MOLECULAR® TESTING LABS

Compliance Program Guide for First-Tier, Downstream, and Related Entities (FDRs)

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Introduction

Molecular Testing Labs is committed to maintaining a robust compliance program in accordance with all rules and regulations under federal law. This program extends to all affiliated business associates contracted with Molecular Testing Labs to provide healthcare services to patients. These associates include subcontractors, also referred to as First-Tier, Downstream, and Related Entities (FDRs) by The Centers for Medicare & Medicaid Services (CMS).

Molecular Testing Labs has created the following comprehensive compliance program guide under the Code of Federal Regulations (CFR) Title 42, detailing the Medicare compliance program requirements for FDRs to follow the standards as required by CMS.

Please review this guide to make sure you understand the policies and procedures you must follow to support the compliance requirements of this program. Thank you for your participation!

What is an FDR?

Current Definitions from CMS:

A **First-Tier Entity** is any party that enters a written arrangement, acceptable to CMS, with a Medicare Advantage (MA) organization, or part D plan sponsor/applicant. These arrangements provide administrative or healthcare services to a Medicare-eligible individual.

A **Downstream Entity** is any party that enters a written arrangement, acceptable to CMS, with persons or entities.

A **Related Entity** is any party that holds common ownership or control of an MA organization or part D sponsor.

The compliance requirements in this guide apply to healthcare providers contracted with our Medicare network, including physicians and hospitals and other provider types. This also applies to entities performing administrative services relating to MA or part D contracts with CMS *(i.e. hotline operations, credentialing)*.

Medicare Compliance Program Requirements

All organizations and downstream entities providing healthcare services must comply with the following compliance program requirements per Medicare:

- General Compliance Training
- Distribution of compliance program policies and avenues to report
- Screen for excluded entities
- Maintain record retention
- Report FWA, offshore subcontracting, or general compliance concerns
- Monitor and audit Downstream and Related Entities

FDRs that are noncompliant by failing to meet CMS compliance standards outlined in this guide will be subjected to the following actions:

- Creation of a corrective action plan
- Retraining the employee/entity
- Termination of contract with Molecular Testing Labs

Depending on the severity of the noncompliant behavior, the FDR must take quick action to fix any issues and prevent future occurrences from happening again.

Medicare Compliance Program Attestation Requirements

An authorized representative from your organization must attest to compliance with the Medicare compliance program requirements on a **yearly** basis.

This authorized representative must be someone responsible for all employees, contracted employees, providers, and vendors who provide healthcare or administrative services under Medicare. They may be your compliance officer, manager, or a senior executive.

Our FDR compliance attestation will be sent to you **once** a year by our Customer Relations department. It is mandatory that you keep record of your compliance with CMS requirements for 10 years.

Our attestation document can also be found at:
https://moleculartestinglabs.com/compliance

Monitoring and Auditing of FDRs

Molecular Testing Labs will conduct yearly audits verifying the following:

- Submission of attestation form (yearly)
- Distribution of a Code of Conduct (its own, or MTL's)
- Distribution of General Compliance Training for FDRs

Ongoing monitoring and yearly compliance audits to ensure that all entities/vendors continue to adhere with the Centers for Medicare & Medicaid Services' (CMS) compliance program requirements.

What Is a Compliance Program and Why Do We Need It?

A compliance program is the summary of all policies, procedures, and daily operations developed and implemented, and actions taken by, an organization to ensure compliance with applicable statutes and regulations to prevent and detect illegal or unethical activity including fraud, waste, and abuse.

We need a compliance program to comply with a law passed as part of healthcare reform legislation, which requires Medicare and Medicaid providers and suppliers to have a compliance program. This program also meets the expectations of the Health and Human Services (HHS) Office of Inspector General (OIG), Centers for Medicare & Medicaid Services (CMS), and their contractors, entities, and various state agencies.

This program ensures that all vendors are aware of and understand their legal and ethical obligations when acting on behalf of Molecular Testing Labs.

Benefits of an Effective Compliance Program

- Demonstrates a strong commitment of excellence to employees and the community, as well as builds trust.
- Lessens probability that improper conduct will occur and INCREASES the likelihood that improper conduct will be reported and detected.
- Establishes a proactive, rather than reactive, approach for detecting and addressing problems.
- Reduces likelihood of investigations, enforcement actions, and whistleblower suits.

Elements of an Effective Compliance Program

Compliance programs are not one-size-fits-all. The structure depends on the size and character of the organization and the nature of its business.

A compliance program typically includes:

- Code of conduct
- Structural policies and procedures
- Substantive policies and procedures
- Compliance Officer
- Compliance Committee

Who Oversees the Compliance Program?

- **Compliance Manager**
  - Provides direction and oversight through open communication
  - Identifies and assesses compliance risk
  - Prepares and distributes all compliance program documents
  - Develops and implements education and training programs
  - Oversees a retaliation-free, anonymous internal reporting process
- **Compliance Committee**
  - Assists the compliance manager in fulfilling their duties
  - Permanent members are detailed in the committee charter, which is part of the compliance program manual

How Do Employees Report Concerns or Ask Questions?

- Employees must promptly report suspected violations through proper channels, and they are encouraged to raise compliance-related issues at any time.
- Reports can be made in person, by phone, or in writing (e.g., by email) to an immediate supervisor, the compliance Manager, or any compliance committee member.
- Reports also can be made to the compliance Hotline 24 hours a day, 7 days a week.
    - Allows for anonymous reports by telephone or through online submission to a third party
        - Online: www.lighthouse-services.com/moleculartestinglabs
        - Telephone: 855-400-6002
- Anonymous reports are acceptable but employees are encouraged to identify themselves to allow for a complete investigation. Reports are confidential unless disclosure is necessary for legal reasons.
- Retaliation is NOT permitted, but action can be taken if involved in wrongdoing.

How Will MTL Respond to Compliance Violations?

- The Compliance Manager will document and assess the credibility and severity of all reports and will consult with the Compliance Committee and legal counsel as needed.
- All credible reports and matters referred by the board will be the subject of an internal investigation conducted according to investigative protocol.
- Disclosure to enforcement authorities may be necessary.
- The Compliance Manager has broad authority to take corrective action.
- All internal investigations and corrective action plans will be documented. Record retention, including attendance records, training certificates, and any documents demonstrating compliance with program requirements are maintained for 20 years.

Molecular Testing Labs' Code of Conduct

- The Code of Conduct (the "Code") is a summary of the fundamental legal and ethical standards with which FDRs must comply when conducting business on behalf of Molecular Testing Labs. FDRs may provide their own Code of Conduct to all Downstream Entities providing services for Molecular Testing Labs. If an FDR does not have a Code of Conduct, MTL's will be provided for distribution.

- The policies and procedures set forth in the Compliance Program Manual, the Employee Handbook, and other applicable policies and procedures provide more detailed rules designed to ensure that FDRs and Downstream Entities act legally and ethically at all times.

Molecular Testing Labs' Code of Conduct (cont.)

All employees and other agents are expected to exhibit the highest level of integrity at all times. The Code of Conduct and the Policy on Relationships with Healthcare Professionals, which are attached to the Manual as Appendices 2 and 3, are intended to be clear and concise statements of the fundamental ethical standards that all individuals acting on behalf of Molecular Testing Labs must uphold and the legal requirements with which they must comply. The Manual and other policies and procedures implemented by the Company to guide Employees and others in carrying out their duties are more detailed rules designed to ensure that Molecular Testing Labs conducts business in accordance with applicable ethical standards and legal requirements.

Molecular Testing Labs Code of Conduct

Molecular Testing Labs' Code of Conduct (cont.)

All employees and FDRs must:

1. Comply with laws and regulations
   a) Healthcare fraud and abuse
   b) Billing and claims submission
   c) Health and safety
   d) Equal employment opportunity
   e) Non-harassment and sexual harassment

2. Act ethically and avoid conflicts of interest
   a) Fair dealing
   b) Limits on gifts
   c) No exclusion or relevant criminal convictions

3. Protect and properly use company assets
   a) Company property, confidential information, or patient information

4. Participate in compliance training sessions, report any compliance violations, and cooperate with internal/external investigations

Federal Statutes/Regulations to Know

The following federal laws and statutes must be followed and understood by all parties associated with Molecular Testing Labs:

- **Anti-Kickback Statute (AKS)** – employees may not knowingly and willfully offer, solicit, pay, or receive any remunerations (the transferring of anything of value in any form or manner) to induce or in return for a referral, or recommending a referral, or purchasing or arranging for the purchase, of a covered item/service paid for (in whole or in part) by any federally funded program.
    - Remuneration includes: cash, free items or services, discounts, or otherwise below-fair-market-value items or services.
    - Safe harbor regulations define payment and business practices that will not be considered kickbacks, bribes, or rebates that unlawfully induce payment by Medicare or Medicaid programs.
    - Penalties include: substantial fines, imprisonment for up to five years, and exclusion from federal healthcare programs.

Molecular Testing Labs does not allow anything of value, no matter how small, to be offered to a customer (clinic, hospital, other healthcare professional, or employee of such). Any employee found to be in violation of this policy will be immediately terminated and Molecular Testing Labs may be obligated to report the matter to the Office of the Inspector General and the Department of Health and Human Services.

Federal Statutes/Regulations (cont.)

The Stark Law

- Prohibits a physician (or an immediate family member) from referring specimens to a lab with which he/she has a “financial relationship”
- A “financial relationship” is an investment or ownership interest or a compensation arrangement
- No proof of intent required (hard to understand but easy to violate!)
- Exceptions protect legitimate business arrangements only if all conditions are met
- Penalties include mandatory Medicare refunds, civil monetary penalties, exclusion

Federal Statutes/Regulations (cont.)

Civil Monetary Penalties Law

- Prohibits wide range of conduct, including:
  - Beneficiary inducement
  - Employing/contracting with an individual or entity the provider knows or should know is excluded
  - Billing for services requested by an unlicensed physician or excluded provider
  - Billing for medically unnecessary services

- Substantial per-item or -service penalties, damages of up to three times the amount owed, exclusion

Federal Statutes/Regulations (cont.)

False Claims Act

- Forbids knowingly submitting (or causing another person or entity to submit) false claims for payment to the federal government
- Penalties include fines from $5,500 to $11,000 per false claim and damages of up to three times the amount owed
- Suit can be filed by the Department of Justice or a whistleblower (or both)
- Violations of the Anti-Kickback Statute (AKS) or the Stark Law can serve as the basis of a False Claims Act case

Molecular Testing Labs is subject to a variety of state laws because it receives specimens from a variety of states and holds out-of-state laboratory licenses. Fraud and abuse prohibitions (which may apply even if the testing is not covered by a government healthcare program) are:

- Kickback, self-referrals, fee-splitting, false claims

OIG Guidance

OIG Guidance on Application of the AKS to Clinical Laboratory Services Arrangements:

- OIG Fraud Alert, Federal Register, vol.59, Dec.19, 1994
- AKS implicated by provision of phlebotomy services to physicians when phlebotomist performs additional tasks usually performed by office staff
- AKS implicated by other free equipment or services if one purpose is to induce referral
- Includes computers and fax machines (unless used exclusively for the lab's work), professional courtesy testing, free pickup of waste products unrelated to collection for the lab

OIG Guidance (cont.)

OIG Guidance on Application of the AKS to Clinical Laboratory Services Arrangements:

- OIG Letters on free equipment, goods, services
- Multi-use fax machines and computers, fax lines, biopsy needles, phlebotomy services
- The “substance over form” principle that financial statements give a complete and accurate picture of any transactions that take place (substance), rather than looking at it from a legal standpoint (form)
- AKS implicated if the item or service has independent value
- Any reasonable foreseeable “‘misuse’” of equipment implicates both parties

OIG Guidance (cont.)

OIG Guidance on Offering Gifts and Other Inducements to Beneficiaries

- *OIG Special Advisory Bulletin, August 2002*
- Prohibited by the Civil Monetary Penalties Law
- Illegal to offer valuable gift to a beneficiary if person making offer knows or should know it is likely to influence beneficiary's choice of supplier
- No intent required: deliberate ignorance or reckless disregard is enough
- Statutory exceptions apply (including waivers of cost-sharing amounts based on financial need in specified circumstances)

CMS Guidance – Medical Necessity

The Centers for Medicaid Medicare Services (CMS) requires all test orders to be documented in the patient's medical record and must include the following pieces of critical information:

- Date of service
- Provider notes detailing why the test is being ordered for the patient
- Test results acknowledged by the provider and results available in the patient medical record
- Provider notes detailing how the test results were used to either validate or alter the patient's treatment plan

Contact

For any inquiries about this compliance guide, general compliance questions, or to submit a request for additional information, please contact the following Molecular Testing Labs personnel. Thank you!

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