

CUIMC Clinical Compliance Program Charter

Purpose

- Columbia University Irving Medical Center (CUIMC), as an operating unit of Columbia University, is committed to operating with integrity in compliance with applicable laws, regulations, and policies. The University expects all members of the University to conduct themselves consistent with the highest ethical standards.

As a Medicaid program provider, the CUIMC Clinical Compliance Program outlines the adoption and implementation of a compliance program to meet the requirements of New York State Social Services Law (SOS) § 363-d and 18 NYCRR subpart 521-1, and all related guidance. This Compliance Program is aimed to, among other things, reinforce a control structure to prevent and detect fraud, waste, and abuse.

The CUIMC Clinical Compliance Program is led by the CUIMC Clinical Compliance Officer and supported by the CUIMC Clinical Compliance Committee. The responsibilities and duties of each are outlined in this charter.

Duties and Responsibilities of the CUIMC Clinical Compliance Officer/ Chair of the CUIMC Clinical Compliance Committee

With the support of the CUIMC Clinical Compliance Committee, the CUIMC Clinical Compliance Officer shall:

- Serve as the focal point for the compliance program
- Be responsible for the day-to-day operation of the compliance program
- Monitor the compliance program's adherence to applicable laws, regulations, and guidance
- Oversee and monitor the adoption, implementation, and maintenance of the CUIMC Clinical Compliance Program and evaluate its effectiveness
- Draft, implement, and update annually a compliance work plan reflecting any changes to Federal and State laws, rule, regulations, policies, and standards
- Review and revise the Compliance Program and related written policies and procedures and standards of conduct, to incorporate changes based on CUIMC's organizational experience and promptly incorporate changes to Federal and State laws, rules, regulations, policies, and standards
- Provide quarterly updates to the senior leadership and CUIMC Clinical Compliance Committee on the progress of adopting, implementing, and maintaining the compliance program, and compliance issues detected and/or addressed during the relevant quarter
- Assist in establishing methods to improve CUIMC's efficiency, quality of services, and reducing CUIMC's vulnerability to fraud, waste, and abuse
- Document, report, coordinate, and pursue any remediation or corrective action in response to compliance issues identified in any audit or investigations
- Be responsible for coordinating the implementation of the fraud, waste, and abuse prevention program
- Have access to all records, documents, information, facilities, and individuals needed to carry out Compliance Program activities

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- Manage and monitor risk mitigation strategies in related compliance areas
- Manage and monitor compliance issues that are detected to ensure that compliance issues are remediated, and appropriate auditing and monitoring or targeted training is implemented to address the issue and prevent recurrence
- Publicize and communicate the lines of communication available for confidential reporting of compliance concerns
- Complete compliance training annually
- Serve as Committee Chair to the CUIMC Clinical Compliance Committee and oversee the CUIMC Clinical Compliance Committee
 - Convene the CUIMC Clinical Compliance Committee quarterly
 - Direct the CUIMC Clinical Compliance Committee sub committees to present to the CUIMC Clinical Compliance Committee
- Ensure that policies and procedures are available to all affected individuals. “Affected individual” as used herein means all persons who are affected by CUIMC’s risk areas, including employees, the chief executive and other senior administrators, managers, contractors, agents, subcontractors, independent contractors, and governing body and corporate officers.

The CUIMC Clinical Compliance Officer shall be allocated sufficient staff and resources to satisfactorily perform all of the above duties.

The CUIMC Clinical Compliance Officer shall report directly to [the CUIMC chief executive or other senior administrator designated by the chief executive] and shall periodically report directly to the University governing body on the activities of the CUIMC Clinical Compliance Program.

Duties and Responsibilities of the CUIMC Clinical Compliance Committee

The CUIMC Clinical Compliance Committee is responsible for coordinating with the CUIMC Clinical Compliance Officer and ensuring that it is conducting business in an ethical and responsible manner, consistent with its compliance program and will be comprised of senior managers.

In addition to carrying out any other responsibilities delegated to the CUIMC Clinical Compliance Committee by the Chair, the CUIMC Clinical Compliance Committee shall:

- Be responsible for coordinating with the CUIMC Clinical Compliance Officer to ensure that business is conducted in an ethical and responsible manner, consistent with the Compliance Program
- Coordinate with the CUIMC Clinical Compliance Officer to ensure that the written policies and procedures, and standards of conduct are current, accurate and complete, and that the required trainings are timely completed
- Assist in designing and administering a compliance training program for all affected individuals
- Coordinate with the CUIMC Clinical Compliance Officer to ensure communication and cooperation by affected individuals on compliance related issues, internal or external audits, or any other function or activity required
- Coordinate internal or external audits, or any other function or activity required, with the CUIMC Clinical Compliance Officer
- Advocate for the allocation of sufficient funding, resources, and staff for the operation of

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the Compliance Program

- Ensure that CUIMC has effective systems and processes in place to identify Compliance Program risks, overpayments and other issues, and effective policies and procedures for correcting and reporting such issues
- Ensure that required modifications to the compliance program are adopted and implemented
- Establish, implement, and publicize the availability of effective lines of communication
- Make available a website with information relating to the CUIMC Clinical Compliance Program and standards of conduct
- Determine, establish, and implement an effective system for routine monitoring and identification of compliance risks
- Conduct an annual Compliance Program review
- Complete compliance training annually

The CUIMC Clinical Compliance Committee reports directly and is accountable to the CUIMC chief executive and the University's governing body.

Membership

The CUIMC Clinical Compliance Committee shall be composed of:

- CUIMC Clinical Compliance Officer, as Committee Chair
- Senior Faculty, Chair level
- Such other persons as determined by the Committee from time to time.

Current CUIMC Clinical Compliance Committee members are set forth on Appendix A.

Collectively, the CUIMC Clinical Compliance Officer and the CUIMC Clinical Compliance Committee will ensure that the CUIMC Clinical Compliance Program: (i) is well-integrated into CUIMC's operations and supported by the highest levels of the organization, including the chief executive, senior management, and the University's governing body; (ii) promotes adherence to CUIMC's legal and ethical obligations; and (iii) is reasonably designed and implemented to prevent, detect, and correct non-compliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for CUIMC's risk areas and organizational experience.

Meetings

The Chair shall preside at meetings of the CUIMC Clinical Compliance Committee and shall set the agenda.

The CUIMC Clinical Compliance Committee shall meet no less than four times annually, no less than once per calendar quarter, and as often as deemed necessary or appropriate, in its judgment, to discharge its duties and responsibilities. Meetings of the CUIMC Clinical Compliance Committee may be held in-person and/or via telephonic or electronic conference, and at such times and places as the CUIMC Clinical Compliance Committee determines. A majority of the members shall constitute a quorum. If a quorum is present, a majority of the members present shall decide any matter brought before the CUIMC Clinical Compliance Committee. The Chair may call an ad hoc meeting of the CUIMC Clinical Compliance

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Committee upon due notice to all other members for urgent matters. Notice by electronic mail shall be considered sufficient notice. The CUIMC Clinical Compliance Committee may also act by written consent signed by all its members.

The CUIMC Clinical Compliance Committee, through its Chair, may request that any member of Medical Center staff attend a meeting of the CUIMC Clinical Compliance Committee or for such person to meet with the members of or any advisors to the CUIMC Clinical Compliance Committee.

The University Office of General Counsel shall have access to the CUIMC Clinical Compliance Committee.

Subcommittees

The CUIMC Clinical Compliance Committee will create the following subcommittees, which will each conduct oversight of the relevant subject matter area and periodically report on its activities and findings to the CUIMC Clinical Compliance Committee, as set forth in more detail below.

- Billing Compliance
- Communication and Training
- Auditing and Monitoring
- Managed Care and Credentialing
- Revenue Cycle
- Quality

Duties of the Subcommittees

In addition to carrying out any other responsibilities delegated to the subcommittees by the Chair or the CUIMC Clinical Compliance Committee members, the subcommittees shall maintain policies and procedures in accordance with the guidelines of the CUIMC Clinical Compliance Committee. Each subcommittee will report to the Chair and the CUIMC Clinical Compliance Committee, as necessary, and no less than quarterly, on the following issues related to the subcommittees:

- Policies and Procedures
- Compliance Risk Assessment
- Billing Compliance
- Communication and Training
- Other issues, as necessary

Policies, Procedures, and Standards of Conduct

Through policies, procedures and Standards of Conduct, the CUIMC Clinical Compliance Committee shall:

- Outline the structure of the CUIMC Clinical Compliance Program through policies and procedures, including the responsibilities of all affected individuals in carrying out the functions of the compliance program
- Review and coordinate written policies and procedures and standards of conduct that govern the CUIMC Clinical Compliance Program
- Establish a process for drafting, revising, and approving the written policies and procedures

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- Make available, accessible, and applicable the written policies and procedures to all affected individuals
- Communicate to all affected individuals the obligation to comply with all applicable federal and state standards
- Identify governing laws, and regulations that are applicable to CUIMC's risk areas
- Describe the compliance expectations as outlined in the standards of conduct
- Outline responsibilities of all affected individuals in carrying out the functions of the CUIMC Clinical Compliance Program
- Provide guidance to affected individuals on dealing with potential compliance issues including:
 - Identifying potential compliance issues, questions, and concerns
 - Set expectations for reporting compliance issues
 - Explain how to report such issues, questions, and concerns to the CUIMC Clinical Compliance Officer
- Outline the duty to report unethical or illegal conduct promptly to the CUIMC Clinical Compliance Officer or other appropriate compliance personnel
- Describe how potential compliance issues are investigated and resolved by CUIMC and the procedures for documenting the investigation and the resolution or outcome.
- Maintain a non-retaliation policy that:
 - Identifies the methods and procedures for communicating compliance issues to the appropriate compliance personnel
 - Includes a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to reporting potential compliance issues to appropriate personnel, participating in investigation of potential compliance issues, self-evaluations, audits, remedial actions, reporting instances of intimidation or retaliation and reporting potential fraud, waste or abuse to the appropriate State or Federal entities.
- Review policies and procedures at least annually to determine if they have been implemented, followed, effective, and whether any modifications are required
- Policies will describe CUIMC's fundamental principles and values, and commitment to conduct business in an ethical manner.
- Written policies will address the following laws, including detailed information about the topics listed below:
 - **Federal False Claims Act, Title 31 United States Code §§ 3729 to 3733, excluding § 3730(h):**
 - liability
 - damages and penalties,
 - the knowledge requirement, and
 - the qui tam provisions.
 - **Federal administrative remedies for false claims and statements, Title 31 United States Code §§ 3801 to 3812:**
 - liabilities,
 - civil penalties and damages, and
 - periodic adjustment to civil penalties by Congress.
 - **NYS False Claims Act, NYS Finance Law §§ 187 to 194, specifically §§ 187 to 190 and 192 to 194:**
 - liability,

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- damages and penalties,
- false claims and reverse false claims, and
- the qui tam provisions.
- **NYS laws pertaining to civil liabilities, penalties, and administrative sanctions for false claims and statements:**
 - Social Services Law § 145-b—False Statements; actions for treble damages, and
 - Social Services Law § 145-c—Sanctions.
- **NYS laws pertaining to criminal liabilities and penalties for false claims and statements:**
 - Social Services Law § 145—Penalties,
 - Social Services Law § 366-b—Penalties for Fraudulent Practices,
 - Penal Law Article 155—Larceny,
 - Penal Law Article 175—Offenses Involving False Written Statements,
 - Penal Law Article 176—Insurance Fraud, and
 - Penal Law Article 177—Health Care Fraud.
- **federal and state whistleblower protections, including application, protections, prohibited actions, and available remedies:**
 - Federal False Claims Act (31 U.S.C. § 3730(h)),
 - NYS False Claims Act (State Finance Law § 191—Remedies),
 - NYS Labor Law § 740, and
 - NYS Labor Law § 741.

Disciplinary Action

Through policies, procedures and Standards of Conduct, the CUIMC Clinical Compliance Committee shall:

- Maintain a disciplinary action policy, consistent with the University’s faculty handbooks (as applicable), which among other things provides that affected individuals who fail to comply with CUIMC’s written policies and procedures, standards of conduct, or State and Federal laws, rules and regulations will be subject to disciplinary action as appropriate based on the particular circumstances, and that these guidelines will be carried out and enforced fairly and consistently regardless of the personnel position within the CUIMC organization (subject to certain applicable contractual and legal requirements, e.g., collective bargaining agreements and faculty rights).
- Establish standards for escalating disciplinary actions that must be taken in response to non-compliance, with intentional or reckless behavior being subject to more significant sanction.
- Publish, communicate, and disseminate the disciplinary action policy and any related procedures.

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Training and Education

The CUIMC Clinical Compliance Officer, members of the CUIMC Clinical Compliance Committee, CUIMC leadership, employees, relevant vendors, and all other affected individuals shall complete the compliance training program promptly at the time of initial hire or contracting and no less frequently than annually thereafter. All training and education will be designed to be easily understandable and accessible for all affected individuals.

- Training on the structure of the CUIMC Clinical Compliance Program including:
 - The role of the CUIMC Clinical Compliance Officer and Committee
 - Where to find materials relating to the compliance program
 - Where to go for help
 - Duty to report, and process for anonymously reporting, compliance concerns
 - Commitment to compliance and ethics
 - Overview of CUIMC risk areas and organizational experience
 - Disciplinary standards, with an emphasis on those standards related to the prevention of fraud, waste, and abuse
 - How CUIMC responds to compliance issues and implements corrective action plans
 - Coding and billing requirements and best practices
 - Claim development and the submission process
- The CUIMC Clinical Compliance Officer and CUIMC Clinical Compliance Committee will develop and maintain a training plan that will address, at a minimum, the following:
 - Key subject matter areas for training
 - Timing and frequency of the training
 - Outline affected individuals that are required to complete training
 - How completion of training and competency will be tracked (e.g., will a certain score be required to consider a training “complete” for a relevant individual)
 - How the effectiveness of the training will be periodically evaluated
 - Include written policies and procedures relating to disciplinary standards and procedures
 - Consequences for failure to complete required training
 - Targeted training that may be conducted on an ad hoc basis in response to identified compliance issues (e.g., training on billing and coding requirements, medical record, and documentation requirements, etc.)

Auditing and Monitoring

- The CUIMC Clinical Compliance Program Compliance Officer and Compliance Committee will adopt an effective system for the routine monitoring and identification of compliance risks, including internal monitoring and audits and, as appropriate, external audits, to evaluate compliance with the requirements of applicable law and the overall effectiveness of the compliance program.
- Audits will be conducted by auditors with expertise in applicable laws and the subject matter of the audit.
- The CUIMC Clinical Compliance Program Compliance Officer and Compliance Committee will

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ensure that all affected individuals are screened at the time of initial hire or contracting and monthly thereafter against the Department of Health and Human Services (HHS) Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and the New York State Medicaid Program exclusion list.

- Results of auditing and monitoring activities will be promptly shared with the Compliance Committee.

Reporting

The CUIMC Clinical Compliance Committee shall:

- Report regularly to the Executive Vice President for Health Sciences and select senior leaders
- Report potential fraud, waste or abuse to the appropriate State or Federal entities (as appropriate)
- Maintain a summary of compliance issues reported, including how each issue was investigated, remediated, resolved, and any follow-up training, auditing and/or monitoring conducted
- Summarize results of auditing and monitoring efforts
- Maintain minutes of Committee meetings and materials including dated meeting minutes, attendance, and documents relating to the discussion of auditing and monitoring activities
- Provide periodic updates to the University's Audit Committee
- Maintain an anonymous compliance reporting hotline through which individuals can report compliance issues to the Compliance Officer
- Ensure that lines of communication are publicized and accessible to all affected individuals and Medicaid recipient patients of CUIMC, and allow for questions to be submitted and compliance issues to be reported
- Ensure that the confidentiality of persons reporting compliance issues are maintained to the extent feasible unless the matter is subject to a disciplinary proceeding; referred to, or under investigation by a governmental agency or law enforcement; or disclosure is required during a legal proceeding; and such persons shall be protected under CUIMC's policy for non-intimidation and non-retaliation.

Responding to Compliance Issues

- The CUIMC Clinical Compliance Program Compliance Officer and Compliance Committee will adopt an effective system for: promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of internal auditing and monitoring, correcting such problems promptly and thoroughly to reduce the potential for recurrence; and ensuring ongoing compliance with state and federal laws, rules, regulations.
- Upon the detection of potential compliance risks and compliance issues, the Compliance Officer and Compliance Committee will ensure that prompt action is taken to investigate the conduct in question and determine what, if any, corrective action is required, and promptly implement such corrective action. Any investigation of compliance issues and any disciplinary action taken in relation to compliance investigation will be documented in specific detail.
- Credible evidence that applicable law was violated will be reported to the relevant governmental entity.

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Annual Evaluation

The CUIMC Clinical Compliance Committee shall conduct an annual evaluation of the performance of the Compliance program including a review of the adequacy of this Charter annually and recommend such amendments and improvements as appropriate.

Liaison

The liaisons to the CUIMC Clinical Compliance Committee will be the Controller’s Office and the Faculty Practice Office.

REVISION HISTORY	
Effective Date	[●] March 28, 2023
Revision Dates	[●]

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Appendix A

Members of the CUIMC Clinical Compliance Committee

#	Name	Title
1	Jim Mc Kiernan	CUIMC Clinical Compliance Officer Chair, CUIMC Clinical Compliance Committee Senior Vice Dean for Clinical Affairs and CEO of Columbia Doctors Chair, Department of Urology
2	Fran Caracappa	Vice President, CUIMC Finance and Controller
3	Mary D'Alton	Chair, Department of Obstetrics and Gynecology
4	Jeff Hensley	Associate Vice President Finance, Internal Audit
5	Manasa Gopal	Associate General Counsel
6	Larry Lustig	Chair, Department of Otolaryngology Head and Neck Surgery
7	Angela Mills	Chair, Department of Emergency Medicine
8	Rudi Odeh-Ramadan	Vice Dean for Finance and Administration
9	Jordan Orange	Chair, Department of Pediatrics
10	Craig Smith	Chair, Department of Surgery
11	Joel Stein	Chair, Department of Rehabilitation and Regenerative Medicine
12	Rae Vagg	Chief Operating Officer, Faculty Practice Organization