office space and personal services contracts with physicians must be in writing, and signed by the parties. Any premises leased must be specifically described and must not exceed the space reasonably needed for the physician's legitimate purposes. Rental charges must be set in advance, at fair market value, without regard to the volume or value of referrals by the physician. A lease must be commercially reasonable regardless of referrals made between the parties. Similarly, a personal service contract must specify the services to be provided by the physician to VUMC, which must be reasonable and necessary for legitimate purposes, and must be for at least one year. Compensation paid to physicians must also be set in advance at fair market value in a manner that does not take into account the volume or value of referrals, and must be commercially reasonable. Contract services may not involve the counseling or promotion of an illegal business arrangement. Physician incentive plans, which may include volume-based compensation, will be acceptable if certain requirements are met.

Physicians purchasing clinical laboratory services or other items or services from VUMC must pay fair market value. An arrangement whereby VUMC bills for a group practice may be acceptable if it meets certain requirements. A pathologist, radiologist, or radiation oncologist may provide VUMC laboratory, pathology, diagnostic radiology, or radiation oncology services on his or her own order or on a consultation request from another physician.

Penalties for violating the Stark law include (i) no Medicare, TennCare or Medicaid payment for the service referred illegally; (ii) a refund to the beneficiary of any amounts collected; (iii) fines of up to \$15,000 levied on both the physician and the entity for each service referred illegally, plus additional fines based on the amounts billed; (iv) civil monetary penalties of up to \$100,000, plus other assessments for arrangements designed to circumvent the Stark rules; and (v) exclusion from the Medicare, TennCare and Medicaid programs.

Physician Recruitment

The recruitment and retention of physicians requires special care to comply with VUMC policy and applicable law. Physician recruitment has implications under the anti-kickback laws, the Stark law, and the IRS rules governing VUMC's tax-exempt status. Each recruitment package or commitment should be in writing, consistent with guidelines established with VUMC. New or unique recruitment arrangements should be reviewed by the Compliance Officer in consultation with legal counsel. In general, support provided to a new physician who will not be a staff member is most likely to be acceptable if it is provided in order to persuade the physician to relocate to VUMC's geographic service area in order to become a member of the professional staff after conducting a community needs assessment indicating a shortage of the particular specialty, or if it is provided to a new physician completing his or her training. Support should be of limited duration and the overall compensation provided to the physician should be determined to be reasonable (by a disinterested Board) and the rationale for the determination documented. The non-staff member physician cannot be required to refer patients to VUMC, and the amount of compensation or support cannot be related to the volume or value of referrals. Income guarantees for non-staff member physicians present special issues and should be reviewed by the Compliance Officer and legal counsel on a case-by-case basis.

Group Practice Acquisition

To improve the delivery of health care services, VUMC may, from time to time, acquire physician practices. These acquisitions require special care to comply with applicable law because they have implications under the anti-kickback laws, the Stark law, and the IRS rules governing Vanderbilt University's tax-exempt status. All transactions must be reviewed by the Compliance Officer and legal counsel to ensure compliance.

(a) Anti-Kickback Laws

As discussed previously, federal law makes it illegal for VUMC to provide or accept "remuneration" in exchange for referrals of patients covered by Medicare, TennCare or Medicaid. Acquisitions of physician practices may implicate the anti-kickback laws because they may be construed as illegal payments to induce the referral of Medicare, TennCare or Medicaid patients.

Generally, acquisitions will comply with federal law when the amounts paid by VUMC reflect the fair market value of the acquired practice. Fair market value should be determined through an independent appraisal. Payments in excess of fair market value may violate the anti-kickback laws, particularly when there is an ongoing relationship between VUMC and the acquired practice. Several specific types of payment are subject to scrutiny:

- X payment for goodwill
- X payment for value of ongoing business unit
- X payment for covenants not to compete

- X payment for exclusive dealing agreements
- X payment for patient lists
- X payment for patient records.

The "safe harbor" protections discussed previously may also apply to a particular acquisition. Staff members should not, however, make unilateral judgments on the availability of a safe harbor. These situations must be brought to the attention of the Compliance Officer for review with legal counsel. Any questions should be directed to legal counsel, and any proposed acquisition of a physician practice should be reported to legal counsel.

Violation of the anti-kickback laws is a felony, punishable by a \$25,000 fine or imprisonment for up to five years, or both. Violation of the law could also mean that VUMC and/or physicians are excluded from participating in the Medicare, TennCare and Medicaid programs.

(b) Stark Law

Physician practice acquisitions also implicate the Stark law discussed earlier. Because the law is particularly complex, all transactions must be reviewed by the Compliance Officer and legal counsel.

(c) IRS Scrutiny

The IRS retains authority to audit the activities of tax-exempt organizations. In particular, the IRS may revoke VUMC's tax-exempt status if payments for the acquisition of group practices are deemed "excessive." The IRS can also impose monetary penalties, known as "intermediate sanctions," for such conduct. While current, independent appraisals are important, equally important are the rationale and support for the reasonableness of the assumptions on which the valuation is based. Any questions should be directed to the Office of General Counsel.

Emergency Medical Conditions and Women in Labor (EMTALA)/Patient Transfers

Operation of emergency departments is an integral part of VUMC's service to the community under its charitable mission. An emergency department is known as a place where any sick or injured person may come for care regardless of his or her ability to pay. The federal government has enacted an "anti-dumping" law to ensure that emergency medical conditions and women in labor are screened and stabilized and that patients are not transferred from an emergency room to another facility unless it is medically appropriate.

Prompt and effective delivery of emergency care may not be delayed in order to determine a patient's insurance or financial status. Each patient who presents at the emergency department must receive an appropriate medical screening examination. Patients with emergency medical conditions and patients in active labor must be cared for in VUMC's emergency department until their condition has stabilized. An emergency may include, but is not limited to, psychiatric disturbances, symptoms of substance abuse, or contractions experienced by pregnant women.

A stabilized patient may be transferred to another provider that is qualified to care for the patient, has space available, and has agreed to accept the transfer. If a patient is not stabilized, transfers may only be made in limited circumstances, such as when the medical benefits reasonably expected from treatment at another medical facility outweigh the increased risks to the patient (and, if appropriate, the unborn child associated with the transfer). A physician must sign a certification stating that this is the case. No physician will be penalized for refusing to

authorize the transfer of an individual with an emergency condition that has not been stabilized. The transfer must be performed by qualified personnel and transportation equipment, including life support measures during transfer if medically appropriate. A copy of the patient's record, including complete records of the emergency department encounter and any other relevant records that are available, must be sent to the receiving provider.

Any staff member who believes that an emergency patient has been transferred improperly must report the incident to the Compliance Officer. No staff member will be penalized for reporting a suspected violation of the patient transfer law in good faith. If a staff member or professional staff member believes that an emergency patient has been transferred to VUMC improperly, the suspected violation must be reported to the Compliance Officer and to proper authorities within 72 hours of its occurrence. If an on-call physician refuses or fails to appear within a reasonable time to provide necessary stabilizing treatment of an emergency medical condition or active labor, the name and address of that on-call physician should be reported immediately to the Compliance Officer.

In addition to VUMC's medical records, the emergency department will maintain an on-call duty roster and a log documenting each individual who comes to the emergency department seeking assistance. The log must document whether the patient refused treatment or was refused treatment, was transferred, was admitted and treated, was stabilized and transferred, or discharged. When a patient or a patient's legal representative requests a transfer or refuses a transfer, the informed consent or refusal must be documented in writing. If there are questions

about the records required under the patient transfer law, the Compliance Officer will answer them or refer them to legal counsel.

This federal law is enforced through civil monetary penalties and through damages in private civil actions. If a provider violates the statute, it can be fined up to \$50,000 for each violation. A physician, including an on-call physician, who is responsible for the examination, treatment, or transfer of an emergency patient and who negligently violates the law may be fined up to \$50,000 for each violation. If the violation is gross and flagrant or repeated, the physician may be excluded from participation in the Medicare, TennCare and Medicaid programs.

Discharge Planning and Ancillary Services Referrals

Federal regulations under the Medicare program and Tennessee regulations administered by the Department of Public Health govern VUMC's discharge planning process. In accordance with VUMC's long-standing procedures, it is the policy of VUMC to abide by these regulations in every respect. We all must recognize that the discharge of a patient to a residence or some post-hospitalization provider is a critically important decision that must be made in the best interests of the patient and with the patient's fully-informed consent. Improper discharge planning or referral to ancillary services provider not only might imperil the health of our patient, but might also place in jeopardy VUMC's licensure and continued ability to treat Medicare, TennCare and Medicaid patients.

Market Competition

VUMC is committed to complying with all state and federal antitrust laws. The purpose of the antitrust laws is to preserve the competitive free enterprise system. The antitrust laws in the United States are founded on the belief that the public interest is best served by vigorous competition, free from collusive agreements among competitors on price or service terms. The antitrust laws apply fully to health care services provided by VUMC, its faculty-physicians, and the health care professionals who have been granted privileges, and VUMC is firmly committed to the philosophy underlying those laws.

While the antitrust laws clearly prohibit most agreements to fix prices, divide markets, and boycott competitors, they also proscribe conduct that is found to restrain competition unreasonably. This can include, depending on the facts and circumstances involved, certain attempts to tie or bundle services together, certain exclusionary activities, and certain agreements that have the effect of harming a competitor or unlawfully raising prices. Any questions that arise should be addressed to the Compliance Officer who will confer with legal counsel.

(a) **Discussion With Competitors**

VUMC policy requires that the rates it charges for VUMC care and related items and services, and the terms of its third-party payer contracts, must be determined solely by VUMC. In independently determining prices and terms, we may take into account all relevant factors, including costs, market conditions, widely used reimbursement schedules, and prevailing competitive prices, to the extent these can be determined in the marketplace. There can be,

however, no oral or written understanding with any competitor concerning prices, pricing policies, pricing formulas, bids, bid formulas, discounts, credit arrangements, or related terms of sale or service. To avoid the possibility of misunderstanding or misinterpretation, VUMC policy prohibits any consultation or discussion with competitors relating to prices or terms which VUMC or any competitor charges or intends to charge. Joint ventures and affiliations that may require pricing discussions must be individually reviewed for antitrust compliance. Discussions with competitors concerning establishment of markets, down-sizing, or elimination of duplication ordinarily implicate market division and must be avoided.

Providers are often asked to share information concerning staff member compensation. VUMC policy prohibits the sharing with competing providers of current information or future plans regarding individual salaries or salary levels. VUMC may participate in and receive the results of general surveys, but these must conform to the guidelines for participation in surveys provided in the following section entitled "Trade Associations".

Similarly, VUMC policy prohibits consultation or discussion with competitors with respect to its services, selection of markets, territories, bids, or customers. Any agreement or understanding with a competitor to divide markets is prohibited. This includes an agreement allocating shares of a market among competitors, dividing territories, or dividing product lines or customers.

(b) Trade Associations

VUMC and its health care providers are involved in a number of trade and professional associations. These organizations promote quality patient care by allowing VUMC and other providers to learn new skills, develop policies and, where appropriate, speak with one voice on public issues. However, it is not always appropriate to share business information with trade associations and their members. Sharing information is appropriate if it is used to better inform consumers or to promote efficiency and competition.

VUMC may participate in surveys of price, cost, and wage information if the survey is conducted by a third party and involves at least five comparably sized providers. Any price, cost, or wage information released by VUMC must be at least three months old. If a staff member is asked to provide a trade association with information about VUMC's charges, costs, salaries, or other business matters, he or she should consult the Compliance Office who will confer with legal counsel.

Joint purchasing through a trade association is probably acceptable, but any joint purchasing plan should be reviewed in advance by legal counsel. If a staff member or professional staff member has any question or concern about an activity of a trade association, he or she may raise the question or concern with the Compliance Officer who will seek guidance from legal counsel.

(c) Boycotts

VUMC policy prohibits any agreement with competitors to boycott or refuse to deal with a particular person or persons, such as a vendor, payer, or other provider. These agreements need not be written to be illegal; any understanding reached with a competitor (directly or indirectly) on such matters is prohibited. All negotiations by VUMC agents and staff members must be conducted in good faith. Exclusive arrangements with payers, vendors, and providers must be disclosed to the Compliance Officer who will confer with VUMC administration in consultation with legal counsel.

(d) Services by Health Care Professionals: Physicians and Nurses

VUMC credentialing and peer review activities also may carry antitrust implications. Because of the special training and experience of physicians and nurses, their skills may best be evaluated by other physicians and nurses. It is appropriate for physicians and nurses to review the work of their peers. Because a physician reviewing another physician may, by virtue of his or her medical specialty, be the reviewing physician's competitor, special care must be taken to ensure that free and open competition is maintained. As a result, credentialing, peer review and physician and nurse discipline at VUMC are conducted only through properly constituted committees. Health care professionals participating in these activities are expected to use objective medical judgment.

If any VUMC staff member is involved in negotiating a contract of employment or a personal services contract with a physician, nurse or other health care provider, it is important to

review with care any non-competition provisions incorporated in the agreement. The appropriate geographic scope and duration of a non-competition agreement may vary from case to case. Questions about the appropriateness of a non-competition provision should be directed to legal counsel.

(e) Penalties

Penalties for antitrust violations are substantial. Individuals and corporations can be fined \$350,000 and \$10,000,000 respectively, for each antitrust violation, and individuals can be sentenced for up to three years in prison for each offense. In addition, actions giving rise to antitrust violations may violate other federal criminal statutes, such as mail fraud or wire fraud, under which substantial fines and even longer prison sentences can be imposed.

Antitrust violations also create civil liability. Private individuals or companies may bring actions to enjoin antitrust violations and to recover damages for injuries caused by violations. If successful, private claimants are entitled to receive treble damages, i.e. three times the amount of damages suffered, plus attorneys' fees. Moreover, if the antitrust violation was a conspiracy, each member of that conspiracy may be liable for the entire damage caused by the conspiracy.

Tax-Exempt Organizations

(a) General Principles

As a non-profit provider serving charitable and educational purposes, VUMC holds federal tax-exempt status under section 501(c)(3) of the Internal Revenue Code (AIRC@). In order to qualify for that exemption, and to be eligible to receive tax-deductible contributions, VUMC must be operated for charitable purposes -- a standard that is generally met by operating an emergency department open to all, providing care to all who can pay, offering medical staff privileges to all qualified physicians, complying with anti-dumping and fraud and abuse laws, and maintaining a governing body comprised primarily of community members rather than VUMC insiders. Treas. Reg. 1.501(c)(3)-1; Revenue Ruling 69-545; IRS Manual Transmittal 7(10)69-38; General Counsel Memorandum 39862. VUMC's exempt status may be revoked if it permits any private inurement of its assets to VUMC insiders or allows individuals to enjoy more than an insubstantial private benefit from VUMC activities. Even if exempt status is retained, VUMC and participating disqualified persons may be subject to "intermediate sanctions," which are penalty taxes if VUMC enters into transactions that excessively benefit private individuals. IRC ' 4958. In addition, VUMC will be subject to tax (at corporate rates) on any income it receives from unrelated trade or business activities. IRC ' ' 511-514.

(b) Private Inurement

As a 501(c)(3) organization, VUMC is prohibited from engaging in activities that result in "inurement" of its assets or earnings to VUMC insiders -- that is, individuals whose special relationship offers them an opportunity to exercise substantial influence over the affairs of VUMC. In the context of health care organizations, the IRS has broadly interpreted the term "insiders" to include not only founders, directors, and officers, but also physicians who possess the ability to exercise such influence. If private inurement occurs, the IRS may revoke VUMC's tax-exempt status.

Physician compensation often raises private inurement concerns, particularly in the context of revenue-sharing arrangements. An agreement to pay a specialist a fixed percentage of a department's gross income without a corresponding benefit to VUMC for those payments, for instance, may create private inurement. Legal counsel should review compensation arrangements to ensure that the total compensation paid is reasonable, that the recipient has no substantial control over VUMC, and that the arrangement is negotiated at arm's-length. Legal counsel should also review other forms of incentive compensation for reasonableness, particularly if bonus payments are not capped and are based primarily on financial targets rather than patient satisfaction or the quality of care provided. Other potential sources of private inurement, which should be brought to the attention of the Compliance Officer if the arrangement is not negotiated at arm's-length, include:

- X sales, exchanges, or leases of property between VUMC and a private individual or a company;
- X loans or other extensions of credit between VUMC and a private individual or company;
- X contracts for goods, services, or facilities between VUMC and a private individual or company;
- X VUMC payment or reimbursement of a private individual's expenses;
- X partnerships or joint ventures between VUMC and physician groups.

(c) Private Benefit

In contrast to the prohibition on private inurement, which only applies to VUMC insiders, the private benefit restriction applies to all individuals, regardless of their relationship to VUMC. The private benefit limit requires VUMC to serve public rather than private interests.

Unlike the absolute prohibition on private inurement, however, very minor and incidental private benefit will not jeopardize VUMC's exempt status. The Compliance Officer, in consultation with legal counsel, may review contracts with commercial providers of goods or services, compensation packages of non-insiders, and joint ventures or partnerships with non-VUMC personnel or entities to ensure that the arrangements are reasonable and primarily benefit VUMC's charitable functions rather than private interests.

(d) Intermediate Sanctions

Many situations that raise concerns about private inurement or private benefit are also likely to create a tax liability under the "intermediate sanctions" rules. IRC ' 4958. Intermediate sanction rules allow the IRS to assess penalty taxes on an individual receiving a benefit (not the exempt organization) when certain individuals or entities, referred to as "disqualified persons," receive "excess benefits" from an exempt organization like VUMC. A "disqualified person" is defined as any person or entity that is in a position to exercise substantial influence over an organization. VUMC's trustees and officers, as well as substantial donors and the five highest-paid staff members, are likely to be considered disqualified persons. Physicians may also be "disqualified persons" subject to intermediate sanctions if they in fact possess substantial influence over VUMC, as may be the case with department chairs and other key executive or administrative staff. The Compliance Officer, in consultation with legal counsel, should identify those who are likely to be considered "disqualified persons."

Intermediate sanctions will be imposed if a disqualified person receives an excess benefit from VUMC -- in other words, if VUMC provides an economic benefit to a disqualified person, the value of which exceeds that of any consideration (including the performance of services) received in return from the disqualified person. Likely sources of excess benefits are compensation packages (including fringe benefits and deferred compensation); sales, leases, or exchanges of Vanderbilt University property and assets; and joint ventures or partnerships with private individuals or entities. If an excess benefit transaction occurs, the disqualified person will be subject to an excise tax equal to 25% of the excess benefit received, and to an additional

200% tax if the benefit is not repaid or otherwise corrected within a given time after receiving notice from the IRS. In addition, any VUMC "manager" (trustee, officer, or person with similar responsibilities) who knowingly and willingly allowed VUMC to provide the excess benefit will be subject to a 10% tax, capped at \$10,000. Please be mindful of the fact these penalty taxes are imposed on individuals and cannot be paid by the exempt entity.

To create a presumption that a given arrangement will not create an excess benefit, the compensation packages of disqualified persons, as well as any other potential excess benefit transactions, should be approved pursuant to the intermediate sanctions safe-harbor procedure. Accordingly, the University has adopted and has implemented a Compensation Policy for Executive Officers (individuals who would be deemed disqualified persons within the meaning of Section 4958 of the Internal Revenue Code).

Any questions regarding whether a transaction may be improper under private benefit, private inurement, or intermediate sanctions laws and regulations should be referred to the Office of General Counsel.

(e) Physician Recruitment and Practice Acquisitions

The IRS closely scrutinizes incentives provided by tax-exempt providers to newly recruited physicians. Incentives, such as a signing bonus, payment of malpractice premiums, below-market rental of office space, or income guarantee may be attacked by the IRS if those amounts, when added to the physician's base salary and benefits package, result in a total compensation package that is unreasonable. Unreasonable compensation, if provided to a

physician with substantial influence over VUMC (e.g., a department chair), may subject the physician and provider managers to intermediate sanctions penalties. In an extreme case, the IRS may revoke VUMC's tax exemption on private inurement or private benefit grounds. To avoid incurring penalty taxes or risking the loss of Vanderbilt University's tax exemption, legal counsel should be consulted and recruitment packages offered to physicians expected to possess substantial influence over VUMC, or to physicians expected to be among VUMC's highest paid staff members, should be approved by a disinterested board or committee of the board, with careful attention paid to data from comparable arrangements, and adequately documented to demonstrate the reasonableness of the total compensation package.

From a tax standpoint, physician practice acquisitions raise issues similar to those in physician recruitment. If VUMC pays more than fair market value for the practice, the IRS may impose penalty taxes under intermediate sanctions on the physicians, if they possess substantial influence over VUMC, and on provider managers who approve the transaction. Whether or not penalty taxes are imposed, the IRS may revoke Vanderbilt University's tax exemption if the over-payment constitutes private inurement or private benefit. To guard against penalty taxes or loss of tax exemption, the Compliance Officer or legal counsel should promote a procedure whereby practice acquisitions are reviewed by VUMC's board (or a board committee) in accordance with the intermediate sanctions= safe harbor procedure discussed above.

(f) Unrelated Business Taxable Income ("UBTI")

As a 501(c)(3) organization, Vanderbilt University, which includes the VUMC, will generally be exempt from federal income tax. VUMC will be taxed at regular corporate rates, however, on income that it receives from an unrelated trade or business ("UTB") that it regularly conducts. IRC ' 512(a)(1). Investment income or gains generally will not constitute UBTI unless those proceeds are debt-financed or are received from a controlled corporation. IRC ' 512(b)(1)-(5). UBTI may be offset by deductions for costs -- such as rent or labor -- that are incurred in connection with the generation of the UTB.

A UTB is any activity that is performed by VUMC and does not substantially relate to its exempt purpose. IRC ' 513(a). Generally, an activity will be substantially related if it contributes substantially or is causally related to VUMC's exempt purpose, but will not be so related if conducted on a scale larger than reasonably necessary to perform functions in furtherance of that purpose. IRC Regulation. ' 1.513-1(d) Any trade or business, substantially all the work for which is performed without compensation or which is carried on primarily for the convenience of VUMC's patients, staff members, or officers, will generally not be considered a UTB. IRC ' 513(a). The following businesses, although often exempt from tax under that "convenience" exception, tend to attract IRS scrutiny and should be reviewed by the legal office to determine whether UBTI is being generated:

- X laboratory services
- X pharmacy sales
- X leasing of medical buildings

- X parking facilities
- X laundry services
- X cafeterias, coffee shops, and gift shops

Income from medical research is also an occasional source of UBTI. Basic research -- that is, research without an application-oriented testing component -- generally will not give rise to UBTI, even if the research is privately sponsored. Likewise, research in which the drug or device being tested is used therapeutically is unlikely to create UBTI, as is research that serves to educate medical students or personnel. UBTI may result, however, from research incident to commercial operations, such as the ordinary testing or inspection of materials or products that benefit private rather than public interests. Thus, the more VUMC's activities resemble routine testing (in particular, testing that could be done commercially), the more likely UBTI will be generated. The legal office should review sponsored research contracts that may raise UBTI issues.

(g) Tax-Exempt Bonds

The Internal Revenue Code imposes strict limits on "private business use" of proceeds derived from the sale of tax-exempt bonds ("bond proceeds"). A private, or non-permitted, business use, generally speaking, is the use of bond proceeds or the use of a facility, the construction or renovation of which was financed with bond proceeds, by a person in a private trade or business. Use of such proceeds or facilities by VUMC (or by another section 501(c)(3) organization) in furtherance of its exempt purposes is a permitted use and does not constitute

private business use. IRC ' ' 141, 145. Many of VUMC's facilities, such as the Vanderbilt University Hospital, The Vanderbilt Clinic and the Medical Research Building 1, were financed with bond proceeds.

Examples of private business use include:

- X leasing all or a part of a bond-financed facility to a for-profit endeavor, such as private physician offices, gift shops, or other concessions;
- X entering into contracts with service providers -- management organizations, physicians, cafeterias, janitorial service companies, vending machine companies, and the like -- that do not satisfy management contract safe harbors set forth in Revenue Procedure 97-13, or do not constitute incidental use under the private use regulations;
- X operating parking garages that are not available to the general public on a first-come, first-served basis or for patients or staff members of VUMC;
- X loaning bond proceeds to a for-profit person or endeavor;
- X constructing facilities to be used as private physician offices;
- X engaging in activities that give rise to UBTI;
- X entering into research agreements for the benefit of private companies;
- X selling bond-financed property in violation of the change-in-use restrictions.

Controlled Substances

VUMC, through its pharmacy, is registered to purchase, acquire, compound and dispense narcotics and other controlled substances. Improper use of these substances is illegal and extremely dangerous. Accordingly, VUMC must comply with all federal and state laws and regulations governing the manufacture, possession, distribution and use of controlled substances.

VUMC requires that its staff members, as well as faculty-physicians who maintain DEA registration, comply with all federal and state laws regulating controlled substances. Under VUMC policy, which is referenced below, access to controlled substances is limited to persons who are properly licensed and who have express authority to handle them. No health care professional may dispense controlled substances except in conformity with state and federal laws and the terms of the health care professional's license. Staff members should carefully follow record-keeping procedures established by their departments and the Pharmacy Department. Any staff member who knows of unauthorized handling of controlled substances is to provide the information immediately to his or her supervisor or the Compliance Officer.

In accordance with the University's Drug-Free Workplace policy, Vanderbilt and VUMC prohibit the unlawful manufacture, distribution, possession or use of a controlled substance by any staff member in the workplace or while a staff member is conducting University business off the University's premises. Any staff member violating this policy will be disciplined appropriately, up to and including discharge.

Federal law may impose sentences of up to 20 years in prison and fines of up to \$1,000,000 for violation of criminal drug laws. If VUMC or its staff member is convicted under federal or state law of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance, VUMC can be excluded from the Medicare, TennCare and Medicaid programs.

Confidentiality

VUMC staff members and health care professionals possess sensitive, privileged information about patients and their care. Patients properly expect that this information will be kept confidential. VUMC 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 VUMC personnel who need the information and other authorized persons, is a violation of patient confidentiality and may subject the staff member to disciplinary action. Staff members should not discuss patient information outside VUMC or with their families.

Under state law, VUMC is the owner of the medical record that documents a patient's condition and the services received by the patient at VUMC. Medical records are strictly confidential, which means that they may not be released to parties outside VUMC except with the consent of the patient, as provided by state law, or in other limited circumstances. Special protections apply to mental health records, records of drug and alcohol abuse treatment, and records relating to HIV infection. Medical records should not be physically removed from VUMC, altered, or destroyed. Staff members who have access to medical records must preserve their confidentiality and integrity, and no staff member is permitted access to the medical record of any patient without a legitimate, VUMC-related reason for so doing. Any unauthorized release of or access to medical records should be reported to a supervisor or the Compliance Officer.

Tennessee has enacted a series of computer crime laws that are designed to punish and deter computer crime. In compliance with the law, VUMC prohibits unauthorized access to its computer system, either directly or by network or telephone. An individual who does not have a legitimate password will be held to know that access is unauthorized. VUMC also prohibits the destruction or corruption of electronically stored or processed data. Persons who violate these rules will be prosecuted to the full extent of the law.

Purchasing

Purchasing decisions must be made in accordance with applicable VUMC policy. In addition, the prohibitions discussed in a preceding section of this Guide entitled "Payments, Discounts, and Gifts," apply to purchasing decisions made on behalf of VUMC. Purchasing decisions must in all instances be made free from any conflicts of interest that could affect the outcome. VUMC is committed to a fair and objective procurement system that results in the acquisition of quality goods and services for VUMC at a fair price. Any concerns about the legality of the terms of a proposed transaction, including but not limited to, inducements offered by a vendor or supplier, should be discussed with the Compliance Officer.

Conflicts of Interest

VUMC staff members should avoid all potential conflicts of interest. Adherence to this policy ensures that VUMC's staff members act with objectivity in carrying out their duties for VUMC and that faculty and staff, including physicians and other health care professionals, comply with their obligation to give primary loyalty and support to Vanderbilt University and VUMC. VUMC faculty are referred to the Conflicts of Interest Policy set forth in the **Faculty Manual**, and staff are referred to the Conflicts of Interest Policy set forth in the **Staff Handbook**.

Any personal or business activities by a staff member that may raise concerns along these lines must be reviewed and approved in advance in accordance with the appropriate conflicts of interest policy.

In order for VUMC to comply with requirements of the Medicare program, every staff member must notify VUMC if he or she was at any time during the year preceding his or her employment with VUMC employed by the Medicare intermediary or carrier. A staff member's failure to make this disclosure at the time of employment could cause VUMC to lose its right to participate in Medicare.

Because VUMC participates in state programs such as Medicaid and TennCare, VUMC staff members must inform VUMC, through the Human Resources Office or the Compliance Officer, if they have previously been employed by the State of Tennessee.

Independent Contractors & Vendors

VUMC purchases goods and services from many consultants, independent contractors, and vendors. VUMC's policy is that all contractors and vendors who provide items or services to VUMC must comply with all applicable laws and VUMC policies. Each consultant, vendor, contractor, or other agent furnishing items or services worth at least \$25,000 per year may be given a copy of VUMC's Legal Compliance and Integrity Plan and Policy Guide, or in the judgment of the Compliance Officer, a relevant summary, and shall provide a written certification that it is aware of and will comply with VUMC's Compliance Plan. Contractors should bring any questions or concerns about VUMC practice or their own operations to the Compliance Officer.

VUMC staff members who work with consultants, contractors, and vendors or who process their invoices should be aware that VUMC's compliance policies apply to those outside companies as well. Staff members are encouraged to carefully monitor the activities of contractors in their areas. Any irregularities, questions, or concerns on those matters should be directed to the Compliance Officer.

Regulation

VUMC operates in a highly regulated industry and must monitor compliance with a wide variety of highly complex regulatory rules. VUMC requires the cooperation of staff members and professional staff members in complying with these regulations and bringing lapses or violations to the attention of appropriate VUMC officials, including the Compliance Officer. While failure to comply with all regulations may not carry criminal penalties, regulations often control the licenses and certifications that allow VUMC to deliver care to its patients. VUMC's continued ability to operate and serve the community depends upon each staff member's help in regulatory compliance.

Some of the regulatory programs which staff members may deal with in the course of their duties include the following:

- X Tennessee licensure
- X JCAHO accreditation
- X Medicare certification and conditions of participation
- X Determination of Need
- X Controlled substance registration
- X Pharmacy licensure and registration
- X Clinical laboratory licensure and regulation
- X Union rules and collective bargaining agreements
- X Occupational Safety and Health regulation

X Building, safety, food service and fire codes

X Nurse Practice Act

The Compliance Officer can provide staff members or arrange for staff members to be provided with information on these rules, and can direct questions or concerns to the proper person.

Federally Funded Grants and Contracts

Federal regulations impose duties and obligations upon the recipients of federal grants. As a recipient institution, VUMC expects its personnel to abide by all applicable federal regulations, including but not limited to regulations relating to accurate reporting and appropriate expenditure of grant or contract funds. Questions relating to matters concerning federal grants should be directed to the VUMC Department of Finance or the Compliance Officer to ensure that all regulations are observed

1. In accepting government sponsored projects (grants, contrast, and other types of agreements) VUMC agrees to abide by government regulations regarding the use of those funds. Office of Management and Budget Circular A-21 sets forth general criteria for determining the allowability of direct costs on government sponsored projects at educational institutions. Many government agencies such as the National Institute of Health (NIH) publish additional cost guidelines specific to those agencies, and familiarity with such regulations is also necessary.
2. Although generally not as stringent as government requirements, non-governmental agencies may also have cost guidelines with which Vanderbilt faculty (principal investigators), departmental business officer, and/or grant administrators should be familiar.

The booklet entitled *AGuidelines for Budgeting and Charging Direct Costs on Sponsored Projects*, summarizes pertinent overall government regulations and VUMC practices used to determine whether or not a particular cost item would be considered an allowable direct cost for budgeting and/or charging on a government sponsored project. These direct charge considerations include a decision tree including reasonableness, allocability, and consistency with VU practices, allowability and funds availability. Government auditors may use the same guidelines when conducting audits of government sponsored projects awarded to VUMC.

3. The roles and responsibilities for sponsored grants and contracts are as follows:

A. Principal Investigator

The principal investigator is responsible for justifying the appropriateness of direct costs budgeted and charged on sponsored projects in accordance with overall government regulations, sponsoring agency guidelines, conditions made as a part of an individual award, and VUMC policies and guidelines. Providing this justification both in budgeting for and charging sponsored projects requires close familiarity with the programmatic and technical aspects of the sponsored project. For this reason, primary responsibility for justifying the appropriateness

of direct costs in accordance with government regulations, sponsoring agency guidelines and Vanderbilt guidelines rests with the principal investigator.

B. Department Chair/Administrator

The Department Chair/Administrator=s role is to be a resource for principal investigators, advising on proper direct cost charging and budgeting practices within government and other sponsoring agency regulations and VUMC guidelines. Department offices should maintain copies of government, other sponsoring agency and VUMC policies and guidelines pertaining to sponsored projects.

C. Dean/Director

The Dean/Director=s role is to ensure guidance is provided to principal investigators and departments on criteria used to determine allowable direct costs on sponsored projects. Each Dean/Director is responsible for having a mechanism in place to ensure principal investigators and administrators understand accountability for direct cost budgeting and charging to sponsored projects.

D. Central Offices

These offices are responsible for providing Medical Center-wide guidance on criteria used to determine allowable direct costs on sponsored projects.

4. The Central Office Contacts are:

Office of Biomedical Sciences, CCC-3322 MCN, 322-2281

Tom Barnes, Director

Elaine Barnes, Associate Director

Responsible for assisting investigators in identifying funding sources, developing proposal, and coordinating compliance activities related to proposal budget development and post-award budget actions for the Medical Center.

Department of Finance, CC-2100 MCN, 322-2381

Craig Carmichel, Director

Steve Todd, Associate Director

Melissa Smith, Senior Accounting Manager

Responsible for coordinating compliance activities related to post award management including reviewing selected transactions, reporting financial results to sponsoring agencies, and coordinating agency audits of Medical Center **contracts and grants.**

5. The Central Officer should be contacted for related training courses and materials. In addition the following web sites provide policies and procedures, as well as, rate schedules:

VUMC: <http://mcapps01.mc.vanderbilt.edu/policy.html>

Vanderbilt University: <http://www.vanderbilt.edu/ocga/>

Scientific Integrity

VUMC receives federal funds and grants to conduct scientific research and must, therefore, comply with the federal regulations imposed upon the recipients of those funds. These regulations generally prohibit "misconduct in science," which includes intentional fabrication, falsification, or plagiarism in proposing, conducting, or reporting research. Honest errors or differences in interpretations of data are not considered violations.

These so-called "misconduct regulations" are designed to prevent dishonesty and fraud in federally-funded research programs. VUMC is committed to complying with the regulations and avoiding any practice that may be interpreted as misconduct. Towards this end, and in compliance with federal regulations, Vanderbilt has adopted and published in the **Faculty Manual** policies and procedures relating to misconduct in research. Staff members in the laboratory, medical staff and administration, and any department receiving federal funds to conduct research must be vigilant in identifying violations of these regulations and reporting them in accordance with the provisions of the **Faculty Manual**.

The federal regulations provide procedures for a thorough and confidential internal inquiry and investigation of any allegation of misconduct. Because evaluating these claims is complex and depends upon the specific facts and circumstances of each case, VUMC shall appoint an inquiry team consisting of legal counsel and at least two scientists experienced in the particular scientific field to determine whether a violation may have occurred. If further investigation is recommended, VUMC is required to notify the Office of Research Integrity of the Department of Health and

Human Services, which monitors such investigations and is authorized by law to conduct its own review of the allegations.

Violation of these federal regulations could result in VUMC's and/or the scientist's exclusion from eligibility for federal grants and contracts generally up to three years. Federal law also provides criminal sanctions for making false written or oral statements to the Office of Research Integrity during the course of an investigation.

Response to Investigations

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

If a department, a staff member, or a practitioner member receives an investigative demand, subpoena, or search warrant involving VUMC from a state or federal agency, excluding requests received by Medical Records to release records as part of patient litigation, the Compliance Officer should be notified immediately. Do not release or copy any documents without authorization from the Compliance Officer or legal counsel. If an investigator, agent, or government auditor comes to VUMC, contact the Compliance Officer immediately. In the Compliance Officer's absence, contact the Office of General Counsel and the Hospital Administrator on call. Ask the investigator to wait until the Compliance Officer or designee arrives before reviewing any documents or conducting any interviews. If the investigator has a search warrant, it is possible that the investigator will choose not to wait until the Compliance Officer or designee arrives. Do not obstruct the investigator's investigation, but take careful notes of everything the investigator does. The Compliance Officer, Compliance Officer's designee, or an attorney with the Office of General Counsel is responsible for assisting with any interviews, and VUMC will provide legal counsel to staff members, where appropriate. If VUMC staff members are approached by government investigators and agents, the

staff member has the right to insist on being interviewed only at VUMC, during business hours or with legal counsel present.

If a professional staff member receives an investigative demand at his or her private office and the investigation may involve VUMC, the staff member is asked to notify the Compliance Officer immediately.

Except in accordance with established policies regarding document correction or document retention, VUMC staff members are not permitted to alter, remove, or destroy documents or records of VUMC. This includes paper, tape, and computer records.

Subject to coordination by the Compliance Officer, VUMC and its staff members will disclose information required by government officials, supply payment information, provide information on subcontractors, and grant authorized federal and state authorities with immediate access to VUMC and its personnel. Failure to comply with these requirements could mean that VUMC will be excluded from participating in the Medicare, TennCare and Medicaid programs.

Subcontractors of VUMC who provide items or services in connection with the Medicare, TennCare and/or Medicaid programs are required to comply with VUMC's policies on responding to investigations. Subcontractors must immediately furnish the Compliance Officer, VUMC counsel, or authorized government officials with information required in an investigation.

Legal Compliance and Integrity Plan Policy Guide for Vanderbilt University Medical Center and Vanderbilt Affiliated Health Care Organizations

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