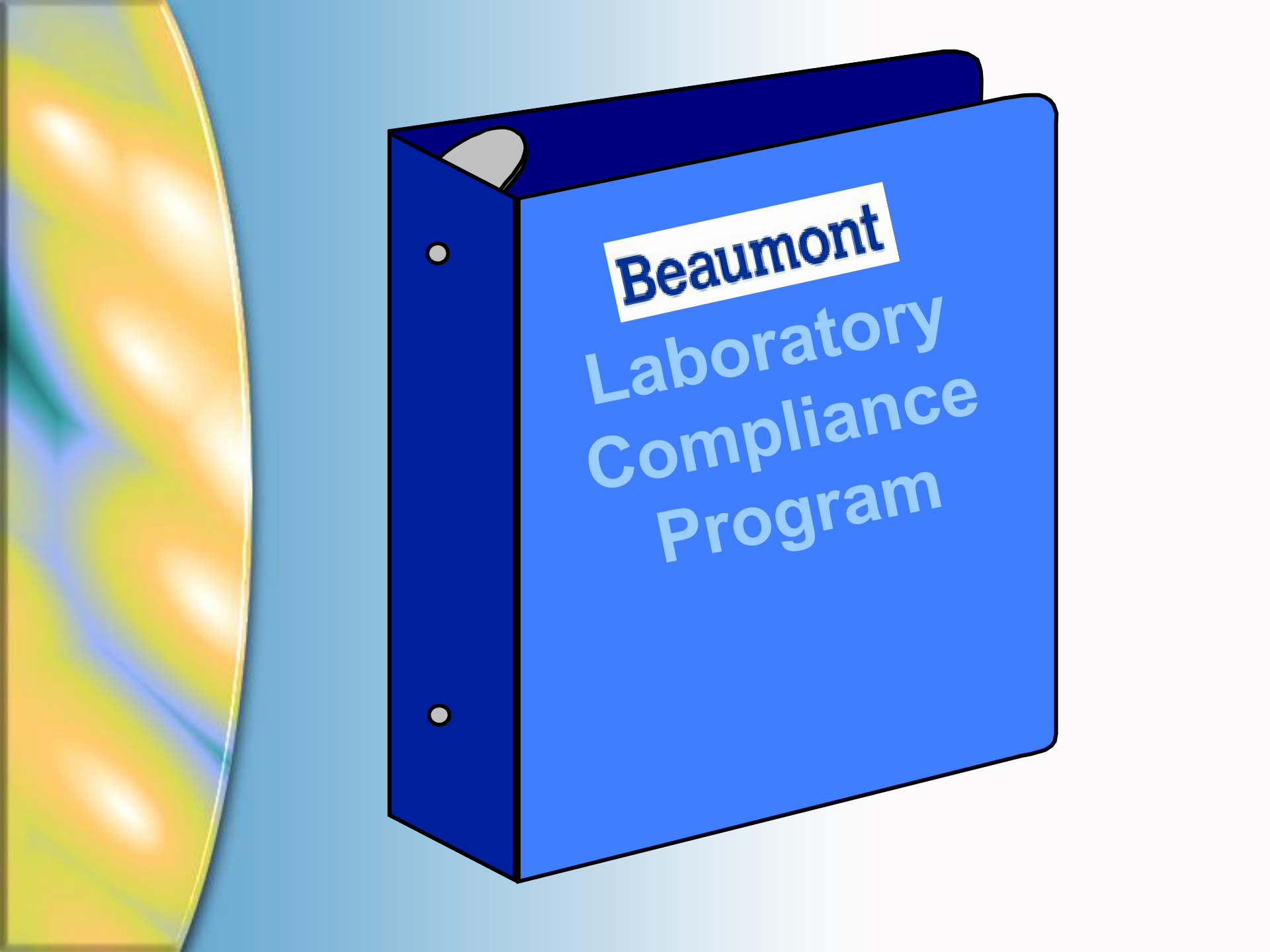

Beaumont
Laboratory
Compliance
Program

Course Objectives

- Understand the importance of Beaumont Laboratory Compliance Program as outlined in the Laboratory Compliance Plan
- Identify the components of the Laboratory Compliance Plan
- State the roles of the Laboratory Compliance Coordinator and Laboratory Compliance Committee
- State the need for risk area auditing and monitoring, investigations, corrective actions, discipline, and staff education and training
- Provide an example of laboratory risk area monitoring
- Comment on Just Culture and Safe Choices

Why laboratory compliance is important…..

- Federal laws govern the way we deal with Medicare & Medicaid patients
  - Our relationship with payers, providers and vendors
  - Services we provide, and
  - How we charge & bill for those services

- Office of the Inspector General is the policing arm of the government
  - Issued guidance for laboratory compliance plans
    - Purpose: To provide healthcare entities guidelines for self monitoring in order to prevent and correct fraud and abuse in national health care programs.

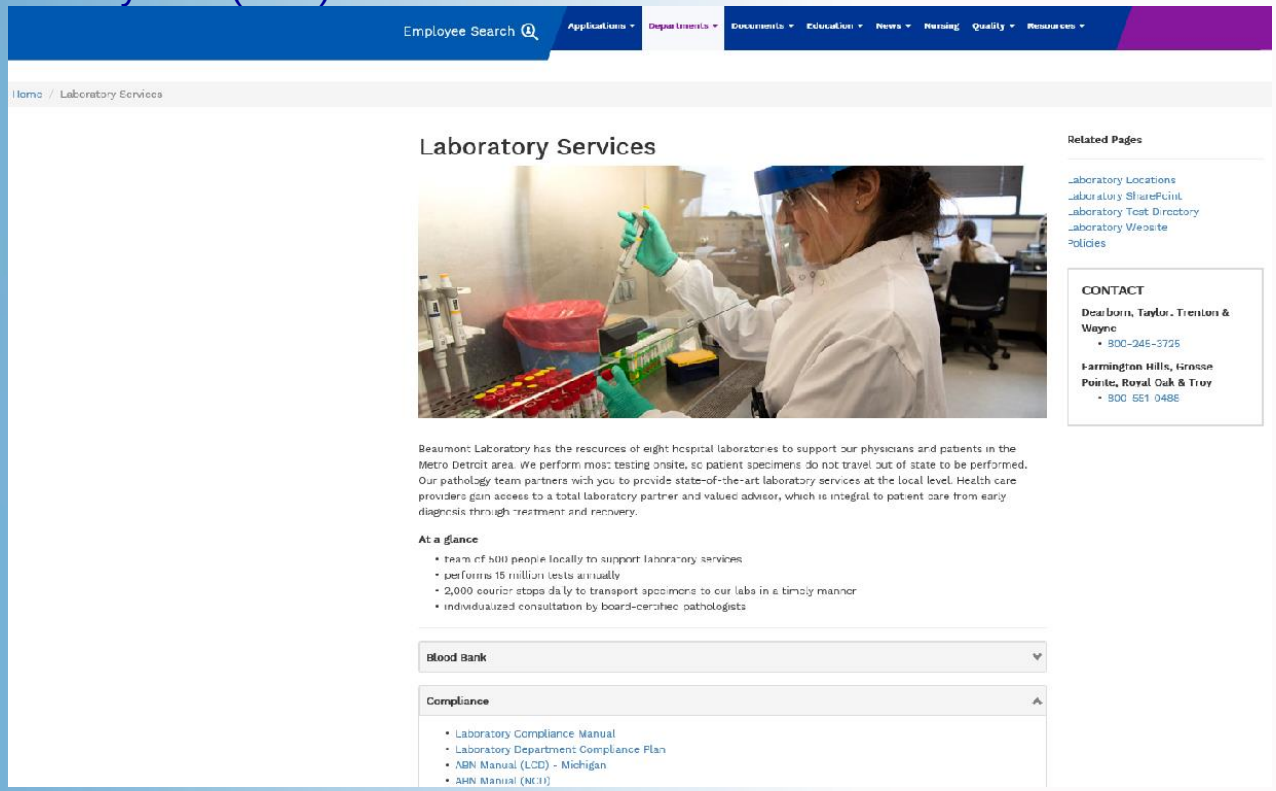
Why laboratory compliance is important…..

- OIG notes four major benefits of an active compliance plan
  - assure prompt payment of claims
  - minimizes billing mistakes
  - reduces chance of audit by CMS or the OIG
  - avoids conflict with self referral and anti-kickback statutes
- Provides direction on conducting business in a **Legal** and **Ethical** manner
  - Beaumont Health Business Ethics and Compliance Policy
  - Everyone's responsibility to prevent fraud and abuse

The Right Way.

LABORATORY COMPLIANCE PROGRAM

- **COMPONENTS:**
  - Laboratory Compliance Plan and the Laboratory Compliance Policies
    - Found on Beaumont Intranet, Compliance link under Laboratory Services Department
  - Compliance Education Program on the Beaumont Learning Management System (LMS)



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LABORATORY COMPLIANCE PROGRAM

Element 1:
LABORATORY COMPLIANCE COORDINATOR

Manages day-to-day operations of the Laboratory's Compliance Program including:

- Interacting with the Compliance, Audit, Accreditation Risk and Information Security Department;
- Developing and maintaining the Laboratory's Compliance Plan and associated Policies/Procedures in collaboration with the Laboratory Compliance Committee;
- Developing learning content and monitoring Laboratory compliance education and training activities;
- Monitoring regulations and communications from the government and laboratory accrediting agencies for potential impact on the Laboratory's compliance plan;
- Maintaining and participating in the Laboratory's self-monitoring and auditing program; and
- Providing audit summary reports to Compliance

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LABORATORY COMPLIANCE PROGRAM

Element 1: LABORATORY COMPLIANCE COMMITTEE

- Consists of Laboratory, Medical and Corporate management-level employees with varying roles within Beaumont and the Laboratory.
- Works cooperatively with and provides support to the Laboratory Compliance Coordinator in the following activities:
  - identifying risk areas specific to Laboratory Operations
  - establishing policies used to direct staff in compliance related activities
  - updating the Laboratory Compliance Plan annually to ensure the effectiveness of overall compliance efforts of the Laboratory
  - determining the most appropriate strategy to promote compliance and to detect and correct potential violations
  - maintaining open lines of communication to promote reporting of suspected violations and improper business conduct
  - taking appropriate corrective action when violations are reported
  - developing and implementing laboratory compliance education program, and
  - overseeing the Laboratory's self-monitoring and audit program for identified risk areas

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LABORATORY COMPLIANCE PROGRAM

Element 2:

WRITTEN POLICIES & SUPPORT DOCUMENTS

- Identify areas of regulatory risk exposure specific to our operation
  - Review existing policies and procedures for possible revision
  - Develop new policies, procedures and support documents
  - On-going process based on monitoring outcomes and regulatory changes

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LABORATORY COMPLIANCE PROGRAM

Element 3:

TRAINING & EDUCATION

Education Materials and Formats:

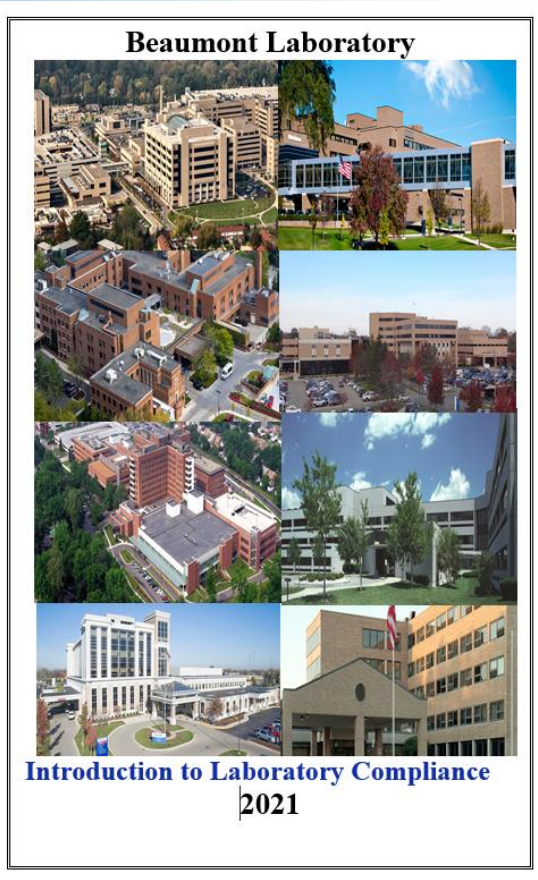
- Beaumont Learning Management System mandatory education on Beaumont Intranet
- Live presentations
- Additional annual training

Tracking Mechanism:

- Completion/attendance is recorded
- May be used in annual performance reviews

To access the Beaumont Learning Management System go to *Beaumont Intranet* Online under **Education** and log on using the **HealthStream** access link.

Mandatory Education Material



Link to Introduction to Laboratory Compliance Booklet

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LABORATORY COMPLIANCE PROGRAM

- **Element 4:**

  LINES OF COMMUNICATION

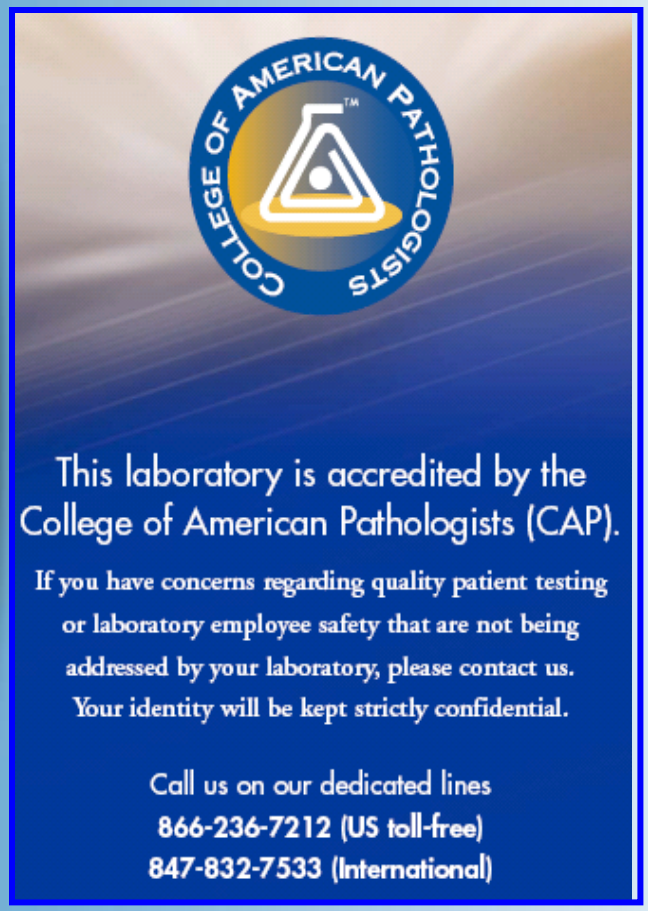
  - Beaumont Laboratory Compliance Coordinator, Beaumont Laboratory Director or Lab Section Supervisor/Manager
  - Compliance Trust Line at

    1-800-805-2283 with questions or concerns or visit the web-based portal
  - Compliance, Audit, Accreditation, Risk and Information Security staff
  - All reports will be kept confidential

Internal Communication Resources…

- Beaumont Intranet: Departments: Compliance, Audit, Accreditation, Risk and Information Security

External Communication Resources…



What information should I provide when reporting a complaint?

Please provide as much of the following information as possible when reporting a complaint:

- name and address of the laboratory,
- who has been involved or affected,
- a complete description of your concern,
- date(s) and time(s) of the incident(s),
- your view of the frequency and pervasiveness of the issue,
- names of any other agency you have contacted,
- your name, address, and telephone number (optional), and
- any other details or documentation that will verify the problem.

Am I required to provide my contact information?

You may choose not to provide your name and/or contact information. However, the investigating entity will not be able to contact you to gather any further necessary information or to inform you of the outcome of the investigation.

Will I remain anonymous if I provide my contact information?

If you provide your name and contact information, the investigating entity will make every attempt to maintain your anonymity as permitted by Federal or State laws.

You can be assured of the privacy and anonymity of your complaint. A complainant's identity is disclosed only to those individuals who are acting in an official capacity to investigate the complaint.

What happens after I report a complaint?

Every complaint is investigated and documented. If you have provided contact information, you will receive a written acknowledgement that the complaint is being investigated. Once the investigation is complete, you will be notified of the outcome.

Complaints that are not related to CLIA regulatory compliance will be referred to the appropriate entity, whenever possible.

Where can I find additional information about CLIA?

For more information and resources regarding the CLIA program, please visit the CMS/CLIA website at:

www.cms.hhs.gov/clia

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

August 2009

CMS

Clinical Laboratory Improvement Amendments (CLIA)

COMPLAINTS

Do You Have a Concern About a Laboratory's Operation?

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LABORATORY COMPLIANCE PROGRAM

- **Element 5:**

  MONITORING, AUDITING & SUPPORT

  - Monitors and audits are done to verify that we are following our policies and to identify process improvement opportunities.

  - The Laboratory Compliance Coordinator works in collaboration with the Laboratory Compliance Committee in overseeing the monitoring and auditing program.

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LABORATORY COMPLIANCE PROGRAM

- **RISK AREA CATEGORIES:**
  - Determination of Service Coverage
  - Documentation of Medical Necessity
  - Coding, Charge Master and Lab Billing (covered under Patient Financial Services Compliance Plan)
  - Pricing Practices
  - Arrangement with Physician and Provider Customers
  - Clinical Laboratory Improvement Amendment (CLIA), CAP, The Joint Commission, and CMS
  - Confidentiality, Privacy, Security and HIPAA (Hospital Information & PHI-Protected Health Information)
  - Vendor Relationships
  - Environmental/Occupational Safety (Employee and Patient)
  - EMTALA (Emergency Medical Treatment and Active Labor Act)
  - Record Security and Safeguards

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LABORATORY COMPLIANCE PROGRAM

- **EXAMPLE AUDIT**:
  - RISK: **Confidentiality/Privacy**
    - **Access of patient information by employees**
  - AUDIT:
    - **Information system users are continually monitored for inappropriate access to electronic protected health information . Beaumont uses an automated patient privacy monitoring tool to provide feedback to hospital leadership regrading employee access to patient records in both HIS and LIS.**

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LABORATORY COMPLIANCE PROGRAM

Element 6:
INVESTIGATIONS / RESPONSE

- Deficiencies found on an audit or employee reports
- Fact finding and assessment to determine substance of the issue
- Revisions or corrections to operations are made as needed

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LABORATORY COMPLIANCE PROGRAM

- **Element 7:**

  DISCIPLINARY MECHANISMS / ENFORCE

  - Staff MUST follow:
    - hospital policies and procedures
    - Laboratory policies and procedures
  - Formal in-services
  - Performance improvement teams
  - Retraining
  - Hospital corrective action for **deliberate, proven non-compliant activities**

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ETHICS & EMPLOYEE RESPONSIBILITIES

- Do things the right way
- Commit to Beaumont Health Code of Conduct and the Business Ethics and Compliance Policy
- Know the legal requirements that apply to your duties and responsibilities
- Ask the right questions and "SPEAK UP".

The Right Way.

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OBSERVE HIGH STANDARDS OF HONESTY AND INTEGRITY

- Doing favors or giving anything away for free to Beaumont Laboratory referral sources could been seen as “inducements”.
- If there are questions about a physician’s written order, you must contact the physician or his/her office for clarification.
- Beaumont Health Code of Conduct and the Business Ethics and Compliance policy provides guidelines for Beaumont workforce relationship with established vendors.

Beaumont

OBSERVE HIGH STANDARDS OF HONESTY AND INTEGRITY

- If it "doesn't feel right", question the practice or procedure.
- You have a responsibility to prevent fraud and abuse.
- Early detection of problems will reduce Beaumont's costs and liabilities.

The Right Way.

Beaumont

QUESTIONS? CONCERNS?

- **Where do I start?**
  - **Supervisor/Manager**
  - **Administrative or Operations Director**
  - **Laboratory Medical Director**
  - **Laboratory Compliance Coordinator**
  - **Compliance, Audit, Accreditation, Risk and Information Security staff**
  - **Trust Line (24/7): Call 1-800-805-2283 (anonymously or with identification) with your questions and concerns or use Beaumont Health Intranet link to access the web based portal**

All reports remain confidential and will be investigated!

Just Culture- Overview

What is Just Culture?

Beaumont Laboratory is strives to maintain an open, fair and just culture by:

- Proactively managing risks and behavioral choices
- Designing safe systems
- Responding in a fair and consistent manner to adverse events
- Learning through transparent dialogue about risks and safety expectations

Just Culture- Overview

Why is it important?

A safe environment encourages reporting of mistakes and hazards. Knowing that we will be managed fairly when we make a mistake or are involved in an adverse event is essential to creating this safe culture.

Just Culture- Overview

What will success look like?

- Leaders will identify and correct safety hazards.
- Expectations for safe performance will be clear and well defined.
- Staff will feel safe reporting their mistakes and work place hazards, knowing that safety issues will be addressed and they will be treated in a just, fair and consistent manner.
- Leaders will investigate events by using a standard approach/algorithm and teach staff the importance of making safe behavioral choices.

Making Safe Choices

- This module provides critical information/steps needed to ensure that our patients consistently receive safe care. It is **your responsibility** to notify your supervisor/educator if you have questions about the information in this module, or if you are unable to complete the steps as described.
- Not following these steps may cause harm to our patients, ourselves or others and is called at-risk behavior. You should expect to be coached if you misstep, or drift, from the described procedures.
- Should you choose to not follow this procedure (after being coached on the correct procedure) that may be considered reckless behavior and may result in punitive action.