



HEALTHCARE COMPLIANCE PLAN

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INTRODUCTION

The University of Toledo (“UToledo”) is bound to many federal and state laws and regulations as we strive to improve the health and human condition in the communities and region we serve. These laws and regulations are complex and are ever-changing with requirements or guidance issued by federal and/or state health care payors, such as the Centers for Medicare and Medicaid Services (CMS); guidance issued by the Food and Drug Administration (FDA) or Department of Health and Human Services (HHS), Office of the Inspector General (OIG); and relevant industry standards and practices.

This document is the Healthcare Compliance Plan (“Plan”) for UToledo. It supersedes all prior versions of the Plan, as well as the “Compliance Plan for Health Care Operations” dated October 2013. The purpose of the Plan is to describe the UToledo Compliance Program and create a framework for its effective operation.

PURPOSE

The Plan outlines the expectations of behavior and performance and establish a framework for legal and ethical compliance by UToledo employees, faculty, and staff as well as affiliated persons (“Personnel”) regarding healthcare operations. UToledo departments, in addition to compliance, will support the Plan by training Personnel on UToledo policies and applicable federal and state laws and regulations. The ultimate objective is to create a Plan that establishes a culture of honesty and integrity into all operations at UToledo.

This Plan is not intended to set forth all substantive programs and practices of UToledo that are designed to achieve compliance. UToledo already maintains or is developing various compliance practices and those practices continue to be part of its overall legal and ethical compliance efforts. UToledo intends that this Plan embrace all elements of an effective program to prevent and detect violations of law and UToledo policies, procedures, and ethical standards, regarding healthcare operations.

Key components of the Plan are:

1. **Administrative Responsibility.** The designation of UToledo officials responsible for compliance efforts, including a compliance officer, legal counsel, and a healthcare compliance committee representing a cross-section of departments and employees.
2. **Policies.** UToledo has policies and procedures and a Code of Conduct that govern healthcare operations, including federal and state laws and regulations and accrediting body rules that sets forth standards to guide UToledo Personnel. Adherence will ensure that UToledo 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.
3. **Employee Screening.** A screening process for employees and others, to ensure they have not been sanctioned from participation in a federal or state healthcare program.
4. **Education and Training.** An education and training program for UToledo Personnel on the Plan, policies and procedures, and their role in the UToledo compliance program and specific federal and state regulations.

5. **Monitoring and Auditing.** Monitoring and auditing to help prevent, detect, and report civil and criminal conduct concerning fraud and abuse as well as to regularly review the compliance efforts. This ensures that UToledo practices reflect current requirements and, if needed, other adjustments are made to improve the program. This includes a mechanism for UToledo personnel to raise questions and receive appropriate guidance concerning compliance issues or to report suspected violations.
6. **Reporting System and Anonymous Compliance Hotline.** Several reporting mechanisms are in place for employees to report compliance concerns including an anonymous phone line.
7. **Investigation and Corrective Action.** A process for investigating, auditing, monitoring, and resolving compliance issues is in place. Early detection and reporting minimize any financial loss to government and taxpayers, as well as any corresponding financial loss to UToledo.
8. **Enforcement and Discipline.** Policies and procedures are followed to ensure that appropriate disciplinary action is enforced. Compliance violations of policies and procedures is addressed. Employees who report in good faith and participate in the compliance program do so without fear of retaliation.

COMMITMENT TO CORPORATE COMPLIANCE

UToledo believes that compliance is critical to its healthcare operations and has an ongoing commitment to ensure that healthcare operations are conducted in accordance with applicable laws and regulations and UToledo policies and procedures. The UToledo Board of Trustees and Senior Leadership under the direction of UToledo President has approved the formation of the Compliance department and the designation of a Chief Compliance Officer to ensure institutional compliance at UToledo and a healthcare Compliance Officer for healthcare operations. The time, money, and energy devoted to compliance efforts should be viewed as an investment by UToledo to assist in realizing its full mission.

BOARD OF TRUSTEES

The UToledo Board of Trustees has the ultimate responsibility to govern UToledo and establish the strategic direction to realize the UToledo mission. The Board of Trustees will receive periodic reports regarding healthcare compliance matters.

SCOPE

The Plan applies to all UToledo Personnel as defined above, including but not limited to, faculty, staff, physicians, including physicians with University of Toledo Medical Center (UTMC) Medical Staff privileges, fellows, residents, student interns, volunteers and contractors who conduct medical, business, and legal activities with or at UToledo. 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 Personnel in becoming familiar with this document, being aware of all regulations impacting their areas of responsibility and reporting all concerns through proper channels; The UToledo Plan has all the necessary elements to be deemed effective.

UTOLEDO PERSONNEL ROLE

UToledo personnel must:

- Read and attest to the online Compliance Support Manual
- Comply with UToledo policies and procedures.
- Know and promote the values and mission of UToledo.
- Adhere to the Compliance Program principles (where appropriate adherence to these principles will become part of all Personnel member's performance program)
- Treat all patients, students, employees, and anyone affiliated with UToledo 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 the anonymous reporting line as defined below in "Reporting Compliance Issues."
- 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 UTMC COMPLIANCE OFFICER

The Compliance Officer has primary responsibility for implementing and managing the Plan. The Compliance Officer is approved by the UToledo Board of Trustees, as are all UToledo employees.

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

- Resolve all routine and customary compliance issues through the UTMC Health Care Compliance Committee ("Committee"), engaging UTMC leadership as needed. The Chief Audit and Compliance Executive will refer to UToledo leadership for resolution all issues of high risk and high exposure to the institution. The Chief Audit and Compliance Executive will report to the UToledo Board of Trustees, the President and executive administration 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 Plan.
- Ensure that compliance issues and concerns within UToledo are appropriately evaluated, investigated, and resolved and oversight reviews are monitored.
- Provide Personnel with adequate education and training and ensure that Personnel participate in compliance-related activities as a part of Personnel performance evaluation.
- Document compliance-related activities.
- Monitor the performance of the Plan and related activities on a continuing basis, taking appropriate steps to improve the effectiveness; and continue to identify and address potential compliance vulnerabilities.
- Maintain a mechanism to ensure personnel are screened prior to employment or participation at UToledo.
- Effectively and efficiently address complaints and other concerns regarding compliance.

OVERSIGHT AND ADMINISTRATION OF COMPLIANCE

The Committee is chaired by the Compliance Officer and additional members are comprised of key leadership individuals that are representative of a variety of UTMC departments invested in UToledo compliance efforts. The Committee will strive to meet quarterly, or as needed, but no less than four times per year.

The charge of the Committee is to provide oversight of compliance with appropriate business and regulatory requirements, advise the Compliance Officer in the implementation and operation of the 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 issues or areas of concern.

POLICIES AND PROCEDURES

The Compliance Officer is responsible for developing policies and procedures that pertain to the operation of the Plan. The Committee will adopt and recommend approval of all compliance policies and procedures for the Compliance Program. It is the responsibility of all UToledo Personnel to comply with the Plan and associated policies and procedures. All UToledo Personnel are also responsible to adhere to the Standards of Conduct policy.

EDUCATION AND TRAINING

The Compliance Officer oversees training and education of employees on the Plan, the Compliance Manual, and the Code of Conduct with the assistance of the UToledo Human Resources and Internal Audit and Compliance departments.

The Compliance Manual is provided to all newly hired personnel involved in healthcare operations to ensure that employees understand their responsibility to conduct business with the highest of ethical standards. Additional new-hire and ongoing compliance training will include information on Clery Act and Title IX, Business Ethics, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and Diversity and Inclusion using courses developed by EverFi. Other training may vary based upon job classification, level of authority and individual responsibilities.

MONITORING AND INVESTIGATING COMPLIANCE ISSUES

The Compliance Officer will monitor UToledo performance to ensure that UToledo is striving for and demonstrating continual improvement on compliance activities. Reviews will be conducted based on relevant Fraud Alerts and the OIG Work Plan. The review will be limited in scope, generally conducted through a risk management review of compliance issues suggested by the OIG Work Plan, other government regulatory agencies, and internally reported noncompliance. 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 the Office of Legal Affairs to determine whether there has been any activity inconsistent with UToledo policies or relevant laws or regulations and what further action is necessary. Material items will be brought to the Committee.

UToledo strives to comply with all applicable law, regulations, and policies that apply to state and federal healthcare programs, including but not limited to the following:

- State and Federal Criminal Fraud Statutes
- State and Federal Civil False Claims Act
- The Federal Anti-Kickback Law
- The Physician Self-Referral (Stark) Law
- State and Federal prohibitions against employing or contracting with debarred, excluded, or ineligible individuals.
- HIPAA
- Health Information Technology for Economic and Clinical Health Act
- Family Educational Rights and Privacy Act
- Improper Claims for Organ Acquisitions Costs
- Improper Claims for Clinical Trials
- Fair Market Value
- Grants
- Federal Healthcare Aid (i.e., aid for healthcare such as the CARES Act; student financial aid is not included within this scope)
- Research

REPORTING COMPLIANCE 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 (refer to the “No Retaliation” section). Where to best raise concerns depends on the 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 Plan, applicable law or UToledo policy. To determine whether a violation has occurred and how to respond to protect the UToledo from future violations and enforcement actions, investigations will be coordinated with the Office of Legal Affairs, using internal or external investigators, auditors, consultants, attorneys, or other independent contractors as appropriate.

GUIDELINES FOR REPORTING

Personnel 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 UToledo policies or any Federal, State or Local laws and regulations.

How to Report

- Local Resolution – The best place to raise a concern typically begins at the 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 Resources department for concerns regarding employment or discrimination; The Title IX Office for sexual harassment; or Athletic Compliance Officer for possible National Collegiate Athletics Association violations.
- 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) 383-4215
- Anonymous Reporting Line (Confidential) UToledo has an Anonymous Reporting Line to provide a simple way to report any situation or UToledo conduct believed to violate UToledo policy, federal, state, or local laws and regulations, government contract or grant requirements. The toll-free number is (888) 416-1308. A trained interviewer documents the concern, and the information is relayed to the appropriate UToledo office to investigate.
- Report Directly to the Fiscal Intermediary or CMS 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 the following:

- 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 UToledo personnel. Matters involving allegations of misconduct, serious violations of law or policy will be directed to the Office of Legal Affairs.

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

Due to the nature of certain claims, UToledo 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.

UToledo is committed to safeguarding the confidentiality of individuals who submit reports. Employees are the best asset in monitoring compliance. Therefore, UToledo 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. Please refer to “No Retaliation” section below.

Status and resolution of a complaint

To determine the status or resolution of a complaint:

- UToledo 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 for communication and to 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. Students should use the anonymous student reporting line <https://www.utoledo.edu/title-ix/anonymous-reporting.html> for reporting academic related events. Students, staff, and faculty should report issues of sex discrimination, harassment, and sexual violence through Title IX https://cm.maxient.com/reportingform.php?UnivofToledo&layout_id=7.

CORRECTIVE ACTION PLAN

Whenever a compliance issue has been identified, through monitoring, reporting of possible issues, investigations, or otherwise, the appropriate UToledo 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 employees and, when necessary, discipline in accordance with UToledo policies and procedures.

NO RETALIATION

Employees who report in good faith possible compliance issues will not be subjected to retaliation or harassment because of their report. Concerns about possible retaliation or harassment should be reported to the Compliance Officer. 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 because 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.

ENFORCMENT AND DISCIPLINE

Failure to comply with UToledo 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.

Imposition of any disciplinary action shall be consistent with applicable law, human resource policies, medical staff bylaws and other standards. Discipline will be imposed fairly and equitably based upon full consideration of the circumstances.

REVISIONS TO THE PLAN

This 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.

UTOLEDO MISSION, VALUES AND VISION STATEMENT

The UToledo Mission, Vision, and Value statements are located on the UToledo website at the following address:

<http://www.utoledo.edu/campus/about/mission.html>

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