

Corporate Compliance Program

Introduction

Mako Medical Laboratories, LLC (“MAKO”) and its administration are committed to quality and efficient patient care; high standards of ethical, professional and business conduct; and full compliance with all applicable federal and state laws affecting the delivery or payment of health care, including those that prohibit fraud and abuse or waste of health care resources.

The purpose of this Compliance Program and its component policies and procedures is to establish and maintain a culture within MAKO that promotes quality and efficient patient care; high standards of ethical and business conduct; and the prevention, detection and resolution of conduct that does not conform to MAKO’s standards and policies, applicable law, and health care program or payor requirements. The Compliance Program applies to all MAKO personnel, including but not limited to its Leadership Team, administration, employees, volunteers, and other entities providing services on behalf of MAKO.

The Compliance Program includes the following elements:

- Written standards, policies and procedures which promote MAKO’s commitment to compliance with applicable laws and regulations.
- The designation of a Compliance Officer and Compliance Committee charged with the responsibility of implementing and monitoring the Compliance Program.
- Regular, effective education and training programs for all affected MAKO personnel as appropriate to their functions.
- A process to receive complaints concerning possible Compliance Program violations, procedures to protect the anonymity of complainants to the extent possible, and policies that protect complainants from retaliation.
- A process to respond to allegations of improper activities and the enforcement of appropriate disciplinary action against MAKO personnel who have violated MAKO policies, laws, regulations, or health care program requirements.
- Periodic audits or other methods to monitor compliance and assist in the reduction of problems in any identified areas.
- A process for investigating and resolving any identified problems.

Compliance Governance

The Compliance Committee is responsible for ensuring an effective Compliance Program, appointing a qualified Compliance Officer and Committee, and providing appropriate resources. The Compliance Committee includes leaders from billing, clinical, legal, and administrative functions and meets monthly to review risk areas and support ongoing compliance efforts.

The Compliance Committee has the following duties:

- Meet quarterly or more frequently as deemed necessary.
- Advise and assist the Compliance Officer in implementing and monitoring the Compliance Program throughout MAKO.
- Assist the Compliance Officer and department leaders in identifying, analyzing, and prioritizing specific areas of concern.
- Assist in developing, implementing, monitoring and evaluating standards, policies and procedures to ensure compliance in specific departments.
- Assist the Compliance Officer in developing procedures to promote the detection of compliance problems through employee reports and complaints.

- Assist the Compliance Officer in developing procedures to evaluate and respond to compliance complaints and problems.
- Participate in periodic training concerning issues relevant to the Compliance Program.
- Maintain the confidentiality of any compliance issues brought before the committee consistent with applicable MAKO policies, laws and regulations.

The Compliance Officer has the following duties:

- Oversee, monitor, and coordinate the implementation and maintenance of an effective Compliance Program.
- Serve as chairperson of the Compliance Committee.
- Periodically revise the Compliance Program as necessary to meet the needs of MAKO and comply with relevant laws, regulations, and third-party payor program requirements.
- In cooperation with Human Resources, develop and direct programs that educate and train MAKO personnel concerning the Compliance Program and applicable legal requirements.
- Ensure that contracts, financial arrangements, marketing initiatives, or other transactions that may implicate fraud and abuse laws and regulations are reviewed for compliance.
- Work with MAKO managers and the Compliance Committee to establish appropriate internal compliance reviews and evaluation procedures.
- Develop policies and procedures that encourage and allow MAKO personnel to report suspected compliance violations and other improprieties without fear of retaliation, including anonymous reporting where possible.
- Take appropriate action on matters that raise compliance concerns, including designing and coordinating internal investigations and any resulting corrective action.
- Promptly report any apparent intentional violation of any state or federal regulation to the Administrator, who may notify legal counsel and coordinate any appropriate disclosure to the appropriate government agency.

Standards of Conduct

All MAKO personnel must adhere to ethical and professional behavior, comply with laws and regulations, and avoid improper conduct. Prohibited activities include offering or receiving remuneration for referrals, entering unauthorized financial relationships with physicians, waiving copays improperly, upcoding, unbundling, duplicate billing, and submitting unsupported claims. Privacy and confidentiality obligations are strictly enforced, including adherence to HIPAA. Violations are subject to disciplinary action, including termination.

Education and Training

New employees and board members receive Compliance Program training during onboarding, including MAKO's ethical commitments, standards of conduct, and reporting procedures. Annual refresher training is mandatory, and departments such as billing, coding, and marketing receive additional targeted education. Training attendance is documented and monitored by Human Resources and the Compliance Officer.

Reporting and Investigations

MAKO offers confidential and anonymous channels for reporting concerns, including direct access to the Compliance Officer, committee members, and a secure compliance lock box. All reports are logged, investigated, and resolved per documented procedures. MAKO follows a non-retaliation policy and complies with the 60-day repayment obligation for overpayments.

Auditing and Monitoring

Departments conduct ongoing self-assessments and periodic audits. Billing and coding are reviewed quarterly using sampling to confirm medical necessity and correct billing practices. Custom test profiles are monitored annually for compliance, and utilization reviews are conducted when growth exceeds baseline thresholds. Findings inform training and process improvements.

Enforcement and Discipline

Violations of our Compliance Program are met with appropriate disciplinary action. Enforcement is consistent and aligned with our policies and applicable legal requirements.

Other Policies and Procedures

This Compliance Policy is intended to establish a procedural framework for compliance by MAKO. It is not intended to set forth fully all of the substantive programs and practices of MAKO. MAKO maintains various compliance practices and policies in addition to this Corporate Compliance Policy, all of which continue to be a part of the overall Compliance Program at MAKO.