COMPLIANCE PLAN FOR HEALTH CARE OPERATIONS

Originally approved by The University of Toledo Board of Trustees on November 13, 2006

Revised and Approved: October 2013
INTRODUCTION

The University of Toledo is growing and expanding to enhance the experience for both patients and students and has an ongoing commitment to ensure that health care operations are conducted in accordance with applicable laws and regulations and University policies and practices. In order to achieve this goal, its faculty and staff must be fully informed about applicable laws and regulations, and pertinent policies and practices so that they do not inadvertently engage in conduct that may raise compliance issues. Since the laws and regulations that apply to our activities are extensive, complex and ever-changing, the University has adopted a formal Compliance Plan to ensure our employees are aware of their obligations, and to address potential areas of compliance concern. The University of Toledo Physicians, LLC, the University’s faculty practice plan, has a separate compliance plan with distinctive compliance obligations.

Key features of the University’s Compliance Plan (“Compliance Plan” or “Plan”) are:

- the oversight of health care compliance functions by a designated committee;
- an identification of the University policies, procedures and applicable Federal and State laws;
- incorporation of standards and policies that guide University personnel and other third parties affiliated with the University in regards to practice in compliance areas;
- an education and training program for personnel and persons affiliated with the University in regards to procedures in compliance areas;
- a publicized and uniform mechanism for University personnel and persons affiliated with the University to raise questions and receive appropriate guidance concerning practice in compliance areas;
- a publicized process for University employees and affiliated persons to report possible compliance issues;
- a procedure for investigating and resolving reports of possible compliance issues;
- review and monitor areas of risk in relationship to the Federal and State guidelines, the OIG Work Plan; and
- formulation of corrective action plans to address any compliance problems that are identified.

COMMITMENT TO CORPORATE COMPLIANCE

The University of Toledo believes that compliance is critical to its health care operations. The Board of Trustees and Executive Administration approved the formation of a Compliance Department and the designation of a Compliance Officer to ensure compliance for healthcare operations.
The Compliance Plan (“Plan”) is the principal plan that outlines the expectations of behavior and performance for University personnel and affiliated persons with regard to healthcare operations. University departments in addition to compliance will support the Compliance Plan by training personnel on University policies. The ultimate objective is to create a Plan that establishes a culture for The University of Toledo, to weave concepts of honesty and integrity into all operations. The time, money, and energy devoted to this effort should be viewed as an investment by the University to assist in realizing its full mission.

The compliance program described in this document is intended to establish a framework for legal and ethical compliance by The University of Toledo and its employees for healthcare operations. It is not intended to set forth all of the substantive programs and practices of the University that are designed to achieve compliance. The University of Toledo already maintains or is developing various compliance practices and those practices continue to be part of its overall legal and ethical compliance efforts. The University of Toledo intends that this Compliance Plan embrace all elements of an effective program to prevent and detect violations of law and University policies, procedures and ethical standards, with regard to healthcare operations.

Under the Federal Corporate Sentencing Guidelines If an individual or organization is found guilty of intentional criminal conduct (not errors/mistakes) against the Federal Guidelines; the Corporate Sentencing Guidelines are invoked for determining the sentence. The process is based on a series of tables used in calculating a culpability score. The score increases based on the severity of the offense, proof of intent, etc. The maximum monetary fine that can be imposed against a convicted organization under the guidelines is $290,000,000. In a criminal prosecution, managers or officers may be criminally charged and the organization could lose its license to treat Medicare patients.

However, the structure of the guidelines allows for significant reduction in the score/penalties if the organization can demonstrate it made a good faith effort to implement an effective Compliance Program, designed to prevent and detect errors/irregularities. To be effective, the plan must be customized to the organization, all employees need to be familiar with it, and it must have a mechanism for reporting concerns. With the involvement of all employees in becoming familiar with this document, being diligent of all regulations impacting their areas of responsibility, and reporting all concerns through proper channels, our Compliance Plan has all of the necessary elements to be deemed effective.

BOARD OF TRUSTEES

The Board of Trustees has the ultimate responsibility to govern The University of Toledo and establish the strategic direction to attain the University’s mission.

INTENT OF THE PLAN

The intent of the Plan is to incorporate the following components:

1. Policies. The University of Toledo has policies and procedures that govern healthcare operations, including Federal and State regulations and accreditation body rules that sets forth standards that guide The University of Toledo personnel and affiliated persons. Adherence will ensure that the University maintains its standards in medical, business and legal practices while promoting an ethical workplace, a commitment to honest, responsible practices and encouraging compliance within the letter and spirit of the law.
2. **Administrative Responsibility.** The designation of University officials responsible for compliance efforts, including a Compliance Officer, Legal Counsel, and Compliance Committee.

3. **Employee Screening.** A screening process for employees and others, to ensure they have not been previously charged with violations of law or ethical standards.

4. **Education and Training.** An education and training program for University personnel and affiliated persons regarding the Compliance Plan and their role in the University compliance program.

5. **Monitoring and Auditing.** Monitoring and auditing will be conducted to help prevent, detect and report civil and criminal conduct concerning fraud and abuse as well as to regularly review the compliance efforts to ensure that practices reflect current requirements and that other adjustments are made to improve the program, including a mechanism for University personnel and affiliated persons to raise questions and receive appropriate guidance concerning compliance issues or to report suspected violations.

6. **Investigation and Corrective Action.** A procedure for investigating and resolving reports of possible compliance issues will be conducted through auditing and monitoring. Early detection and reporting, minimizes any financial loss to government and taxpayers, as well as any corresponding financial loss to the University.

7. **Enforcement and Discipline.** Follow University procedures for appropriate disciplinary action that is enforced and addresses compliance violations while ensuring that employees who report in good faith and participate in the compliance program will do so without fear of retaliation.

**SCOPE**

The Compliance plan applies to all of The University of Toledo faculty, staff, physicians, including physicians with UTMC Medical Staff privileges, fellows, residents, student interns, volunteers and contractors who conduct medical, business and legal activities with or at the University.

**THE UNIVERSITY OF TOLEDO EMPLOYEES’ ROLE**

Employees of The University of Toledo must:

- Read and attest to the Compliance Manual;
- Comply with The University of Toledo policies and procedures;
- Know and promote the values and mission of the University;
- Adhere to the Compliance Support Program principles (where appropriate adherence to these principles will become part of every employee’s performance program);
Treat all patients, students, employees and anyone affiliated with the University with respect, dignity and deliver quality care;

Conduct responsibilities in a manner which demonstrates commitment to compliance with all applicable laws and regulations;

Attend educational sessions that relate to job responsibilities;

Attest to the fact that one has received education in, understands, and will follow the rules and regulations relating to employment;

Report known or suspected violations to supervisors, a department head, the Compliance Officer or Anonymous Reporting Line;

Investigate or participate in an investigation to the point of resolution of an alleged violation;

Strive to prevent errors and provide suggestions to eliminate errors.

**ADMINISTRATIVE RESPONSIBILITY**

**COMPLIANCE OFFICER**

The Health Care Compliance Officer (“Compliance Officer”) has primary responsibility for implementing and managing the Compliance Plan. The Compliance Officer will be approved by the Board of Trustees, as are all University employees.

The Compliance Officer will direct the development, implementation and monitoring of the Compliance Plan. The Compliance Officer’s responsibilities are to:

- Report to the Board of Trustees, the President and Internal Audit to provide information regarding the operation and progress of compliance efforts as appropriate.

- Address all compliance-related matters, including all policies relating to compliance issues. The Compliance Officer will work closely with representatives of the Departments and administration to foster and enhance compliance.

- Review and implement policies and procedures and work with legal counsel to update the policies and the procedures based on changes in the law;

- Ensure there is a practice in place for educating employees on the Compliance Plan;

- Ensure that compliance issues and concerns within the University are appropriately evaluated, investigated, and resolved and monitor oversight reviews;

- Ensure that employees receive adequate education and training and that employees participate in compliance-related activities as a significant part of employee performance evaluation;

- Ensure that compliance-related activities are appropriately documented;
• Monitor the performance of the Compliance Plan and related activities on a continuing basis, taking appropriate steps to improve the effectiveness; and continue to identify and address potential compliance vulnerabilities;

• Ensure that employee screening mechanisms are in place and operating properly;

• Effectively and efficiently address complaints and other concerns regarding compliance.

OVERSIGHT AND ADMINISTRATION OF COMPLIANCE

The Compliance Committee comprised of the Compliance Officer, Vice President of Medical Affairs, UTMC Executive Director, Associate Vice President and Senior Legal Counsel, Admin Director Revenue Cycle, UTMC Finance and Director of HIM and the Director of Internal Audit and Chief Compliance Officer will meet monthly or as needed. The charge of the committee will be to provide oversight of compliance with appropriate business and regulatory requirements, advise the Compliance officer in the implementation and operation of the compliance plan and receive reports and recommend actions to review compliance issues and ensure processes are in place to mitigate risk of noncompliance with applicable Federal and State laws. The committee will have the ability to create sub-committees for specific areas, i.e. RAC.

HEALTH CARE OPERATIONS DEPARTMENT AND ADMINISTRATIVE STANDARDS AND PROCEDURES

The Office of Compliance will develop necessary policies and procedures to carry out health care compliance functions. In addition, a Compliance Support Program will be developed to ensure proper training of appropriate University personnel.

EDUCATION AND TRAINING

The Compliance Officer will oversee training and education of employees on the Compliance Plan and the Compliance Support Program.

The Compliance Officer will provide access to a Compliance Manual to all employees involved in health care operations to ensure that employees understand their responsibility to conduct business with the highest of ethical standards. The Compliance Office will distribute the Compliance Support Overview training document to pertinent University employees.

MONITORING

The Compliance Officer will monitor the University’s performance to ensure that the University is striving for and demonstrating continual improvement on compliance activities. Reviews will be conducted based on relevant Fraud Alerts and the Office of Inspector General Work Plan. The review will be limited in scope, generally conducted through a random sampling of the specific compliance issue. The Compliance Officer will request and subsequently house all reviews.

If any of these reviews identify instances of possible non-compliance, the Compliance Officer will review the situation with Legal Counsel to determine whether there has been any activity inconsistent with University policies and what further action is necessary. Material items will be brought to the Compliance Committee.
REPORTING AND INVESTIGATING HEALTH CARE COMPLIANCE ISSUES

The University of Toledo strives to comply with all applicable, federal and state laws and regulations. The following laws are identified as material laws applicable to the University with regard to health care operations.

Fraud

Fraud is defined as an intentional, false representation or concealment of a material fact intended to induce another to act in a particular way, due to reliance on the false representation or concealment to his or her injury.

False Claims

The False Claims Act (FCA) includes both civil and criminal provisions used in enforcement of the law, which makes it an offense for any person/entity to present a false claim to the United States government. The elements necessary to establish a civil FCA violation are (1) presentation of a claim, (2) to the United States government, (3) with actual knowledge that the claim is false or fraudulent or with reckless disregard or deliberate ignorance of the truth or falsity of the claim.

Anti-Kickback Statute

The Medicare/Medicaid Anti-Kickback statute makes it a crime for a person (normally a physician) to knowingly and willfully solicit or accept payment or other remuneration for referring a patient to another for the furnishing of any item or service for which payment may be made in whole or in part by the Medicare or Medicaid programs. The statute also makes it a crime to knowingly and willfully offer or pay remuneration to “induce” such a referral. An “inducement” is any act intended “to exercise influence over the reason or judgment of another in an effort to cause the referral or program-related business.”

Stark Laws

Prohibits physicians from referring Medicare and Medicaid patients to a hospital or other entity for the provision of “designated health services” if the physician or immediate family member has a financial relationship with that entity. Financial relationships are defined as both ownership/investment interests and compensation relationships. Designated health services include physical and occupational therapy, radiology services (including MRI, CAT scans, and ultrasound services), radiation therapy, durable medical equipment, orthotics and prosthetic devices, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.

HIPAA

The Health Insurance Portability and Accountability Act, also known as Administrative Simplification, has been called the most sweeping legislation to affect the healthcare industry in over 30 years. The Health Information Technology for Economic and Clinical Health (HITECH) Act,
enacted as part of the American Recovery and Reinvestment Act of 2009, was signed into law on February 17, 2009, to promote the adoption and meaningful use of health information technology. Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules. Generally, HIPAA legislation is sub-divided into four categories:

- Transaction standards for the transmission of claims, enrollment, eligibility, premium payments, claims status, referrals, and the coordination of benefits.
- Code set standards for diagnosis codes, medical procedure codes, national drug codes, and dental procedure codes.
- Privacy standards that require all individually identifiable health information be kept private and not disclosed without the patient’s permission.
- Security standards that require processes be implemented to ensure data integrity, confidentiality, and availability.

**FERPA**

The Family Educational Rights & Privacy Act is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

**Improper Claims For Organ Acquisitions Costs**

Hospitals that are approved transplantation centers may receive reimbursement on a reasonable cost basis to cover the costs of acquisition of certain organs. Organ acquisition costs are only reimbursable if a hospital satisfies several requirements, such as having adequate cost information, supporting documentation, and supporting medical records. Hospitals must also ensure that expenses not related to organ acquisition, such as transplant and post-transplant activities and costs from other cost centers, are not included in the hospital's organ acquisition costs.

**Improper Claims For Clinical Trials**

Since September 2000, Medicare has covered items and services furnished during certain clinical trials as long as those items and services would typically be covered for Medicare beneficiaries, but for the fact that they are provided in an experimental or clinical trial setting. Hospitals that participate in clinical trials should review the requirements for submitting claims for patients participating in clinical trials.

**Billing**

Will be consistent with Medicare/Medicaid rules. Charges will be substantiated with physician orders, medical necessity, and with medical services provided.

**Documentation**

Documentation is required that will accurately reflect the patient’s condition, medical treatment and procedures provided.

**Coding**

All coding will accurately reflect procedures performed or diagnosis as documented.
<table>
<thead>
<tr>
<th>Claims</th>
<th>Claim submission will adhere to all governmental regulations.</th>
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<tbody>
<tr>
<td>Cost Reports</td>
<td>Cost reports will be completed according to Medicare/Medicaid rules and regulations.</td>
</tr>
<tr>
<td>Contracts</td>
<td>All transactions must be at fair market value and are subject to contract review and approval policy, which includes review by Legal Counsel or a legal representative.</td>
</tr>
<tr>
<td>Grants</td>
<td>Grant contracts will be followed as stipulated in the contract.</td>
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<tr>
<td>Federal Aid</td>
<td>Federal Aid requirements will be followed as stated in the requirements.</td>
</tr>
<tr>
<td>Research</td>
<td>Research contracts and projects will adhere to the requirements set forth by the contract, Federal and State regulations, including conflicts of interest and applicable University policy and Ohio law.</td>
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**REPORTING OF ISSUES**

Employees have a duty to ask questions regarding potential healthcare operation issues and to report potential compliance concerns to their supervisor, central office, the Compliance Officer, or the anonymous reporting line. If any employee knows of or suspects a compliance violation, they are to report it immediately without fear of retaliation (See No Retaliation section). Where to best raise your concerns depends on your particular concern and situation. Issues not related to healthcare operations will be referred.

The Compliance Officer will be notified of any complaints or other information that suggest a violation of the Compliance Plan, applicable law or University policy. To determine whether a violation has occurred and how to respond to protect the University from future violations and enforcement actions, investigations will be coordinated with Legal Counsel, using internal or external investigators, auditors, consultants, attorneys or other independent contractors as appropriate.

**GUIDELINES FOR REPORTING**

Employees should review these guidelines to assist in the decision of what issues should be reported, what method to use to report, information needed from the reporter and methods to determine the status and resolution of the report.

**When to Report**
Employees should report if they have information about or have observed a possible violation of The University of Toledo policies including any Federal, State or Local laws and regulations.

**How to Report**
- **Local Resolution** – The best place to raise a concern typically begins with your own college, department, or through supervisory channels.
• **Central Offices** – Due to the subject matter or due to work or personal relationship it may be best to raise questions through a specialized central office. Examples include the Human Resource Department for concerns regarding discrimination or sexual harassment. Athletic Compliance Officer for possible NCAA violations or the Research Compliance Officer for research concerns.

• **Compliance Officer** - If the employee is uncomfortable with the direct approach, needs advice on how to handle an issue or issues have not been resolved satisfactorily, the employee can call and report to the Compliance Officer at 419-383-6933 or 419-215-7901.

• **Anonymous Reporting Line (Confidential)** The University of Toledo has an Anonymous Reporting Line to provide a simple way to report any situation or University conduct believed to violate University policy, Federal, State or Local laws and regulations, government contract or grant requirements. The toll-free number is 1-888-416-1308.

• **Report Directly to the Fiscal Intermediary or Center for Medicare & Medicaid** Should employees feel that the issues or concerns are not being addressed by administration the employee may file a complaint directly to the government. This is called a Qui Tam report and the employee may receive compensation should the complaint meet the requirements set by the government.

**What information should be included in the report?**

Describe the situation completely and if possible include such information as:
- dates,
- names,
- facilities, and departments involved
- be as detailed as possible

**The process to resolving an issue when submitted to the Anonymous Reporting Line**

Reports submitted to the Anonymous Reporting Line will be handled as promptly and discreetly as possible, with facts made available only to those who need to know to investigate and resolve the matter. All reports submitted through the Anonymous Reporting Line will be carefully reviewed by University personnel. Matters involving allegations of misconduct, serious violations of law or policy will be directed to Legal Counsel.

Within 5-10 business days the reporter should return to the website for the status of the investigation. The University may have information on your report, or may require further information in order to proceed with an investigation.

Due to the nature of certain claims, the University may be limited with respect to action(s) it may be able to take in response to a report if the individual submitting the report does not wish to make his or her identity known.

**Will reporting impact employment?**

The University is committed to safeguarding the confidentiality of individuals who submit reports. Employees are the best asset in monitoring compliance. Therefore, the University of
Toledo has a policy that prohibits retaliation against an employee for reporting or inquiring about potential violations or for seeking guidance on how to handle suspected violations. If an employee believes that they have been retaliated against, they should contact the Compliance Officer immediately.

**Status and resolution of a complaint**

To determine the status or resolution of a complaint:

- The university will inform the reporter, if the reporter is known that the investigation has been completed and resolved. Depending on the resolution it is not always possible to provide details.

- If reported through the Anonymous Reporting Line, the reporter can use the password assigned by the Anonymous Reporting Line to communicate and determine the status of the investigation.

**ACADEMIC AFFAIRS**

Reporting Options for Students – the anonymous reporting line does not support reporting of academic matters involving faculty and students. Academic matters should be reported to the Office of Academic Affairs. Non-academic student conduct matters should be reported to the Office of Student Judicial Affairs. Student employees that have concerns regarding their job can use the reporting options listed above.

**CORRECTIVE ACTION PLAN**

Whenever a compliance issue has been identified, through monitoring, reporting of possible issues, investigations, or otherwise, the appropriate University personnel (management) will develop a corrective action plan to address the issue. The corrective action will address the specific issue including training of employees, restrictions imposed on particular employees and, when necessary, discipline in accordance with university policies and procedures.

**NO RETALIATION**

Employees who report in good faith possible compliance issues will not be subjected to retaliation or harassment as a result of their report. Concerns about possible retaliation or harassment should be reported to the Compliance Officer or the Office of Institutional Diversity. To the point possible to pursue an investigation, attempts will be made to make communications anonymous and confidential. It is the intent that no employee will experience retaliation as a result of reporting.

Examples of retaliation: employment actions such as termination, refusal to hire, and denial of promotion, other actions affecting employment such as threats, unjustified negative evaluations, unjustified negative references, or increased surveillance, and any other action such as an assault or unfounded civil or criminal charge that are likely to deter reasonable people from pursuing their rights.
ENFORCEMENT AND DISCIPLINE

Failure to comply with University policies, Federal, State and Local laws and regulations will result in consequences. Any employee (regardless of position) may be subject to discipline, up to and including termination, if it is determined that his/her actions (or inactions) constituted a willful violation of law.

REVISIONS TO THE PLAN

This Compliance Plan is intended to be flexible and adaptable to changes in regulatory requirements. The Plan will be regularly reviewed to assess whether it is working.

The Plan will be reviewed annually and changed as experience shows that a certain approach is not effective or suggests a better alternative.

IMPLEMENTATION OF COMPLIANCE PLAN

The Compliance Officer will work with Legal Counsel and administration to develop an implementation plan.

THE UNIVERSITY OF TOLEDO
MISSION, VALUES AND VISION STATEMENT

The University of Toledo’s Mission, Values, and Vision statements can be located on the University website at the following addresses:

Mission and Values statement: http://www.utoledo.edu/campus/about/mission.html
Vision Statement: http://www.utoledo.edu/campus/about/vision.html
In addition located on the website is the recent merger history at the following site: http://www.utoledo.edu/campus/merger/index.html

SOURCES:

The University of Michigan Health System Corporate Compliance Program- May 2000 Jeanne Strickland, Chief Compliance Officer, Privacy Director & Security Officer
The Ohio State Compliance Plan – Julie E. Chicoine, JD, RN, CPC Compliance Director
Compliance 101 Second Edition Debbie Troklus & Greg Warner
The University of Toledo Policies and Procedures: http://utoledo.edu