Original Approval Date by BE & CCC	Prior Review	Review/Revised
5/9/2003	2/02/2016 5/06/2016 2/2/2017 1/12/2018 9/7/2018 9/24/2019	10/5/2020

Compliance Plan
2020
Beaumont
Laboratory

Department: Beaumont Laboratory

Chief Pathology Service Line: Peter Millward, MD

Beaumont Laboratory Administrator: Sarah Britton
Beaumont Laboratory System Clinical Pathology Ops Director: Brittnie Berger
Beaumont Laboratory Outreach Operations Director, Royal Oak: Joan Wehby
Department Compliance Coordinator: Leana Salka

Beaumont Hospital, Dearborn
Chief of Pathology: Jeremy Powers, MD
Laboratory Ops Director: Kimberly Geck

Beaumont Hospital, Farmington Hills
Chief of Pathology: John Pui, MD
Interim Laboratory Ops Director: Brittnie Berger

Beaumont Hospital, Grosse Pointe
Chief of Pathology: Vaishali Pansare
Laboratory Ops Director: Elzbieta Wystepek

Beaumont Hospital, Royal Oak (Anatomic Pathology):
System Medical Director, Anatomic Pathology BH and BH-RO: Mitual Amin, M
Operations Director: Amy Knaus
Beaumont Hospital, Royal Oak (Clinical Pathology):
Chief Pathology Service Line: Peter Millward, MD
Beaumont Laboratory System Clinical Pathology Ops Director: Brittnie Berger

Beaumont Hospital, Taylor
Chief of Pathology: Muhammad Arshad, MD
Interim Laboratory Ops Director: Kimberly Geck

Beaumont Hospital, Trenton
Chief of Pathology: Muhammad Arshad, MD
Interim Laboratory Ops Director: Kimberly Geck

Beaumont Hospital, Troy
Chief of Pathology: Vaishali Pansare, MD
Laboratory Ops Director: Elzbieta Wystepek

Beaumont Hospital, Wayne
Chief of Pathology: Muhammad Arshad, MD
Interim Laboratory Ops Director: Debbie Poloch

Beaumont Laboratory Outreach:
Chief Pathology Service Line: Peter Millward, MD
Outreach Laboratory Ops Director: Joan Wehby

INTRODUCTION

Beaumont Laboratory is a compliance zone, organizationally described at Beaumont Hospitals as a division, which shares a dual compliance focus: fiduciary and substantive.
Fiduciary compliance designates the duty of care and loyalty vested in management staff to assure compliance with Beaumont's organizational goals and objectives.
Substantive compliance addresses the laws, regulations, and other requirements that all departmental employees must adhere to in order to assure third party regulatory

Beaumont's Corporate Compliance Plan is used to guide the Beaumont Laboratory's Compliance Plan and process. Beaumont Laboratory Compliance Plan will be presented to the Beaumont Hospital Business Ethics and Corporate Compliance Committee for approval and oversight. Beaumont Laboratory is responsible for designating a management level staff member described as a Laboratory Compliance Coordinator, who is responsible for Beaumont Laboratory's compliance activities, including interacting with the Compliance Plan Specialist and Senior Director of Compliance. The Senior Director of Compliance, Legal Affairs, and Internal Audit will provide assistance to compliance zones, as needed.

The Compliance Plan for Beaumont Laboratory will include the following 7 components/elements:
1. Laboratory Compliance Coordinator and Laboratory Compliance Committee
2. Written Policies and Procedures
3. Training and Education
4. Lines of Communication
5. Monitoring, Audit, and Support
6. Investigations
7. Disciplinary Mechanism(s)

Beaumont Laboratory Compliance Coordinator

The Beaumont Laboratory Compliance Coordinator reports directly to Beaumont Laboratory's Outreach Operations Director with a dotted line to the Senior Director of Compliance.

1. Submit Beaumont Laboratory Compliance Plan to the Senior Director of Compliance for approval and subsequent revision approvals. Annual review/revision required.
2. Adjust Beaumont Laboratory Compliance Plan to integrate measures that will address any new risk areas identified by the monthly OIG Work Plan Updates and/or any other regulatory agency.
3. Coordinate, monitor, assist with Beaumont Laboratory compliance activities and maintain associated documentation, as outlined in this plan and report to the Compliance Department according to the frequency indicated in the Lab Compliance Plan.
4. Review and communicate compliance information obtained from the Corporate Compliance web page, as appropriate.
5. Review OIG Work Plan Updates and Trend Analysis.
6. Complete the monthly OIG Work Plan Update acknowledgement if applicable.
7. Coordinate/collaborate with peer Department Compliance Coordinators on above mentioned #1,2,5 and 6 (if applicable).
8. Notify the Senior Director of Compliance of any scheduled and/or unannounced accreditation or regulatory inspection on-site visits.
9. Assure that Beaumont Laboratory staff are made of aware of the Beaumont Health Business Ethics and Compliance Policy as well as all other Compliance Policies.
10. Provide support during scheduled and/or unannounced accreditation or regulatory inspections.
11. Coordinate and monitor the review and revision of encounter forms and as directed, the Charge Master on an annual basis (at a minimum).
12. Assist the Compliance Department with the completion of Conflict of Interest questionnaires if requested.

Additionally, monitor mandatory education requirements for new and current Beaumont Laboratory workforce.

Contact Information:

Name:	**Leana Salka**
Title:	Laboratory Compliance Coordinator
Telephone:	248-551-6575

Beaumont Laboratory Compliance Committee

The Beaumont Corporate Compliance Plan does not require divisions or departments to have a compliance committee. However, because of the number of compliance zones covered by this Plan, the Vice President, Compliance and the Business Ethics and Corporate Compliance Committee have authorized Beaumont Laboratory to form a Laboratory Compliance Committee. This Committee reports to the Business Ethics and Corporate Compliance Committee. All compliance activities of Beaumont Laboratory must be coordinated by and through the Laboratory Compliance Coordinator and Laboratory Compliance Committee, subject to the oversight and direction of the Vice President, Compliance and the Business Ethics and Corporate Compliance Committee.

Written Policies and Procedures

The Department must identify the areas of risk exposure specific to its operation, prior to revising or developing policies and procedures. The Department must evaluate existing departmental policies and procedures, and determine the need to revise the existing or develop new policies and procedures that guide staff in compliance related activities.

Monitoring, Audit, and Support

The Department will develop and implement a program of self-monitoring as a quality assurance mechanism. (To assure compliance with risk areas)
A program of self-monitoring is required to evaluate whether the necessary elements are in place to assure that risk exposure is minimized. The Department may engage in internal or external audit activities, depending on the risk exposure of the Department. The Senior Director of Compliance with Legal Counsel oversight must approve any external audit activity (Corporate Compliance Policy: Compliance Audits and Reviews)

MONITORING/AUDITING

Risk Area	Risk Category	Associated Hospital & Department Policies and Procedures	Monitor/Audit Frequency	Responsible Individual (s) w/titles
Determination of Service Coverage	1. Identify primary and secondary payers (for Medicare secondary payers)- Upfront- Lab, Back-End- Lab Billing (Revenue Cycle)	• Laboratory (Phlebotomy) ABN Procedure (BL.PB.GEN.PR.16) • Lab Compliance: Issuance of Advance Beneficiary Notice of Noncoverage • Laboratory website: NCD/LCD Manual (on-line, current version) • Lab Compliance Documentation of Medical Necessity Policies: • Requisition/Encounter Form Design & Maintenance • Physician Orders and Diagnosis • Laboratory Series Orders • Beaumont Laboratory Distinguishing Hospital Non-Patient from Hospital Outpatient. • Sale of Services, Supplies and IRS Reporting of Unrelated Business Income • PAR Registration procedures or Lab Procedures	1. Quarterly	1. Lab Compliance Coordinator (LCC) or designee (with input from Registration, Lab Phlebotomy/Processing)
	2. Notice of Non-Coverage: Upfront Process- Lab, Back-End-Lab Billing (Revenue Cycle) a. Medicare/ABN: Systems medical necessity checkers b. Other 3rd party payer requirements (as identified by Revenue Cycle)		2. Quarterly	2. Revenue Cycle, LCC or designee (with input from Registration, Lab Phlebotomy)
	3. Distinguish non-patient from hospital patient (inpatient and outpatient) at time of registration or accession.		3. Annually	3. Registration, Lab Billing (Revenue Cycle), Tax Director, LCC or Designee
	4.Review National Coverage Determination (NCD) and Local Coverage Determination (LCD)		5. Quarterly or as needed	5. Revenue Cycle Data Technician, LCC or designee (for processes that support ABN issuance by Lab)
Documentation of Medical Necessity	1. Items & services provided are documented appropriately on the order or requisition and performed by lab with accurate charge designation	Records Management Policy: • Forms Management Program, #104. * Lab Compliance: Requisition/Encounter Form Design & Maintenance • Selection of Diagnosis Codes for Laboratory Services • Laboratory Compliance: Selection of CPT or HCPCS Codes • Lab Compliance: Requisition/Encounter Forms Design & Maintenance • Physician's Orders & Diagnosis • Laboratory Series Orders • Beaumont Laboratory Customized Profiles • Reflexive and Repeat Laboratory Testing • Lab Compliance: Issuance of Advance Beneficiary Notice of Noncoverage	1. Quarterly	1. Lab Operations, LCC (front-end), Back-end-Lab Billing (Revenue Cycle)
	2. Requisition (encounter form) design & maintenance with annual review/update		2. Annually or as needed	2. Lab Operations & LCC with input from Lab Billing (Revenue Cycle)
	3. Physician's orders (or requisition) *Ambiguous orders or missing diagnosis *Physician signature *Duplicate test orders: automated LIS systems in place *Standing (Series) Orders		3. Quarterly	3. Data Technician, Lab Billing, PAR Reg Staff, Lab section staff, LCC or designee
	4. Customized profiles *initial request & annual acknowledgements *Test unbundling (set-up by Revenue Cycle)		4. on-going (new clients) and Annually (letters)	4. Data technician, Operations or designee
	5. Reflex and Confirmatory Testing		5. Annually	5. Lab Section staff, LCC or designee
	6. Verbal orders (or verbal add ons): Automated Systems in place			6. Lab Section, Lab Customer Service or Billing staff, Reg Staff or LCC/designee
	7. Monitor Transcription Practices if applicable (report quality and TAT)		Biannually	7. Lab Section based on feed back from pathologists
Risk Areas Associated with Lab Charge Master, Modifiers, and Lab Billing listed below are covered under BH Revenue Cycle Compliance Plan		Outlined on Next Page	Refer to Revenue Cycle Plan	Refer to Revenue Cycle Plan

MONITORING/AUDITING - continued

Risk Area	Risk Category	Associated Hospital & Department Policies and Procedures	Monitor/Audit Frequency	Responsible Individual (s) w/titles
Coding and/or Charging	1. Items and services provided are coded/charged correctly as applicable (professional and/or facility) * ICD-10 CM code * CPT/HCPCS * Proper use of modifiers * Appropriate bundling/unbundling of items, services or supplies (all payer types)	• Lab Compliance: Requisition/Encounter Form Design & Maintenance. • Forms Management Program, #104 • Charge Description Master (CDM) Maintenance Policy • Selection of Diagnosis Codes for Laboratory Services • Selection of CPT or HCPCS Codes for Laboratory Services		
	2. Encounter forms are updated appropriately (at a minimum annually)	• Forms Management Program, #104 Lab Compliance: Requisition/Encounter Forms Design & Maintenance.		
	3. Charge master is updated appropriately	• Laboratory Charge Master Review • Charge Description Master (CDM) Maintenance Policy		
Billing and Collections	1. Accurate claims are submitted for items and services provided and documented	• Beaumont Laboratory Claim Submission Accuracy		
	2. Reconciliation of claims submitted are reviewed for possible rejections, denials, underpayment or overpayment	• Reconciliation of Submitted Laboratory Claims • Beaumont Laboratory Patient Billing and Collections		
	3. Posting of Payment • Reconciling 3rd party payer payments with correct practitioner/provider PIN • Unapplied Cash			
	4. Patient billing and collection of co-insurance and deductibles			
	5. Unperformed or incomplete tests			
	6. Billing of calculations			
	7. Test unbundling	Beaumont Laboratory: Selection of CPT or HCPCS Codes		
	8. Tests performed within 72 hours of an inpatient admission	Medicare 3-Day Window Payment Rule for Pre-Admission Laboratory Diagnostic Testing		
	9. Laboratory tests for ESRD patients	Billing for End Stage Renal Disease Related		
	10. Organ and disease oriented panels	• Lab Compliance: Selection of CPT or HCPCS Codes		
	11. Credit balances	Reconciliation of Submitted Laboratory Claims		
	12. Duplicate claims for single tests			
	13. Nursing Home, Medicare Part A Billing	• Skilled Nursing Facility Medicare Part A & Part B Billing, LC#411.		
	14. Hospital to Reference Lab Referral Billing	Billing for Referred Laboratory Services		
	15. Third Party Claim Audit/Review Policy			
	16. Billing for: A. Venipuncture B. Travel Allowance	Laboratory Billing for Specimen Collection. Travel Allowance, LC#408.		
	17. Medicare Secondary Payer Status- • Billing Medicare for conditional payment	Beaumont Laboratory: Medicare Secondary Payer Verification		
	18. Billing for accurate provider of service			
	19. Balance Billing			
	20. Direct Billing	Direct Billing, LC#410.		
	21. Non-Coverage of Hospital Acquired Conditions (serious medical errors, "never" events) • ABO blood type incompatibility (hemolytic reaction due to the administration of ABO incompatible blood / blood products)			
	22. Credit Card Processing • Compliance with red flag rules	Corporate Policy: Credit Card Acceptance Policy		

Risk Area	Risk Category	Associated Hospital & Department Policies and Procedures	Monitor/Audit Frequency	Responsible Individual (s) w/titles
Pricing Practices	1. Prices charged to physician customers	• Beaumont Health Pricing Policy • Financial Assistance, Corporate Policy Lab Compliance: • Pricing & Discounting, LC#501 • Billing for End Stage Renal Disease Related Laboratory Testing • Prohibition of Professional Courtesy Laboratory Testing for Beaumont Lab Clients, LC#502 • Prohibition of Routine Waivers of Charges for "Out of Network" Managed Care Patients, LC#503 • Prohibited Discounting Practices between Beaumont Lab and SNFs, LC#504 • Financial Assistance & Uninsured Patient Pay for BL Testing, LC#506	1. Annually	1. Lab Leadership and Revenue Cycle
	2. Lab billing at renal dialysis centers and confirmation of stat charges		2. Biennial	2. Lab Leadership and Revenue Cycle
	3. Professional courtesy, discounts and free services		3. Annually	3. Lab Leadership and Revenue Cycle
	4. Pricing/Lab Fee Schedule (Revenue Cycle)		4. Annually	4. Lab Leadership and Revenue Cycle
	5. Waiver of charges for managed care patients (Revenue Cycle)		5. Annually	5. Management
	6. Skilled Nursing Facilities/Homes (SNF) – Part A billing *Stat Services Charges		6. Biennial	6. Pricing: Lab Leadership and Revenue Cycle , NH Billing- Revenue Cycle
	7. Financial assistance/ charity testing and Patient Pay Discounts (Revenue Cycle)		7. Annually	7. Lab Leadership and Revenue Cycle
Arrangement with Physician and Provider Customers	1. Provision of phlebotomy or other services *Documenting, Processing and Invoicing clients for non-Beaumont Related Services (payment posting/follow-up Revenue Cycle)	Lab Compliance Manual: • Provision of Phlebotomy Services to Beaumont Laboratory Clients • Laboratory Billing for Specimen Collection • Supply Provision to Beaumont Laboratory Clients • Beaumont Laboratory Rental Space Agreements and Real Estate Leases with Potential Referrals • Travel Allowance, LC#408. • Sale of Services, Supplies and IRS Reporting of Unrelated Business Income • Beaumont Laboratory Provider Screening •Notices & Guidelines to Physicians & Provider Customer Requesting Laboratory Services • Provision of Software, Interfaces, Data Lines & Equipment Related to Beaumont Laboratory Services • Infection Control Reports and Other Non-Standard Services Provided by Laboratories to SNFs, LC#609 Risk Area 12 • Laboratory Test Utilization Monitoring and Reporting to Physicians and Clients, LC#610	1. Billable Services: Biennial with on-going record checks by Revenue Cycle	1. Outreach supervisory staff, Lab Administration, Revenue Cycle Data Technician, LCC
	2. Provision of items, devices or supplies (used exclusively for BL specimens)		2. Quarterly	2. Storeroom staff, LCC, Lab Leadership, Acct Rep
	3. Rental of space in physician offices		3. Initial location set-up and prior to end of existing agreement	3. Outreach Leadership, Legal Counsel/REDD, LCC
	4. Medicare Venipuncture Travel Allowance		4. Annually to ensure non-activity	4. Upfront Process (Lab): Long Term Care staff and Data Technician or designee (Revenue Cycle Back-end process to ensure no activity for billing)
	5. Sale of supplies		5. Annually to ensure non-activity	5. Outreach Director, LCC
	6. Screening for physician exclusion		6. Included as part of client set-up with monthly review	6. Sales/Account Rep, Outreach staff, Data Technician, LCC, Compliance Department
	7. Notices to physicians		7. Annually	7. LCC, Outreach staff,
	8. IRS reporting of unrelated business income (UBI)		8. Annually	8. Lab Directors, Revenue Cycle/Tax Director
	9. Provision of computers, fax, and data lines		9. Annually	9. Outreach staff, Lab Admin, Corp. IT
	10. Provision of Infection Control services, Environmental Cultures and other non-standard services provided for the SNF.		11. Annually	11. Outreach Long Term Care Division, Lab Leadership/Medical Staff
	11. Test Utilization-Verify Patterns of Physicians Orders that indicate increased utilization		12. Annually	12. Outreach Sales Account Rep & IT
	12. Contracts and Agreements		13. Annually	13. Lab Leadership, LCC
	13. Marketing Related Non-Monetary Compensation		14. Annually	14. Sales Director, LCC

MONITORING/AUDITING - continued

Risk Area	Risk Category	Associated Hospital & Department Policies and Procedures	Monitor/Audit Frequency	Responsible Individual (s) w/titles
Confidentiality / Privacy /Security / HIPAA	1. Patient consent	All Risk Areas • Compliance With Federal and State Privacy Laws and Regulations • Informed Consent, #304 • Laboratory Provision of Patient Results Requests, BL.PB.PSC.PR.029 • Patient Result Calls, OTR.CS.PR.034 • Information Security Policy • Acceptable Use Policy Corporate Forms: *Authorization to Allow Beaumont Health Workforce Access to Electronic Medical Records Friends and Family Access to Electronic Medical Records *Confidentiality and Computer Systems Usage Agreement • Document Retention Policy and Procedure *Complete Health Organization Record Retention Guide (Michigan) • Lab Compliance: Patient Confidentiality/Privacy- Assurance of, LC#801. • Lab Quality: Document Management Procedure: BHS.QM.PY.002	1. Quarterly	1. Patient Registration, Lab staff (IOP and PSC), LCC
	2. Patient requests for results from Beaumont Laboratory		2. Quarterly	2. MISD, Lab Directors, Customer Service, Phlebotomy, LCC
	3. Protecting patient privacy/unauthorized Access and disclosure of patient information by employees * Including lab instruments that contain stored PHI and transmit/receive data across networks along with vendor support: Supply Chain Department and IT Security * Protecting PII, PCI, or proprietary hospital information		3. Annually	3. All lab sections, Lab Directors, Privacy Office, MISD, Supply Chain, IT Security, Revenue Cycle, LCC
	4. Record retention practices		4. Annually	4. All Directors each lab area, LCC
Employee/ Patient/ Environmental/ Occupational Safety	Introduction: Adherence to MIOSHA (Michigan Occupational Health and Safety Administration) requirements related to occupational exposure to blood borne pathogens i.e., annual in-service for all employees, volunteers, residents and, physicians at facility that have a reasonable risk of exposure to blood or other significant body fluids. Adherence to public health requirements for reporting specific communicable diseases.	*Infection Control Corporate: #3.5 *Standard Precautions Policy *Bloodborne Pathogens Exposure Control Plan *Laboratory Safety : Safety Manual *Laboratory Chemical Hygiene Plan *Hospital Infection Control Manual, Corporate • Lab Compliance: Toxicology Laboratory Security Standards, LC#1002 * Beaumont Laboratory Standards for the Use of ≥190 Proof Grain Alcohol (Ethanol) *Laboratory Compliance: Environmental and Employee Safety, LC#1001. *Hospital Safety Manuals *Hospital Emergency Management Plans *Lab Bioterrorism Procedures, Microbiology section		Safety Comm/Safety Officer, or designee
	1. Employee exposure reporting(blood borne pathogens, or chemical exposure)		1. Training (Spill and Hazard Communication)-Check Quarterly. Per incident Reporting	1. Safety Committee, Safety Officer, or designee
	2. Disposal of chemical/biohazard waste		2. Annually	2. Hospital/Lab Safety Comm, Safety Officer, or designee
	3. Lab security standards related to controlled substances		3. Annually	3. Safety Comm/Safety Officer, LCC or designee
	4. Safe transportation of specimens and chemicals		4. Annually	4. Lab couriers, Phlebotomy, Safety Officer, Lab sections (if applicable), Education Manager (course assignments), LCC
	7. Dangerous Goods Training		7. Annually	7. Lab section managers if applicable, Safety Officer, LCC
	8. Mandatory Employee Safety Training (Beaumont Student Learning Center)		New hires upon hire and annually for current staff Per Incident - On-line Form	8. Lab section managers, LCC

REPORT BY EXCEPTION

Risk Area	Risk Category	Associated Hospital & Department Policies and Procedures	Monitor/Audit	Responsible Individual (s) w/titles
Joint Commission Clinical Laboratory Improvement Amendments, CMS, Accreditation Organizations	1. Joint Commission and Lab Accreditation Organizations	• Comprehensive Accreditation Manual for Hospitals (CAMH) • CLIA Compliance Policy, LC#701. • Blood Bank positive disease marker (HCV&HIV) notification, look-back and follow-up procedures • Reporting Laboratory Device-Related Adverse Patient Events • Disclosure of Safety Events *Safety Event Reporting-RL Solutions *Serious Safety Events *Medical Equipment Management Plan *Medical Equipment Management Programs: General Safety Precautions *Corporate Safety Manuals	CAP, Joint Commission, etc. As required	Laboratory Quality, Lab section managers, LCC
	2. CLIA Testing within scope of certification		CLIA As required	Lab Quality, Lab section managers, LCC
	3. Medicare and Medicaid Program: Conditions of Participation-Lab Services (Revenue Cycle for Blood Bank)		C of P: Disease marker notification & follow-up procedures assessed during interim/self and regulatory/ accreditation inspections	Blood Bank staff and/or FDA, AABB, CAP, and Joint Commission assessors
	4. Reporting of Adverse Events (Quality and RL Solutions): Hospital Quality		Adverse Event Reporting: Per occurrence	Hospital/Lab Quality staff and RL Solutions Process Owners
	5. Reference laboratory selection		Policies for reference lab selection	Sendouts Department manager, LCC
Vendor Relations	1. Disclosure of conflicts of Interest with suppliers	• Business Ethics and Compliance Policy *Code of Conduct *Sanction Screening • Purchasing Policy • Compliance With Federal and State Privacy Laws and Regulations • Beaumont Laboratory Claim Submission Accuracy • Vendor/Supplier Relationships, LC#901. • Vendor Interactions	1. Annually or as needed	1. Lab Directors, Pathologists
	2. Assure the vendor is registered and enrolled in Beaumont's Vendor Relations Program (VRP)-Supply Chain		2. On-going	3. All lab section managers
EMTALA	Assure appraisal of emergencies and referral when appropriate	As per required by law - Emergency Medical Treatment and Active Labor Act ("EMTALA") Policy *Emergency Medical Response-Beaumont Patient Service Centers, LC#3000	Each Occurrence	Hospital/Lab Leadership, LCC

Training and Education

The Department will develop an education plan based on identified risk areas, related to compliance activities specific to departmental operations for all new employees. The Department must establish a method for educating staff regarding changes in compliance plan. In addition, at a minimum, each department will implement annual staff compliance education.

Note: Beaumont workforce includes but is not limited to, employees, students, residents, fellows, volunteers, active medical staff (physicians and non-physician providers), contract individuals, subcontractors, vendors (excluding those whose sole connection with Beaumont is selling or otherwise providing medical supplies or equipment).

Processes Used to Disperse Information to Staff:

1. Document (grid) outlining designated lessons selected based on job category is submitted annually to Beaumont Health Stream Administrators for course assignment purposes. In addition, the original spreadsheet based on job category and risk area is available as a reference when developing new lab compliance education materials.
2. General Compliance Education - Live lecture or on-line course and on-line exam - all new employees
3. Specific Group/Individual Regulatory Requirements - On-line courses/exams, in-services, and/or staff meetings (initially and as needed)
4. Operational and Procedural Changes - Laboratory staff meetings and/or in-services (as needed basis)
5. Annual BH Compliance Education: General - In-service sessions (live or via video) and/or on-line courses plus on line exam - all employees
6. Beaumont Laboratory Compliance Education: Annual Plan Review (revision summary) or Job Specific - In-service sessions, on-line courses, and/or staff meetings - if indicated for specific group/individuals

*Maintain a Record of Information Circulated to Staff:

1. A master file of education sessions and copies of materials presented or distributed at in-services or staff meetings will be retained by Laboratory Manager, Laboratory Compliance Coordinator or Laboratory Education Program Manager.

*Log attendance at Education Programs:

1. A sign-in attendance log for all in-services/staff meetings will be kept in the Laboratory section's education and training documentation file along with the education session's materials. Record keeping process may vary at each Hospital Laboratory location as long as records are available for auditing purposes.
2. A Hospital computer database is maintained on all mandatory on-line courses and group specific on-line courses. In addition, a back-up education records is maintained on the Laboratory Server with oversight by the Lab Education Program Manager and the Laboratory Compliance Coordinator.
3. Hospital or Laboratory orientation records will be maintained for new employee general and lab specific compliance training. Record keeping process may vary at each Hospital Laboratory location as long as participation records are available for auditing purposes.

Educational Activity/Class	Frequency	Responsible Party
1. Beaumont Workforce Compliance Education • Hospital/Corporate Mandatories • Laboratory specific compliance education related to Beaumont Laboratory compliance plan and identified risk areas	**Hospital/Corporate Mandatories:** Upon hire, quarterly, and annually on-line based on corporate assignment (Beaumont Learning Management System) **Laboratory Specific:** Upon hire (manual or online process) and then annually or as needed as determined by the Lab Compliance Committee, Lab Education Committee and/or Lab section management staff (in-services, staff meetings, etc.)	Employee with Manager/Supervisor oversight Lab Compliance Coordinator, Lab Education Program Manager, Lab Section Management Staff **Mandatory and Dept. Specific Education Program (BL.ED.TCA.PR.002)**
2. Educate and train all Beaumont designees on regulatory, operational and procedural requirements/changes related to the identified risk areas.	1. Upon hire (manual process or online) 2. As indicated from various monitoring/auditing mechanisms 3. Based on regulatory changes and updates 4. Each time a relevant policies change or are updated	Lab Compliance Coordinator, Lab Education Program Manager, Lab Physician and Resident/Fellow Compliance Education Task Group, and Lab Section Management Staff

The Department Compliance Coordinator is responsible for communicating the compliance plan and program laboratory sections.

Communication to Lab staff:

<u>This section defines the lines or mechanism of communication that managers should promote to laboratory staff:</u>

1. From the Laboratory Compliance Coordinator to the employees e.g. staff meetings, emails, newsletters, etc.
2. From the employee to the Laboratory Compliance Coordinator. Identify the types of information that employees are encouraged to report to their Compliance Coordinator based on identified risk areas.
3. Service and Business Lines of reporting compliance activity and frequency of the reporting. This should include compliance report to Administration and the Corporate Compliance. (The basis of the report is the identified risk areas, which are monitored by the Laboratory Compliance Coordinator.
4. Assurance that employees are aware of their right to contact the Compliance Line or communicate directly and confidentially with BH Compliance regarding any potential compliance issues or suspected violations.

This section describes how you will communicate with your staff.

Laboratory Compliance Coordinator or lab section manager to Employee(s):

1. Staff meetings - (as needed.)
2. Staff in-services- mandatory and informational (as needed).
3. Distribution of information via e-mail (as needed).
4. Distribution of memos, newsletter, meeting minutes to section mailboxes (as needed).

****Types of information your staff will be encouraged to report.***

Employee(s) to Laboratory Compliance Coordinator to report in person, e-mail, voicemail, in writing or a Quality and Safety Reporting (RL Solutions):

1. Identify the types of information that employees are encouraged to report to their Compliance Coordinator based on identified risk areas.
2. Any information related to the identified risk areas that are potentially non-compliant.
3. Any questions or clarification they have about a risk area, and potential non-compliance.
4. Any and all other potential non-compliant activities.

Service and/or Business Activities-Lines of reporting outside of Beaumont Laboratory including Hospital Administration and the Compliance Office as applicable.

1. Status report to the Compliance Office based on identified frequency with activities related to compliance outlined (education, auditing, monitoring or process improvement initiatives).
2. Beaumont's Compliance Line (1-800-805-2283)

Employee(s) are to be educated and have an awareness of their right and responsibility to contact the Compliance Line or communicate directly and confidentially with the Senior Vice President Chief Compliance Officer.

1. During the orientation process and during the annual compliance training (Beaumont Learning Management System), employees will be made aware of their right to contact the Compliance Line or communicated directly and confidentially with the Senior Vice President Chief Compliance Officer regarding any possible compliance issue or suspected violation.

EDUCATION & COMMUNICATION

Risk Area / Subject	Means of Educating	Frequency	Responsible Individual (s) w/titles	Audience
Educate and train all Beaumont workforce on Regulatory, operational and procedural requirements & changes related to risk areas.	As indicated from various monitoring/auditing mechanisms Based on regulatory changes and updates.	Upon Hire, Annually and each time relevant policies change or are updated.	Department Compliance Coordinator and/or Department Manager for each lab section	All Staff
New Hires	Completion of Mandatory Education Modules on their first day in the department, before they have contact with patients and before they access patient PHI or other confidential information.	Upon Hire	Department Manager	All New Hire
Annual Beaumont Designee Mandatory Compliance Education	Compliance and Confidentiality Modules	Annually (Beaumont Learning Management System)	Appropriate Department Manager, Administrator, Department Compliance Coordinator, Lab Education Program Manager	All Staff

Investigations

The Department will define the intra-departmental actions to be taken when a suspected compliance violation is reported or identified.

1. The suspected violation is reported to the Department Manager/Supervisor, Director, or the Department Compliance Coordinator.
2. The Department Compliance Coordinator is notified (if unaware based on reporting channels initiated) and further investigative efforts are completed and documented.
3. The respective Department Manager, Director is made aware if not initially involved.
4. The Department Compliance Coordinator will notify the Manager of Compliance of the issue and the findings for determination of further follow-up needed.
   - For reports received from external parties, notify the Senior Vice President Chief Compliance Officer immediately.
   - For internal reports, the Department Compliance Coordinator will make a limited preliminary assessment to determine substance of the report once notified.
5. The Department Compliance Coordinator in conjunction with the department manager is responsible for ensuring resolution of findings identified in a compliance audit.
6. Corrective action is taken as indicated.

Disciplinary Mechanism

Employees must be informed of the consequences of failing to adhere to compliance policies and procedures.

1. All staff will follow the policies and procedures as outlined in Departmental policies and procedures.
2. Staff are educated at the expectations of performance.
3. Staff are informed of the consequences of failing to adhere to compliance policies as outlined by the Progressive Discipline Policy.
4. If audits and quality improvement measures indicate less than desirable performance outcomes, formal in-services are conducted with staff to clarify expectations.
5. A Performance Improvement Team is initiated to evaluate process and make necessary recommendations to improve performance and compliance.
6. Deliberate non-compliant behavior will be investigated and Hospital Policy followed as indicated by investigative facts and outcomes.