

Beaumont Laboratory

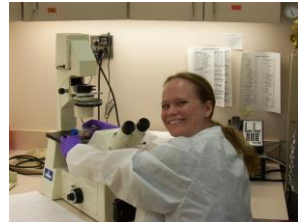


**Introduction to Laboratory Compliance
2022**

BEAUMONT LABORATORY COMPLIANCE PLAN

The purpose of this booklet is to explain the importance of compliance to you and to Beaumont Laboratory. Compliance relates to everyone at Beaumont Laboratory. No matter where you work within Laboratory, you are responsible for complying with the laws, regulations and accreditation standards that govern the Laboratory.

The information in this booklet supplements the content of the **Beaumont Laboratory Compliance Introduction** on-line course in the Beaumont Learning Management System which can be accessed on the Beaumont Health Intranet **Education in addition to other Beaumont Health assigned corporate mandatory education.**



BEAUMONT LABORATORY COMPLIANCE PLAN

TABLE OF CONTENTS

Questions You May Ask About Compliance

What is Compliance?	1
Why is Compliance important?	1
Who is responsible for Compliance?	1
Who are some of the agencies we must comply with?	2
What are some consequences for lack of Compliance?	2
What is the purpose of Beaumont's Compliance Program?	3
How was the Laboratory Compliance Plan developed?	3
What tools are available to assist to me with Compliance?	3
What education and training will I need to complete?	4
What should I report? Who should I contact?	5
Are there other ways to detect problems?	5
What will happen if a problem is identified?	5-6
Are there risk areas identified in the Laboratory Compliance Plan that pertain to ALL laboratory employees?	6-8
Why is ethics training included in our compliance education?	8
What should I do if approached by government or accrediting agencies?	8

Laboratory Compliance Photo Summary.....	9-10
-------------------------------------------------	-------------

Laboratory Compliance Plan Overview	11-18
--------------------------------------------------	--------------

Laboratory Compliance Committee and Education Contacts...19	
--------------------------------------------------------------------	--

Notes and Booklet Content Contacts.....	20
------------------------------------------------	-----------

QUESTIONS YOU MAY ASK ...

What is Compliance?

- Simply put, doing things "**The Right Way**".
- Maintaining high standards of integrity and ethical business practice.

Compliance means that Beaumont Laboratory must abide by all the laws governing health care and be able to prove it. Of particular interest are the laws that govern the way we deal with Medicare and Medicaid patients, our relationships with payers, providers and vendors, the services we provide to them and how we charge and bill for these services.

Why is Compliance important?

- Compliance protects the **patient's rights, privacy and confidentiality** of their records.
- It also ensures that healthcare dollars are appropriately spent on patient care.
- Voluntary compliance may help protect the lab from severe penalties or damages in case of an audit and investigation.

Beaumont Health recognizes that it has an obligation to its patients, payers, employees and the communities it serves to observe and maintain the law and high standards of integrity and business ethics. The *Beaumont Health Business Ethics and Compliance Policy* provides the general principles and guidance for meeting these standards.

Who is responsible for Compliance?

We are ALL responsible for:

- Participating in the training program.
- Seeking advice and asking questions.
- Making a personal commitment to compliance.
- Adhering to the Beaumont **Code of Conduct** in order to perform our jobs "The Right Way".



Who are some of the organizations and agencies we must comply with?

- **CMS** - Centers for Medicare and Medicaid Services is the federal agency that administers as well as defines the rules and regulations of Medicare and Medicaid. CMS has ultimate authority to enforce the Clinical Laboratory Improvement Amendments regulatory standards.
- **OIG** - Office of the Inspector General is the policing arm of the Federal Government. Conducts audits and investigations and takes appropriate action where needed.
- **3rd Party Payers** - Such as the HMOs, PPOs, and other types of insurance carriers that pay for the care and services we provide to our patients.
- **OSHA** - Occupational Safety and Health Administration has specific rules and regulations that we are required to follow to ensure a safe environment for our employees and the community we serve. **MIOSHA** is the Michigan Occupational Safety and Health Administration.
- **JOINT COMMISSION**- The Joint Commission has been accrediting hospitals for more than 50 years. Its accreditation is a nationwide seal of approval that indicates a hospital meets high performance standards. Joint Commission accreditation is required for healthcare organizations to participate in federal programs such as Medicare and Medicaid.
- **CAP** - The College of American Pathologists is the accrediting organization for Beaumont Laboratories. The CAP has deemed status with CMS.
- **OCR** – Office of Civil Rights helps to enforce Federal civil rights laws and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

What are some consequences for lack of compliance?

- The most severe penalty is going to jail or loss of licenses.
- The government can impose monetary penalties or damages depending on the severity or the extent of the violation.
- The government can also negotiate a Corporate Integrity Agreement as part of a settlement of federal healthcare program investigation.
- The government can exclude providers from participating in the Medicare/Medicaid program.
- Loss of public trust.

What is the purpose of the Beaumont Health Compliance and the Beaumont Laboratory Compliance Program?

- To **Educate** all levels of staff and physicians regarding Beaumont's **Code of Conduct** and responsibilities in order to assure compliance with the highest standards of integrity and ethical business practices.
- To **Encourage** staff to seek advice when they have questions about compliance. This can be accomplished through communication with your supervisor/manager, director, the Compliance, Audit, Accreditation, Risk and Information Security Department (CAARIS), or the Hospital's Trust Line.
- To **Enable** Beaumont employees to perform their jobs "**The Right Way**".

How was the Laboratory Compliance Plan developed?

- OIG's *Compliance Program Guidance for Hospitals* was used to develop and implement the Compliance Plan.
- Beaumont Compliance Plan is used to guide the Laboratory's Compliance Plan process.
- OIG's *Compliance Program Guidance for Clinical Laboratories* was used to develop and implement the Laboratory Compliance Plan.
- The Laboratory Compliance Committee first introduced the laboratory compliance plan in the year 2003.
- Today, the Laboratory Compliance Committee remains active in reviewing and revising the Laboratory Compliance Plan in response to changes in laws, regulations, accreditation standards, and the OIG work plan as well as risk area audit outcomes.

What tools are available to assist me with Compliance?

- Compliance, Audit, Accreditation, Risk and Information Security Department web site on the Beaumont Intranet
- ***Beaumont Health Business Ethics and Compliance Policy***
- ***Trust Line 1-800-805-2283*** (24 hours a day)
- Laboratory Compliance Plan and associated polices available on the Compliance section of the Laboratory Services Department on Beaumont Intranet *in addition to the Beaumont policy management system.*
- College of American Pathologists (CAP) ***Quality Line*** poster
- Beaumont Laboratory Compliance Coordinator
- Laboratory Supervisor/Managers, Directors and Medical Chief
- Education and Training (described on the next page)
- Information Technology policies related to IT Security posted on the Beaumont policy management system
- HR and Safety/Quality Communications

What education and training will I need to complete?

- Each new hire orientee **MUST** complete their mandatory education requirements within the first week in their department, or before they have contact with patients or access patient or other confidential information.
- Laboratory employees upon hire, transfer, or service break (greater than six months), must complete the **Laboratory Introduction to Compliance** on-line course and complete the associated exam within their probationary period. Reading this booklet is also required.
- In addition, the above laboratory employees must also read the **Laboratory Compliance – Confidentiality, Privacy, and Information Security Guidelines** booklet and complete the **Laboratory Confidentiality and Privacy Review** on-line course within their probationary period.
- Additional job specific compliance education may be assigned periodically based on associated risks and responsibilities for each job category; audit findings; and operational and regulatory changes.
- Additional compliance information and education may be disseminated as needed, at staff meetings, in-services, or via other means.
- For more information about the on-line Beaumont Health **learning management system**, go to Beaumont Health Intranet under Education to access corporate and department-specific mandatory education.

Beaumont Password Paging Email Inside Beaumont OakNet The Bridge

Home About Us Applications Departments/Services Documents Education News Nursing Quality Events

Education
Continuing Medical Education
Healthstream

HealthStream

To meet ongoing training requirements, employees should take at least two modules a month. The deadline to complete all corporate mandates is Oct. 31.

Employees logging in to the system for the first time will use their new PeopleSoft ID - found on the upper left corner of pay statements - for both the user ID and password fields. You will then be prompted to create a new password.

Step-by-step instructions:

- [How to log in to HealthStream](#)
- [How to enroll in a course or activity](#)

Training for New Hire Employees/Workforce with hire date on or after 12/31/2017

New Hire mandatory education modules are assigned to all new hires in HealthStream, the learning management system for all of Beaumont Health. The number of modules vary based on position, but all new hires will have a core set of corporate modules assigned.

- [Employee module new hire](#)
- [Physician module new hire](#)

Corporate mandatory education modules are now available for all employees in HealthStream, the learning management system for all of Beaumont Health. The number of modules vary based on position, but all employees and physicians will have a core set of corporate modules assigned.

- [Employee modules](#)
- [Physician modules](#)

[HealthStream Login](#)

What should I report?

As stated in the *Beaumont Health Business Ethics and Compliance Policy* and the *Beaumont Fraud, Waste and Abuse Prevention Program* policy, every Beaumont employee has a responsibility to prevent fraud and abuse by reporting potential compliance issues. Avenues have been developed by which you can bring compliance issues to the attention of Hospital Leadership to be investigated and responded to internally. However, you have the right to report potential issues of non-compliance to state and federal agencies. By law and in accordance with Beaumont Health policies, Beaumont is not allowed to penalize you for reporting potential compliance issues.

Who should I contact?

- Whenever possible, first direct your concern to the Laboratory Compliance Coordinator (Nicole Owens, 248-551-6575 or pager #048756) or your Supervisor/Manager, Director or Medical Chief.
- You can contact the Sr. Director of Compliance at 248-551-5120 or any member of Beaumont's Lab Corporate Compliance Team as listed on page 19 of this booklet.
- You can call the Beaumont Trust Line at 800-805-2283(available 24/7) and leave a confidential message.
- The information you provide and your identity will not be revealed unless permitted by you or when required by law.

Are there other ways to detect problems?

- Yes, the Laboratory Compliance Plan includes a monitoring and audit program to help detect potential problems and assure compliance.

What will happen if a problem is identified?

INVESTIGATION:

- The Laboratory must respond to any deficiencies that are noted during an audit or reported by an employee.
- Problems discovered must be properly reviewed and steps must be taken to correct the problem.
- We will take measures to correct any instances where established policies and procedures are not being followed appropriately.
- We will also update or revise policies or procedures as needed.

- In the event that a systemic error in operations is discovered, the Laboratory will report the problem to the CAARIS Department for further guidance and appropriate action will be taken.

What will happen if a problem is identified? – continued:

DISCIPLINARY MECHANISMS:

- Formal In-service: If audits and quality improvement measures indicate less than desirable performance outcomes, formal in-service will be conducted with staff to clarify expectations.
- Performance Improvement: If a process is found to be questionable, a performance improvement team may be initiated to evaluate the process and make necessary recommendations to improve performance and compliance.
- Retraining: If an individual is found not to be performing their job according to established policies and procedures, then employee retraining will take place.
- Corrective Action: If it is found that an employee was deliberately non-compliant with a policy, the employee will be disciplined as directed by the Beaumont Progressive Discipline Policy.

Are there risk areas identified in the Laboratory Compliance Plan that pertains to ALL laboratory employees?

Yes. Some examples of these risk areas include:

- **Pricing Practices**

The Laboratory must NOT provide any FREE testing to clients (physicians or other healthcare providers), their families, or their employees. Such offers could be construed as an inducement (or incentive) for lab test referrals.

- Beaumont Laboratory Pricing

- **Document of Medical Necessity**

Laboratory tests must be ordered by a physician or other qualified non-physician practitioner as authorized by State Law and site-specific Medical Staff Policies.

- Laboratory Compliance: Physician Orders and Diagnosis

- **Arrangements with Physician and Provider Customers**

The Laboratory only provides supplies used to order, collect and process specimens for testing by Beaumont Laboratory.

- –Supply Provision to Beaumont Laboratory Clients
- Provision of Software, Interfaces, Data Lines and Equipment Related to Beaumont Laboratory Services

Are there risk areas identified in the Laboratory Compliance Plan that pertains to ALL laboratory employees? - continued:

- **Clinical Laboratory Improvement Amendments (CLIA)**

This federal law defined the categories of laboratory tests according to their level of complexity, the education level of personnel who perform the procedure, the responsibilities of various laboratory personnel, and issues CLIA certifications to labs qualified to perform testing.

- Clinical Laboratory Improvement Amendments (CLIA) Compliance

- **Confidentiality and Privacy**

The Laboratory will follow Hospital Policies related to defining, recording, accessing, disclosing, and retaining Hospital information and Protected Health Information (PHI). It is every employee's responsibility to protect the confidentiality of patient information.

- Compliance With Federal and State Privacy Laws and Regulations policy
- Laboratory Confidentiality, Privacy and Information Security Guidelines booklet and the Beaumont Laboratory Confidentiality & Privacy online course

- **Environmental and Employee Safety**

Beaumont has an active Safety Department that oversees aspects of employee and patient safety for the Hospital. Education on safety issues is provided in the annual on-line mandatory education courses and Laboratory in-services.

- Laboratory Safety Manuals, Policies and Procedures
- Corporate Safety Policies in the Beaumont policy management system

- **Vendor /Supplier Relationships**

- Relationships with Vendors, Conflict of Interest, and Vendor Eligibility:

In the Beaumont Health *Business Ethics and Compliance Policy* and in the **Purchasing Policy**, there are details that describe appropriate relationships with vendors and conflict of interest. Beaumont will confirm that the vendor is qualified to do business with Beaumont and the vendor does not appear on the Office of Inspector General (OIG) exclusion list

- Beaumont Health Business Ethics and Compliance Policy
- Purchasing Policy
- Vendor Interactions Policy
- Conflict of Interest Program Policy
- Beaumont Fraud, Waste and Abuse Prevention Program

Are there risk areas identified in the Laboratory Compliance Plan that pertains to ALL laboratory employees? - continued:

- **Record Security/Safeguards**
 - Information Security, including Data Integrity
 - Compliance With Federal and State Privacy Laws and Regulations policy
 - Information Security Policy
 - Safeguarding Data and Information, including the Clinical Record, against Loss, Destruction, and Tampering
 - Laboratory Document Management and Record Retention Procedure
 - Document Retention Policy and Procedures
 - Complete Health Organization Record Retention Guide
 - Information Disposal Security Standard
 - Release of Patient Information
 - Compliance With Federal and State Privacy Laws and Regulations policy
 - Authorization for Release of Health Information
 - Signature on General Consent to Treatment and Notice of Privacy Practice
 - Display of Notice of Privacy Practices
 - Compliance With Federal and State Privacy Laws and Regulations policy

Why is compliance and ethics training included in our compliance education?

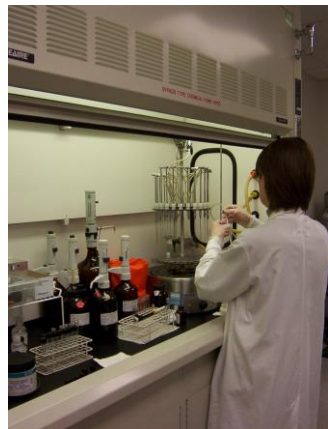
- Our own values and standards guide us in the choices we make.
- We want you to exercise good judgment when making job related decisions or choices.
- As a Beaumont Employee, you must adhere to the highest standards of integrity as outlined in the Beaumont **Code of Conduct**. We want you to “Do Things the Right Way”.
- With good education, maintaining a proper ethical culture, and following the hospital and Laboratory policies, you will be able to seek advice, ask questions, make correct choices, and perform your job properly.

What should I do if approached by government or accrediting agencies?

- Become familiar with the procedure titled “Inspection of Laboratory Operations by Government and Accrediting Agencies” or similar procedures located your laboratory section.
- As outlined in the Laboratory’s inspection procedure, ask the agency representative for proper identification (i.e., ID badge and notice of intent to conduct inspection).
- Be polite and don’t be intimidated. State that you would be happy to help them but Laboratory policy requires you to refer them to one of the members of the Laboratory leadership team (e.g., Supervisor/Manager, Director, and/or the Laboratory Compliance Coordinator).



Remember.....



You are the KEY to assuring that Beaumont does it ...

The Right Way!



OVERVIEW

BEAUMONT LABORATORY COMPLIANCE PLAN

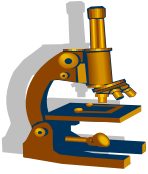
The Beaumont Health Corporate Compliance Plan was used to develop a Division/Department based Compliance Plan Model and associated standards for all divisions/departments of Beaumont Health. The Beaumont Laboratory Compliance Plan was then developed from this Division/Department based Model.

The Compliance Plan for Beaumont Laboratory (BL) includes the following 7 components/elements:

1. Beaumont Laboratory Compliance Coordinator and Beaumont 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)

The above components/elements are based on The Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories as well as the OIG's Compliance Program Guidance for Hospitals. The intention of these guidance documents is to assist clinical laboratories in developing effective internal controls that promote adherence to applicable federal and state law and the program elements of federal, state and private health plans.

The following pages present an overview of Beaumont Laboratory Compliance Plan.



OUTLINE OF THE SEVEN ELEMENTS AND THE CORPORATE COMPLIANCE PLAN STANDARDS

I. Laboratory Compliance Coordinator and Laboratory Compliance Committee

STANDARD: Each Division/Department must have a Compliance Coordinator.

A. Laboratory Compliance Coordinator

- (1) Hospital/Lab leadership is responsible for designating a management level staff member as the Laboratory Compliance Coordinator.
- (2) The Laboratory Compliance Coordinator reports directly to the Laboratory Chief Medical and Administrative Directors with a dotted line to the CAARIS Compliance Manager.

B. Laboratory Compliance Committee

- (1) The Corporate Compliance Coordinator and the Business Ethics and Corporate Compliance Committee have authorized Beaumont Laboratory to form Beaumont Laboratory Compliance Committee.
- (2) All compliance activities of the Laboratory must be coordinated by and through the Laboratory Compliance Coordinator and Beaumont Laboratory Compliance Committee.
- (3) The Beaumont Laboratory Compliance Committee shall meet on a quarterly basis and more frequently if necessary. Its membership shall consist of Laboratory, Medical, Legal and Hospital management-

- level employees with varying perspectives and responsibilities in the Hospital and Laboratory.
- (4) This committee reports to the Business Ethics and Corporate Compliance Committee.

II. Written Policies and Procedures

STANDARD: BL must identify areas of risk exposure, specific to its operation. Prior to revising or developing policies and procedures, BL must evaluate existing laboratory policies and procedures, and determine the need to revise the existing or develop new policies and procedures that guide staff in compliance related activities.

All identified risk areas must have an associated policy. See the Laboratory Compliance Plan posted on the Beaumont Intranet, Laboratory Services Department and Beaumont's policy management system for a list of associated Hospital and BL policies and procedures for each risk area listed on the following pages.

DEPARTMENT RISK CATEGORIES AND ASSOCIATED RISK AREAS:

Determination of Service Coverage

1. Identify primary & secondary payers (for Medicare secondary payers)-
2. Advance Beneficiary Notice of Non-Coverage- Shared responsibility:
Lab, Lab Billing & Revenue Cycle
 - Medicare/ABNS and other 3rd party payer requirements
3. Screening Tests/Quality Assurance
4. Distinguish non-patient from hospital patient (inpatient and outpatient) at time of registration or accession.
5. Review National Coverage Determination (NCD) and Local Coverage Determination (LCD) publications for quarterly updates

Documentation of Medical Necessity

1. Items and services provided are documented appropriately on the order or requisition and performed by Lab with accurate charge designation
2. Requisition (encounter form) design and maintenance with annual review/update
3. Physician's orders/requisitions:
 - Review for ambiguous or missing diagnosis, incomplete order, unperformed or incomplete testing, physician signature, duplicate tests

4. Standing (Series) orders
5. Customized profiles
 - Initial request, set-up (unbundling risk), annual acknowledgements
6. Reflex testing
7. Confirmation testing
8. Verbal Orders and Add-on orders

RISK CATEGORIES & ASSOCIATED RISK AREAS - continued:

Coding: Associated risk areas listed below are covered under Revenue Cycle Compliance Plan.

1. Items and services provided are coded correctly (professional and/or facility)
 - ICD- code
 - CPT/HCPCS
 - Proper use of modifiers if applicable
2. Charge master is updated appropriately

Billing and Collections: Associated risk areas listed below are covered under Revenue Cycle Compliance Plan.

1. Accurate claims are submitted for items and services provided and documented
 - Specialty Consultations
2. Reconciliation of claims submitted are reviewed for possible rejections, denials, underpayment or overpayment
3. Posting of Payment
 - Reconciling 3rd party payer payments with correct practitioner/provider NPI
4. Patient billing and collection of co-payments and deductibles
5. Billing of calculations
6. Tests performed within 72 hours of an inpatient admission
7. Laboratory tests for End Stage Renal Disease (ESRD) patients
8. Medicare billing for Lipid testing
9. Credit balances
10. Duplicate claims for single tests
11. Nursing Home, Medicare Part A Billing
12. Hospital to Reference Lab Referral Billing
13. Third Party Claim Audit/Review Policy
14. Medicare Secondary Payer Status-
 - Billing Medicare for conditional payment
15. Billing for accurate provider of service
16. Balance Billing

17. Direct Billing
18. Non-Coverage of Hospital Acquired Conditions (serious, never events)
 - ABO blood type incompatibility (hemolytic reaction)

RISK CATEGORIES AND ASSOCIATED RISK AREAS - continued:

Pricing Practices

1. Prices charged to physician customers
2. Lab pricing at renal dialysis centers
3. Professional courtesies, discounts and free services
4. Pricing/Lab Fee determination policy
5. Waiver of charges to managed care patients
6. Nursing Homes – Medicare Part A billing
7. Financial assistance/charity testing and patient pay discounts

Arrangement with Physician and Provider Customers

1. Provision of phlebotomy or other services
 - Lab: Document, processing, and invoicing clients for non-Beaumont related services, Revenue Cycle: Payment posting and follow-up
2. Provision of items, devices or supplies (used exclusively for Beaumont Laboratory related phlebotomy or specimen collection).
3. Rental of space in physician offices
4. Medicare Venipuncture Travel Allowance
5. Sale of supplies
6. Screening for physician exclusion
7. Annual Notices to physicians
8. IRS reporting of unrelated business income (UBI)
9. Provision of computers, fax, and data lines
10. Providing retrieval or disposal of biohazards waste
11. Provision of infection control reports, environmental cultures and other misc. services provided for the skilled nursing facility (SNF).
12. Test utilization (Verify patterns of physicians orders related to medical necessity vs. screening)
13. Contracts and Agreements

Joint Commission, Clinical Laboratory Improvement Amendments (CLIA), CMS, Lab Accreditation Organizations

1. CLIA: Testing within scope of certification
2. Medicare and Medicaid program: Condition of Participation- Laboratory (Blood Bank)
3. Reporting of Adverse Events

Confidentiality/Privacy (Hospital information and PHI)

1. Patient consent
2. Authorization for release of patient information
3. Disclosure of patient information by employees
4. Record retention/distribution
5. Patient privacy
6. E-access of protected health information (PHI)
7. Protection of PHI, proprietary hospital information and system usage



RISK CATEGORIES AND ASSOCIATED RISK AREAS - continued:

Vendor Relationships:

1. Disclosure of conflicts of interest with suppliers
2. HIPAA business associate requirements
3. Assure the vendor is registered and enrolled in Beaumont's Vendor Management Program
4. Outside lab usage (e.g., purchase order, subcontract)
5. Compliance w/ other regulatory requirements- CAP, Joint Commission

Environmental and Employee Safety

1. Exposure to blood borne pathogens
2. Laboratory safety
3. Exposure to sharps/other biohazards waste
4. Chemical exposure
5. Disposal of chemical/biohazard waste
6. Lab security standards related to controlled substances
7. Mailing chemical/biohazards
8. Bioterrorism preparedness: select agents (clinical specimens only)
9. Mandatory Employee Safety Training

EMTALA- Emergency Medical Treatment and Active Labor Act:

1. Assure appraisal of emergencies and referrals when appropriate

Record Security/Safeguards

1. Information security, including data integrity
2. Safeguard of data and information, including the clinical record, against loss, destruction, and tampering.
 - Password protection of mobile devices-laptops, tablets, smartphones
 - Encryption of patient data on mobile devices and use of Hospital approved flashdrives
 - Removal of records (when permitted) and protecting data and information against unauthorized intrusion, corruption or damage
 - Preventing falsification of data and information. Developing and implementing guidelines for destroying copies of records
 - Protecting records in a manner that minimizes the possibility of damage from fire and water
3. Release of patient information
 - Proper authorization, verification of requester's identity, timely

- completion (within 30 days), tracking of required disclosures
4. Signature on General Consent to Treatment and Notice of Privacy
 5. Display of Notice of Privacy Practices

III. Training and Education

STANDARD: The Division/Department will develop an education program based on identified risk areas. This program will relate to compliance activities specific to division/departmental operations for all new employees. The Division/Department must establish a method for educating staff regarding changes in compliance and “as needed” education for staff performance related issues.

The specific processes used to meet this element are described on page 4 of this booklet as well as in the Laboratory Compliance Plan available on the Laboratory Services web site on *Inside Beaumont Online*.

In addition, all laboratory compliance education printed materials are included in the Beaumont learning management system.

IV. Lines of Communication

STANDARD: The Division/Department Compliance Coordinator (DCC) is responsible for communicating the Division/Department Compliance Plan and program to all employees/designees of the division/department. In addition, the DCC is responsible for communicating compliance updates to those impacted within the division/department.

The Laboratory Services Compliance Coordinator is Vacant. can be reached at 248-551-6575 or pager # .

The specific processes used to meet this element are described in the Laboratory Services Compliance Plan available on the **Beaumont Intranet, Laboratory Services Department and Beaumont’s policy management system.**

V. Monitoring, Audit, and Support

STANDARD: The Division/Department will develop and implement a program of self-monitoring as a quality assurance mechanism and to assure compliance with all regulatory risk areas associated with the division/department operations. Each risk area must have an associated monitor or audit in place.

The specific processes used to meet this element are described in the Laboratory Compliance Plan available on the **Beaumont Intranet, Laboratory Services Department and Beaumont's policy management system.**

VI. Investigations

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

The specific processes used to meet this element are described in the Laboratory Compliance Plan available on the **Beaumont Intranet, Laboratory Services Department and Beaumont's policy management system.**

VII. Disciplinary Mechanism

STANDARD: Beaumont designees or employees must be informed of the consequences of failing to adhere to compliance policies and procedures.

Note: Beaumont designee refers to hospital employees, contingents and trainees at all levels (students, interns, residents, fellows, post-doctoral trainees, administrators, managers, support, clerical and technical staff, agency temporary staff and others such as volunteers who comprise the Hospital's workforce, including but not limited to agents, independent contractors and consultants, etc.) in any patient care discipline, including specialties of medicine, dentistry, nursing and allied health sciences; as well as private attending staff who provide services in conjunction with Beaumont on Beaumont premises or at

other sites or participate with Beaumont in any type of activity, event or program.

The specific processes used to meet this element are described in the Laboratory Compliance Plan available on the **Beaumont Intranet, Laboratory Services Department and Beaumont's policy management system.**

LABORATORY COMPLIANCE COMMITTEE

Identified as a single compliance zone, Beaumont Laboratory has been authorized by the Compliance Manager and the Business Ethics and Corporate Compliance Committee to form a Laboratory Compliance Committee. The Laboratory Compliance Committee reports to the Business Ethics and Corporate Compliance Committee and meets, at a minimum, once per quarter. All Beaumont Laboratory compliance activities are coordinated by and through the Laboratory Compliance Coordinator and Laboratory Compliance Committee, subject to the oversight and direction of the Corporate Compliance Officer and the Business Ethics and Corporate Compliance Committee.

Co-Chairs:

Dr. Mitul Amin, M.D.

Joan Wehby (lead)

Members:

Muhammad Arshad, M.D.

Kurt, Bernacki, M.D.

Ann Marie Blenc, M.D.

Brittnie Berger

Michael Bossenbroek

Matt Boring

Sarah Britton

Karen Ciambelli

Amy Conners

Kimberly Geck

Amy Knaus

Jeff Mastej

Stacie Okerstrom

Nicole Owens

Vaishali Pansare, M.D.

Jeremy Powers, M.D.

John Pui, M.D.

Nancy Ramirez

Josie Raona

Elzbieta Wysteppek

Invited Guests: Ad hoc based on Beaumont Laboratory organization chart, or agenda and Pathology Residents

Laboratory Compliance Education Contacts: Nicole Owens and Nancy Ramirez

NOTES

Direct any comments/concerns about this booklet to:
Nicole Owens (248-551-6575) or Nancy Ramirez at
(248-898-1904)

Beaumont

October 2021