



# Employee Ethics & Compliance Training



Larry Small, MS, MT(ASCP)  
CEO & Managing Partner

*LabPath is a full-service laboratory consultancy with specialized skills in structuring businesses for success, regulatory compliance, billing financial management, and LEAN operations among others*

# 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.
- This week marks the establishment of the “Office of Ethics & HIPAA Compliance” and the implement a “Ethics & HIPAA Compliance Program”.
- 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*

*Luis Perez, President and CEO*



# ***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 60-minute 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"***



## ***It's all about the money!!!***

Laboratory services is a *“highly competitive”* industry.

*“Service Excellence”* is the *“Key”* for winning. *“Cheating”* is Prohibited

*“Getting Paid”* is a complex error-prone process, filled with payment and legal risks.

*Requires a “Company-wide”* commitment to compliance with meeting the billing information requirements of each payor.

- Authorized Physician signature
- Patient billing & demographic information
- ICD-10 Medical Necessity
- Test results reported
- Accurate test CPT coding
- Timely billing/claim filing

***Any fault or error could result in “non-payment” and/or possible regulatory violation, with company or personal penalties***

# *Government Authorities*

- **CMS (Centers for Medicare and Medicaid Services)**
  - Responsible for ensuring managing government funds spent on healthcare service (i.e., Medicare, Medicaid, Champus, etc.)
  
- **OIG (Office of Inspector General)**
  - Federal police
  
- **DOJ (Department of Justice)**
  - State police



## ***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 fraud, waste, and abuse (FWA)***

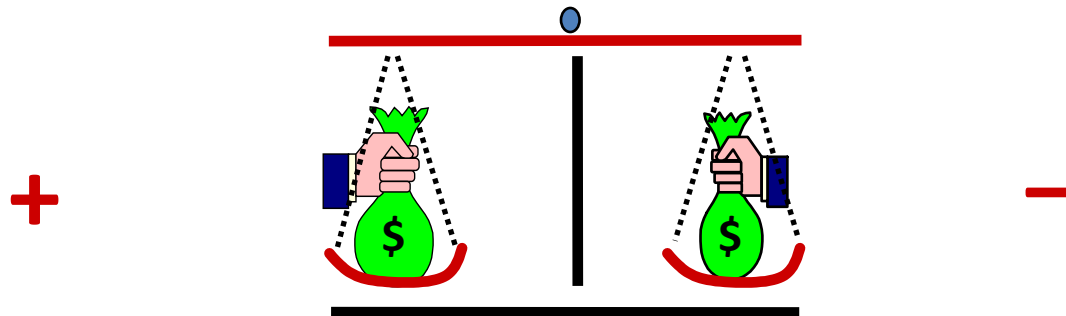
## ***Fraud, Waste, & Abuse (FWA)***

- **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)

- **Independent lab not qualified for Medicare testing**

## Anti-kickback (Inducement)

- **Giving away something you shouldn't**

## 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*

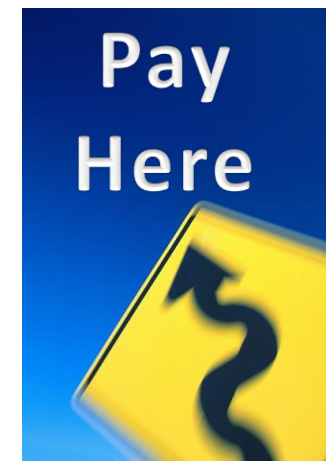
### *CMS Claim Filing Requirements*

- **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) 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.
  - Bonified space rental agreements
  - Bonified purchase arrangements
  - Bonified 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
  - A 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, and
- Fair market value compensation.

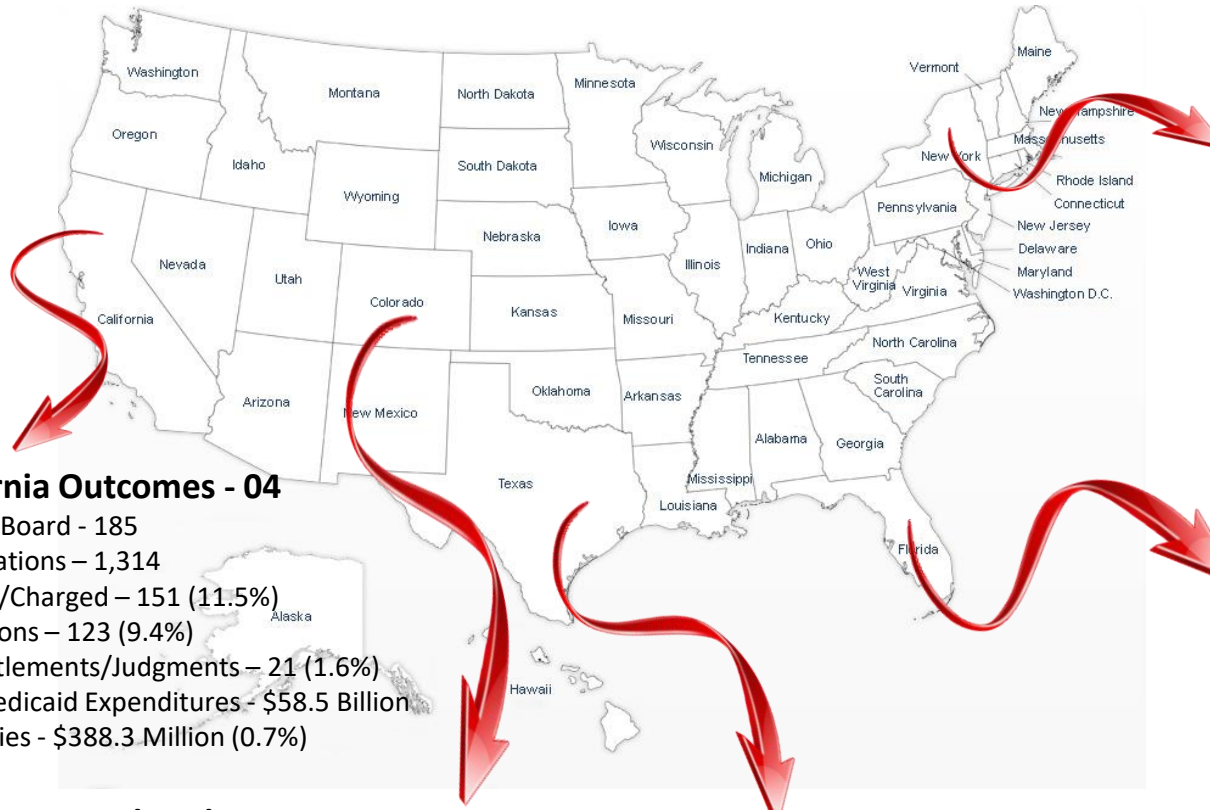
## Enforcement Actions & Settlements

### 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.



# Medicaid Fraud Control Units – FY 2011



## California Outcomes - 04

Staff on Board - 185  
Investigations – 1,314  
Indicted/Charged – 151 (11.5%)  
Convictions – 123 (9.4%)  
Civil Settlements/Judgments – 21 (1.6%)  
Total Medicaid Expenditures - \$58.5 Billion  
Recoveries - \$388.3 Million (0.7%)

## Colorado Outcomes - 01

Staff on Board - 17  
Investigations – 175  
Indicted/Charged – 12 (6.9%)  
Convictions – 4 (2.3%)  
Civil Settlements/Judgments – 10 (5.7%)  
Total Medicaid Expenditures - \$4.5 Billion  
Recoveries - \$7.1 Million (16.0%)

## Texas Outcomes - 03

Staff on Board - 178  
Investigations – 1,339  
Indicted/Charged – 170 (12.7%)  
Convictions – 118 (8.9%)  
Civil Settlements/Judgments – 15 (1.1%)  
Medicaid Expenditures - \$29.1 Billion  
Recoveries - \$190.8 Million (0.7%)

## New York Outcomes 05

Staff on Board – 282  
Investigations – 652  
Indicted/Charged – 80 (12.3%)  
Convictions – 89 (13.7%)  
Civil Settlements/Judgments – 108 (16.6%)  
Medicaid Expenditures - \$53.0 Billion  
Recoveries - \$136.4 Million (0.3%)

## Florida Outcomes -02

Staff on Board - 144  
Investigations – 704  
Indicted/Charged – 90 (12.8%)  
Convictions – 85 (12.1%)  
Civil Settlements/Judgments – 44 (6.3%)  
Medicaid Expenditures - \$18.9 Billion  
Recoveries - \$67.3 Million (0.4%)



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, emails containing PHI, so that the information doesn't go to unauthorized individuals.

## 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 or any member of Senior Management
- 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 occurrence fine, with \$25,000 annual limit
- **Tier B - Reasonable Cause\***
  - \$1,000-\$50,000 occurrence fine, with \$100,000 annual limit
- **Tier C - Willful neglect\*\* – Breach Issue corrected**
  - \$ 10,000-\$50,000 occurrence fine, with \$250,000 annual limit
- **Tier D - Willful neglect\*\* – Breach issue left uncorrected**
  - \$ 50,000-\$250,000 occurrence fine, with \$1.5 million annual limit

*\*By exercising reasonable diligence should have known*

*\*\* Conscious, intentional failure, or reckless indifference*



# ***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.
- ☑️ Under the **Federal Sentencing Guidelines**, up to 95% of the fines and penalties can be mitigated (reduced) with an

***Q. Does “Effective” mean “Perfect”?***

***A. No. “Effective” means demonstrating  
“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***

### **Corporate Compliance Officer**

- Larry Small, CEO of LabPath Consulting
  - Reports to the Executive Leadership

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.

### **Deputy Compliance Officers**

- Amber Macumber, Director of Laboratory Operations and Deputy Compliance Officer
- Wendy Dalton, Quality and Deputy Compliance Officer
  - Reports to the Compliance Officer, with direct access to the Executive Leadership

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.

## ***Ethics & HIPAA Compliance Leadership (cont.)***

### **Corporate Compliance Committee**

- Jim Grossi, Owner
- Luis Perez, President and CEO
- Donald Henderson, VP of Operations
- Jessica Preston, VP of Medical Affairs
- Wendy Dalton, Quality and Deputy Compliance Officer
- Amber Macumber, Director of Operations and Deputy Compliance Officer
- Todd Roy, Director of Sales
- Stephanie Walker, Manager Revenue Cycle
- Shanni Cooper, Director of Phlebotomy and Collector Services
- Marc Blitz, LIS Coordinator
- Amro Almradi, Medical Director

**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

Will be performed with the assistance of the DCO, to evaluate the policies, procedures, and practices, related to ~80 different issues, which are included in the following areas:

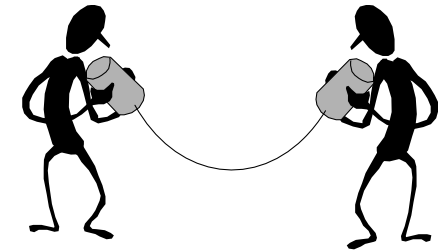
Compliance Program Development (A)	Client Support Services (E)	Laboratory Test Billing Practices (I)
HIPAA Compliance Program (B)	Specimen Receiving and Registration (F)	CPT Coding and Key Test Utilization (J)
Business and Focus Agreements (C)	Medical Necessity and ABN Checking (G)	Billing Revenue Cycle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

## Compliance Report Card - Prioritization Scoring Scale

The issues and recommendations in this report have been prioritized in one of the following categories, to provide guidance in developing an “effective” compliance program.

-  **5.0** **Best Practice** - Creative solution that outperforms common approaches
- 4.0** Compliant practice
- 3.0** Recommend the improvement of an existing compliant practice
- 2.0** Requires policy, training, and/or monitoring improvement
- 1.0** High risk issue

# ***Reporting Process & Open Lines of Communication***



## ***Employee's Obligation***

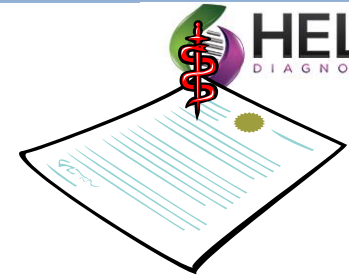
- If there is any situation that you believe may be or is in violation of the provisions of the Code, this Manual or any other Company policies or procedures, you should immediately contact your supervisor, another member of the management team, or the Compliance Officer.

## ***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:
  - ❖ **Larry Small, Chief Compliance Officer**  
(727) 244-1150 or [lsmall@labpathconsulting.com](mailto:lsmall@labpathconsulting.com)



***Questions?***

**Integrity**

**Honesty**

**Equity**

**Accountability**

