

Beaumont

From Laboratory Operations to the Laboratory Business The Bigger Picture

Content provided by
Operations Directors of Beaumont Royal Oak
Clinical Pathology Laboratories

Laboratory Scientists:

What we are trained to do:

- **Specimen collection and integrity**
- **Specimen Analysis**
- **Calibration and QC**
- **Reporting results**
- **Maintenance**
- **Clinical significance of tests ordered**



The Bigger Picture

What do you need to have a laboratory business?

- **Licensing and accreditation**
 - **CLIA '88 Requirements (HHS)**
 - **License – Complexity model (COW, COA, PPM)**
 - **Personnel requirements**
 - **Proficiency Testing (PT)**
 - **Quality Control (QC)**
 - **Accrediting entity with “deemed status”**
 - **CAP, COLA, AABB, FDA, JC**



The Bigger Picture

What do you need to have a laboratory business?

- **Building – rent, insurance, taxes, zoning, drain commission, Fire Marshall, power, water, handicap access and parking, air handling**
- **Personnel – OSHA, MIOSHA, MESC, EEOC**
- **Equipment / Reagents**
- **Referring Physicians**
- **Patients**
- **Specimens**
- **IT**

Moving to Laboratory Leadership:

- **Ability to help people achieve things they don't think are possible. Leaders are coaches with a passion for people!**
- **Leading a department or group of people through daily operations, and an ever growing/changing healthcare environment**



Department Leader Responsibilities:

Daily Operation

- **Scheduling and time records**
- **Interviewing and hiring**
- **Budget (calendar year)**
- **Performance evaluation and competency assessment**
- **Accountability, disciplinary action, termination**
- **Leave of absence (LOA) and Family Medical Leave of Absence (FMLA)**
- **Dress codes, personal phones**
- **ETC.**



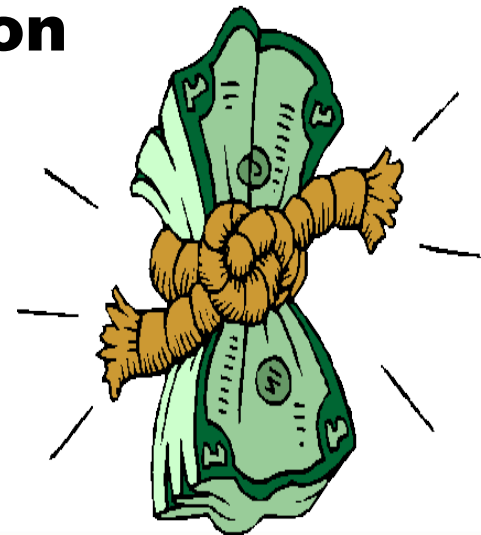
Personnel Administration:

- **Wages and benefits**
- **Education – safety, compliance, travel, tuition**
- **Social Security**
- **Unemployment**
- **Michigan Employment Security Commission (MESCC)**
- **Equal Employment Opportunity Commission (EEOC)**



Budget:

- **Managers and directors are also responsible for creating and maintain their department budgets. Things to consider:**
 - **Cost**
 - **Fixed: rent**
 - **Variable: directly related to production volume(increases as production increases)**
 - **Revenue (gross, net)**
 - **Operating Expense**
 - **Capital**



Equipment Considerations:

- **Purchase or lease**
- **Depreciation**
- **Maintenance and support**
- **Power requirements**
- **Water type I or II**
- **Training**
- **Reagents and Supplies – QC, PT, Patients**
- **Contracts, Vendor negotiation, GPO**



Information Technology (IT):

- **Infrastructure – LAN's (Local Area Network) & WAN's (Wide Area Network)**
- **Laboratory Information System (LIS)**
 - **Sunquest/CoPath**
 - **SCC Soft**
 - **Epic Beaker**
 - **AI / Next generation??**
- **Interface cost and support for equipment**
- **Application costs and support**
- **PC's, printers, faxes, phones, pagers, copiers, scanners**



Additional Responsibilities:

- **Waste**
 - **Cost**
 - **Safety Training**
 - **Department of Environmental Quality (DEQ)**
- **X factor**
 - **Corporate Allocations: “internal taxes”**

Laws and Regulations:

- ***Swimming with the Sharks***
 - Risk assessment
- **Compliance**
 - **Stark law:** Set of United States federal laws that prohibit physician self-referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services ("DHS") if the physician (or an immediate family member) has a financial relationship with that entity.
 - Inducements
- **Taxable or non-taxable income?**



Acquiring New Business:

- **Marketing**
 - **Laboratory and Healthcare are becoming a more competitive business**
- **Physicians- Licensed to order diagnostic procedures**
 - **Inpatient environment – accuracy and TAT**
 - **Outpatient – Offering necessary and marketable tests**

Physician Client Expectations & Additional Requested Benefits:

- **Expectations**
 - **Accuracy and efficient turn-around-time**
 - **Easily accessible Phlebotomy Service Centers (PSC)**
- **Requested Benefits**
 - **In-office Phlebotomist (IOP)**
 - **Custom profiles and requisitions**
 - **Custom reporting**
 - **EMR interfaces**



Patient Expectations:



- **Safety, accuracy, turn-around-time, affordability**
- **Exceptional Service, Service recovery**
- **Assessed through Satisfaction surveys- PG, HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems)**
- **Value Based Purchasing (VBP) – CMS initiative moving from fee for service to quality of care**
- **Providing Compassionate, extraordinary care everyday!**

Other laboratory departments led by laboratory administration:

- **Phlebotomy**
- **Couriers (Specimen Transportation)**
- **Processing**
- **Billing**
- **Client Services**
- **Compliance**
- **Quality**



Specimens: Where do they come from?

Phlebotomists

- **Supplies**
- **Consent to treat**
- **Insurance requirements**
- **Advance Beneficiary Notice (ABN)**
- **ICD-10 codes**
- **Patient ID/ Labels**
- **Centrifuges refrigerators, freezers**
- **Interpretation of orders**



Specimen Transport:

- **Couriers**
 - **Cars – gas, insurance, maintenance**
 - **Drop boxes – must maintain communication with offices and documentation of pick-ups**
 - **Specimen transportation requirements: MDOT, DOT, OSHA**
- **Pneumatic tubes (P-tubes)**
 - **Specimen transport within the hospital**

Processing:

- **Receive specimens from all inpatient and outreach clients**
- **Requisition—registering and ordering specimens from outreach clients**
- **Data entry**
- **Labeling**
- **Distribution of specimens**



Analytical Phase:

- **Many things go into the testing process behind the scenes:**
 - **Thorough documentation such as maintenance logs**
 - **Policies, procedures (SOPs)**
 - **QC review**
 - **Quality monitors**
 - **Performance improvement**
 - **Inspections**
 - **Regulations**



Analytical Phase – cont.:

- **Can also be affected by pre-analytic phase issues that were NOT identified**
 - **Example:**
 - **Microbiology specimens sent beyond collection time limit or not placed in the correct preservative**
- **Final report: “*Results may be compromised*” when a physician insists we run the test instead of cancelling it**
 - **Aka JUNK IN; JUNK OUT**

Post-analytical Phase: Results

- **Manual mode:**
 - **Courier, US Mail**
- **Electronically:**
 - **Interface, fax, remote printer**
- **EMR**
 - **Connectivity**
 - **Availability**
- **Critical Values:**
 - **Resulted and called to ordering physician 24/7**
- **“Copy to” other health practioners**

Billing:

We ran it! What do you mean we didn't get paid?



- **Reports went out, did the charges drop?**
- **Patient demographics**
- **Eligibility checks**
- **Insurance types, managed care, CMS – where's the ABN?**
- **Primaries, secondaries**
- **Dx codes, have you found the ABN yet?**
- **Electronic formats**
- **HEDIS data**
- **Rejections**
- **Charges vs reimbursement – But we charged \$100, we only got \$20?**
- **Co-Pays**
- **The wonderful world of SENDOUTS**

Client Services:

- **This team makes phone calls to physician offices regarding orders, test results, critical results, etc.**
- **They also field calls from physician offices and patients**

CUSTOMER
SERVICE
IS NOT A DEPARTMENT.
It IS AN
ATTITUDE.
-UNKNOWN

Compliance: Internal vs External

Internal Compliance:

- **Legal Affairs**
- **Compliance Committee**
- **Internal audits**



Compliance: Internal Vs External

External:

- **Insurance audits**
- **Government audits – CMS**
 - **Did you find that ABN yet?**
- **Office of Inspector General (OIG)**

