



# Employee Ethics & Compliance Training

January 2023

# Welcome

## Executive Leadership Message

- ▶ Helix Diagnostics (“the Company”) is committed to provide quality clinical laboratory services to its customers, while observing the highest standards of legal and business ethics, in growing a successful business.
- ▶ The purpose of our Compliance Program is to (a) provide a framework for conducting acceptable business practices in an honest and ethical manner, in conformance with the laws, rules, and regulations that govern the laboratory industry and (b) serve as the foundation for establishing a culture within the Company that promotes service excellence and the prevention, detection, and resolution of unlawful or improper conduct.

*Jim Grossi, Owner*



# Compliance Leadership

- ▶ Wendy Dalton – *Director of Quality & Compliance*
  - ▶ Duties & Responsibilities – Appointed to serve as the “Chief administrator” for the implementation and management of an “effective” compliance program, to ensure ongoing compliance with the industry laws and regulations. Works with management and staff to identify and manage regulatory risk.
- ▶ Matthew Edgar – *Manager of Quality & Compliance*
  - ▶ Duties & Responsibilities – Serves as the “Key messenger key messenger (a) in establishing a strong line of communication between the Office of Ethics & HIPAA Compliance and the entire organization and (b) as the key advocate in the administration of the organization’s Compliance Program.
- ▶ Shanni Cooper – *Collector Compliance Coordinator*
  - ▶ Duties & Responsibilities – Ensures collectors are compliant with Helix policies, procedures, collector agreement, Code of Conduct, and HIPAA Compliance.

# Ethics & HIPAA Compliance Program

## What is the “Value”?

- ▶ We are living in an era of increased regulation and enforcement efforts.
- ▶ The risks of non-compliance can be “**crushing**” with devastating penalties.
- ▶ A “**well-balanced**” Ethics and Compliance program will help ensure that the organization is:
  - ▶ Working in harmony to provide service excellence,
  - ▶ Keep customers happy,
  - ▶ Grow the business, and
  - ▶ Achieve the company’s mission for success.



# Training Objectives

The objective of this training program is to help everyone understand the purpose of the Company's Compliance & Ethics Program and its value in building a successful business.

- ▶ **Government Authorities**
- ▶ **Ground Rules For Compliance**
- ▶ **Laws & Regulations that govern the laboratory industry**
- ▶ **Fraud, waste, and abuse**
- ▶ **Enforcement Actions & Settlements**
- ▶ **HIPAA Privacy & Security Compliance**
- ▶ **Helix "Office of Ethics & HIPAA Compliance"**
- ▶ **7 elements of an "effective" Ethics & Compliance Program**
- ▶ **Reporting of Concerning Issues**
- ▶ **Helix "Code of Business Conduct and Ethics"**

# History

- In 1992 the OIG (Office of Inspector General) shook the lab industry with a rampant enforcement climate.
- There was an entirely new emphasis on **medical necessity** as a basis for bringing actions against labs.
- Today, government and private insurance companies, as well as consumers, are aggressively reviewing sales, marketing, and billing practices throughout the healthcare industry to identify wrongdoing.
- The healthcare industry is highly regulated by government agencies and there are many complex laws unique to the laboratory and pathology diagnostic services industry. All organizations that receive funds from Medicare and Medicaid are required to have an effective compliance plan.

A word cloud of healthcare compliance terms on a purple background. The words are arranged in a roughly circular pattern, with some larger and more prominent than others. The colors of the words range from light purple to dark purple. The terms include:

- Monitoring
- Regulations
- Abuse
- Enforcement
- Privacy
- DOJ
- Ethics
- Education
- Committees
- CMS
- Fraud
- Communication
- OIG
- HIPAA
- Anti-kickback
- Compliance
- Prevention
- Conduct
- Standards
- Reporting
- Procedures
- Investigating


# Laboratory Compliance Ground Rules

## ***CMS will only pay for***

- Medically necessary laboratory services,
- Ordered by a physician or authorized individual,
- Accurately performed by a certified laboratory, and
- Reported with valuable diagnostic information

***If all of these requirements are not met, the government could consider the claim to be classified as fraud, waste, and abuse (FWA)***



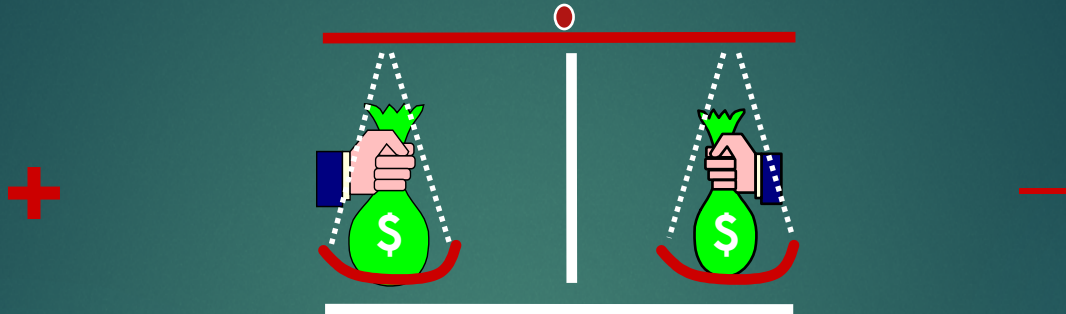
- 
- ▶ Under no circumstance should a Helix employee (collector, lab assistant, or sales rep., etc.) determine a diagnosis code. It should be in writing on an order or requisition form from the ordering provider.
  - ▶ Helix employees should also not guide a client on what tests to order or what diagnosis codes to use.
  - ▶ Lastly, no job aides or cheat sheets should be utilized without the creation and approval by the Compliance Dept. and Executive leadership.

# Fraud, Waste, & Abuse (FWA)

- ▶ **Fraud** – Intentional deception or misrepresentation that could result in some unauthorized benefit or payment
  - ▶ **(Example) Billing for tests or services not ordered, performed or reported**
- **Waste** – Payments that should not have been paid
  - **Medically unnecessary or duplicated services**
- **Abuse** – Payment for services through improper behaviors or billing practices when there is no legal entitlement to that payment
  - **Billing a diagnosis that was not obtained from the patient's medical record**



# Federal Law Basics



## False Claim Act

- **Billing for something you don't deserve**

## Shell Lab (70/30 Rule)

- **Sending out more tests than are performed onsite**

## Anti-kickback (Inducement)

- **Giving away something of value to encourage business**

## Stark Law

- **An inappropriate financial relationship**

The purpose of these laws is to prevent fraud to the government or improper inducements to refer testing, that is reimbursed by the federal government.

# False Claims Act (FCA)

## *It is a crime for any person or organization*

- To **knowingly** or with **reckless disregard**, present a false or fraudulent claim for payment by the federal government; or
- To use a false record or statement to influence the payment of a false or fraudulent claim.

### **Example**

- 1) *Billing for tests not performed or reported*
- 2) *Encouraging the ordering of test(s) that are not medically necessary*
- 3) *Billing with an ICD-10 diagnosis code "not obtained" from the physician*

### **Penalties**

FCA violations will result in a civil penalty per false claim, of not less than \$11,181 and not more than \$22,363, plus triple the government's actual damages.

A person who violates the FCA will also be held liable for the government's costs for bringing a civil action to recover any penalty or damages.

# *False Claim Act*

## *CMS Claim Filing Requirements*



- ▶ **Valid Order** – Order received from a physician or individual with a valid National Provider Identification (NPI), who has not been debarred, sanctioned, or excluded from federally-funded programs
- ▶ **Physician Signature** – Orders must be signed by the physician or non-physician practitioner (NPP) or the ordering physicians or NPPs may be required to furnish medical record evidence of the order upon any internal or external audit to confirm the existence of an order.
- ▶ **Date of Service (DOS)** – The date that the specimen was collected.
- ▶ **Requisition Design** – Fully disclosed non-deceptive marketing practices with an emphasis on choice.
- ▶ **Physician Notice and Diagnosis Information** - Ensure physician awareness of the need to 1) only order medically necessary testing, 2) provide ICD-10 symptomatic diagnosis codes supported in the patient's medical record, and 3) provide a signed Advance Beneficiary Notice (ABN) if required.
- ▶ **Result Report** – Delivered with valuable diagnostic information

# Federal Anti-Kickback Statute (AKS)

Penalizes anyone (physician, laboratory representative, sales representative, etc.) who knowingly and willfully solicits, receives, offers or pays remuneration in cash or in kind to induce the referral of an individual for testing of diagnostic services, which is payable under the Medicare or Medicaid program.

- ▶ Cash kickbacks, bribes, or rebates
- ▶ Free laboratory testing
- ▶ Waiver of co-pays
- ▶ Space rental agreements
- ▶ Free computer equipment
- ▶ Free general use supplies
- ▶ Free non-laboratory pickups
- ▶ Business purchase or lease arrangements



## Penalty

The AKS is a criminal statute and the penalties for violations of the law can be severe. They include fines of up to \$25,000 per violation, felony conviction punishable by imprisonment up to five years, or both, as well as possible exclusion from participation in Federal Healthcare Programs.

- ▶ **Penalties apply equally to the service provider and referring practitioner**

# *Federal Anti-Kickback Statute*

## *Safe Harbor Regulations*

- ▶ The **safe harbor** regulations describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute.
  - ▶ Space rental agreements, commercially reasonable
  - ▶ Purchase arrangements
  - ▶ Consulting arrangements

# Stark Anti-Self Referral Law

## Financial Relationship

Prohibits a physician from referring a Medicare or Medicaid patient to a clinical laboratory with which the physician or an immediate family member has an inappropriate financial relationship with.

- ▶ Stark defines a financial relationship as either
  - ▶ An ownership/investment interest relationship through equity, debt or other means or a compensation relationship.
  - ▶ A focus compensation arrangement with anything of value (cash, goods, or services) being exchanged between a physician (or an immediate family member of the physician) and a provider of laboratory healthcare services.

## Severe Penalties Include:

- ▶ Refund of monies received, civil penalties of up to \$15,000 for each service, and three times the amount of improper payment the entity received from the Medicare program;
- ▶ Exclusion from Medicare and/or state healthcare programs including Medicaid;
- ▶ Payment of civil penalties for attempting to circumvent the law of up to \$100,000 for each circumvention scheme.



# Stark Law “Exemptions”

## Stark Exceptions

- ▶ The Stark Law **mandatory exemptions** detail a number of financial relationships and focus arrangements between physicians and designated health service (DHS) providers that do not result in violations of federal law.

## Exemption Conditions

- ▶ The arrangement must be in writing, signed by the parties, and specify the goods or services to be provided;
- ▶ The written arrangement must specify a timeframe;
- ▶ The compensation for goods or services must be set in advance, equivalent to fair market value, and must not depend on the value or volume of any referrals made between the parties;
- ▶ The arrangement must be commercially reasonable; AND
- ▶ The arrangement must not violate the Anti-Kickback Statute or any other state or federal law.

## Existing Exceptions

- ▶ In-office ancillary services (i.e. in-office testing, X-ray, etc.),
- ▶ Personal service arrangements,
- ▶ Rental of equipment and office space,
- ▶ Fair market value compensation.

# Enforcement Actions & Settlements

## CodeMap® Compliance Briefing November 20, 2013

- ▶ The federal government continues to collect record amounts from providers that find themselves on the wrong side of enforcement actions and subsequent settlements.
  - ▶ In fiscal year 2012, the federal government reported that it had won or negotiated over \$3.0 billion in health care fraud judgments and settlements.
  - ▶ In fiscal year 2012, the Department of Health and Human Services (DHHS), the Office of Inspector General (OIG), and the Department of Justice (DOJ) allocated over \$580 million to combat health care fraud and abuse.



U.S. Department of Health and Human Services

**Office of Inspector General**

*OIG leads the fight against fraud, waste, and abuse in HHS programs and holds wrongdoers accountable for their actions.*

***OIG expects \$4.0 billion in investigative recoveries for FY 2020***

- In FY 2020, OIG brought criminal actions against 624 individuals or organizations engaging in crimes against HHS programs and the beneficiaries they serve, and an additional 791 civil actions.
- OIG also excluded 2,148 individuals and entities from participation in Federal healthcare programs.



# *HIPAA Privacy & Security Compliance*

# Health Insurance Portability and Accountability Act (HIPAA)

## **HIPAA Initiation**

- ▶ Health and Human Services (HHS) regulation initially passed in 1996
- ▶ Entitled “**Standards for Privacy of Individually Identifiable Health Information**”
  - ▶ Commonly known as the “Privacy Rule”
  - ▶ Designed to ensure that patient Protected Health Information (PHI) is secure and confidential
  - ▶ Applicable to all healthcare providers (**covered entities**)

## **HIPAA Expansion**

- ▶ March 26, 2013 – **HIPAA Omnibus Rule** (aka Mega Rule or HITECH Act )
  - ▶ Privacy
  - ▶ Security
  - ▶ Breach Notification Rules (BNR)
  - ▶ Enforcement

## **Enforcement Agency**

- ▶ The Department of Health and Human Services Office of Civil Rights (OCR)

# What is patient Protected Health Information (PHI)?

- ▶ Personal information related to the patient, the patient's health care, or payment

## **Examples:**

- ▶ Patient's name, address, phone numbers
- ▶ Patient's date of birth
- ▶ Patient's social security number
- ▶ Patient's medical record number or health diagnosis

## **Types PHI Breaches**

- ▶ Discarded paper documents, computer hard drives, flash drives, etc.
- ▶ Emails sent to the wrong recipient or inappropriately attached to an email.
- ▶ Lost or stolen paper documents, laptops, flash drives, etc.
- ▶ Sold for monetary gain.
- ▶ Disclosed due to actions of a computer virus.
- ▶ Posted or access provided on a web server.



## How Can I Help Protect PHI?

- ▶ Access only the **minimum** necessary PHI required to perform your job.
- ▶ **Protect** paper records from theft, misplacement and unauthorized access.
- ▶ **Double check** mail, faxes, and emails containing PHI, so that the information doesn't go to unauthorized individuals.
- ▶ When sending PHI to emails outside of Helixmdx.com, ensure that the email is encrypted.

# Reporting PHI Breaches

## Breaches Happen!!

- ▶ All breaches must be reported so that the company can investigate and correct the root cause and report the incident if necessary.



- If you are aware of an ***intentional breach***, you must contact your manager and submit an incident report.
- If you're unsure whether or not an incident is a breach, please report it!



# HIPAA Violation Penalties

## Tiers of Culpability (Liability)

- Tier A - No knowledge of the violation
  - ▶ \$100-\$50,000 per occurrence fine, with \$25,000 annual limit
- Tier B - Reasonable Cause
  - ▶ By exercising reasonable diligence, should have known.
  - ▶ \$1,000-\$50,000 per occurrence fine, with \$100,000 annual limit
- Tier C - Willful Neglect – Breach Issue corrected
  - ▶ Conscious, intentional failure or reckless indifference
  - ▶ \$ 10,000-\$50,000 per occurrence fine, with \$250,000 annual limit
- Tier D - Willful Neglect – Breach issue left uncorrected
  - ▶ Conscious, intentional failure or reckless indifference
  - ▶ \$ 50,000-\$250,000 per occurrence fine, with \$1.5 million annual limit



## *Ethics & Compliance Program Overview*

# OIG Compliance Program

- ✓ OIG believes by implementing an effective compliance program, a lab will: **1)** Achieve better quality control over claims submission and
- 2)** Reduce the risk of future criminal and civil liabilities.
- ✓ Plan to assist laboratories in preventing and correcting fraudulent activity.
- ✓ OIG has zero tolerance towards fraud and abuse.
- ✓ OIG will use its extensive statutory authorities to reduce fraud.

***An effective Compliance Program promotes continual improvement***

# 7 Essential Elements of an “Effective” Compliance & Ethics Program

These 7 elements are identified in the US Sentencing Guidelines as essential to an effective compliance and ethics program. Use them as a road map to establishing and maintaining compliance and ethics at your organization.

01 Standards of conduct, policies, and procedures



**Standards of conduct, policies, and procedures** - Put these policies in writing and use them as the foundation for your entire program

02 Compliance officer and committee



**Compliance officer and committee** - Delegate an individual or group with operational responsibility, autonomy, and authority.

03 Communication and education



**Communication and education** - Create effective, ongoing training methods and establish open lines of communication.

04 Internal monitoring and auditing



**Internal monitoring and auditing** - Use internal tools to evaluate program effectiveness and detect criminal conduct.

05 Reporting and investigating



**Reporting and investigating** - Encourage employees to raise concerns and have investigative procedures in place.

06 Enforcement and discipline



**Enforcement and discipline** - Establish appropriate incentives for compliance and disciplinary actions for violations.

07 Response and prevention



**Response and prevention** - Resolve identified problems promptly and add related issues to monitoring activities.

# *Office of Ethics & HIPAA Compliance*

## **Ethics & Compliance Commitment**

- ▶ Helix Diagnostics is committed to provide quality clinical laboratory services to its customers, while observing the highest standards of legal and business ethics, in growing a successful business.
- ▶ To create a workplace that values the Company's commitment to honesty, fairness, and compliance with the law, all employees must be familiar with and abide by these standards of conduct.

## **Ethics and HIPAA Compliance Program Manual**

- ▶ To further these goals, the Company has adopted a Manual, which articulates the corporate policies and standards
- ▶ Designed to protect and promote Company-wide integrity and enhance our ability to achieve our mission.

# Ethics & HIPAA Compliance Leadership (cont.)

## Corporate Compliance Committee

- James Grossi, Owner
- Liam Dillon, CFO or Melissa Bair, Billing Director (Either one can sit)
- Leo Salvaggio, VP of Sales
- Holly Barber, VP of People
- Michael Wagner, VP of IT
- Wendy Dalton, Quality and Compliance Officer
- Matthew Edgar, Manager, Quality and Compliance
- Amro Almradi, Medical Director
- Bobby Read, VP of Services

### **Ad hoc members:**

- Shanni Cooper, Collector Compliance Coordinator
- Mark Beauchamp, VP of Business Development
- Ashley Story, Interim Manager of Phlebotomy and Collection Services

**Duties & Responsibilities** – This Committee is comprised of a team of selected Company leaders who will meet periodically (quarterly or semi-annually), to assist and advise the Ethics & Compliance Officer in the implementation and maintenance of an “effective” compliance program.

# Compliance and Billing Audit Assessment

## Purpose

- 1) Identify any compliance deficiencies or areas requiring improvement,
- 2) Provide recommendations to improve compliance, and
- 3) Measure the level of compliance of each regulated practice reviewed.

## Approach

Performed by the Compliance Department to evaluate the policies, procedures, and practices, related to ~80 different issues, which are included in the following areas:

Compliance Program Development (A)	Client Support Services (E)	Laboratory Test Billing Practices (I)
HIPAA Compliance Program (B)	Specimen Receiving and Registration (F)	CPT Coding and Key Test Utilization (J)
Business and Focus Agreements (C)	Medical Necessity and ABN Checking (G)	Billing Revenue Cycle Management (K)
Sales and Marketing Activities (D)	Laboratory Specimen Processing (H)	

# *Reporting Process & Open Lines of Communication*

## *Employee's Obligation*



- ▶ If there is any situation that you believe may be or is in violation of the provisions of the Code, this Manual or any other Company policies or procedures, you should immediately contact your supervisor, another member of the management team, or the Compliance Department.

## *Open Door Non-Retaliation Policy*

- ▶ Any employee who reports a violation can be assured that no retaliation will be taken against them for reporting possible violations of Company policies, including the Code. Each employee is responsible for ensuring compliance.



# Code of Business Conduct



- **Team effort** - Creating a workplace culture that values integrity, a commitment to honesty, equity, and compliance with the law is a team effort.
- **Key to achieve our mission** the Company has established an Ethics and Compliance Program, which includes a Code of Business Conduct and Ethics.
- **Promote legal & ethical conduct** - The Company's Code of Conduct is designed to assist its management, employees, contractors, business partners and affiliated providers in complying with applicable state and federal laws and conducting business in an ethical manner.
- **Commitment** - Everyone must be familiar with and committed to abiding by these standards of conduct and report concerning issues and practices.



# Code of Business Conduct and Ethics Requirements

- ▶ **Honesty** - Deal honestly and ethically in all Company matters, both internally and externally.
- ▶ **Integrity** - Comply with all laws, rules and regulations applicable to my work responsibilities.
- ▶ **Commitment** - Advance the Company's business interests whenever the opportunity arises.
- ▶ **Conflict of Interest** - Avoid actual or apparent dealings that may be in conflict with the Company's interests.
- ▶ **Trustworthiness** - Protect the Company's assets and promote their efficient and legitimate business use.
- ▶ **Confidentiality** - Protect the Company's confidential information and the confidential information of the Company's customers, patients and others.
- ▶ **Health and Safety** - Protect the health and safety of all Company employees.
- ▶ **Honor & Respect** – Strive to create an enthusiastic work environment that fosters teamwork, creativity, individual initiative, and personal achievement, with honor, respect, and fairness for fellow employees and the customers we serve.
- ▶ **Communication & Reporting** - Report to a Company manager and or Compliance Officer, any actual or possible wrongdoing, misconduct, or violation of the Code.

# Ways to Report Concerns

- 1) **Your supervisor, manager, director, or senior leadership team member over your work area** will have the most knowledge & experience to address the compliance issue internally.
- 2) **For confidential reporting**, please feel free to contact:
  - [Compliance@helixmdx.com](mailto:Compliance@helixmdx.com) or (888) 275-5221 Ext. 135

