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UNDERSTANDING LABORATORY INFORMATION SYSTEMS COMPLIANCE

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Understanding Laboratory Information Systems Compliance

It is critical to properly implement Laboratory Information Systems not just from an information technology perspective but with a clear vision of creating a safe and compliant interaction with all other hospital systems. To achieve that goal, the expertise of IT specialists must be complemented by the experience of clinical professionals. This helps create a system that not only complies with the letter of the law, but also fulling integrates the Laboratory while improving patient safety, ordering, results, and billing.

BC Solutions has compiled and presented current regulations and recommendations by the agencies tasked with governing this section of the healthcare industry. The goal is to provide a roadmap that can be used by all levels of your implementation team, regardless of their level of laboratory or compliance experience. This common understanding of who the stakeholders are, what governing bodies are involved, as well as what steps should be taken to achieve compliance can be the difference between having a fully integrated functioning system rather than a stand-alone software implementation.

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Introduction

Clinical laboratory testing plays an increasingly critical role in quality healthcare delivery. Test results guide more than 70% of all medical decisions made by healthcare providers and the information entered into and generated from Laboratory Information Systems (LIS) must be closely monitored. As established in the Institute of Medicine report *To Err Is Human: Building a Safer Health System (1999),* it is essential to use information systems as one of the primary means to help improve the quality, safety, efficiency and effectiveness of health care delivery. Subsequently, there currently are several federal mandates and incentive programs that promote wide-spread and more systematic use of electronic data sharing in the healthcare sector to better support health care delivery and public health goals. The exchange of clinical data can happen in numerous ways between the laboratories, physicians, health plans, Health Information Exchanges (HIE), and other authorized recipients.

With the vast applications of clinical data and integrated LIS, the importance of compliance requirements and regulations cannot be over emphasized. This paper sheds light on several key aspects related to laboratory compliance and regulatory needs. Topics discussed here include:

- Which regulatory agencies govern the system
- The regulatory requirements for the different laboratory departments
- The roles affected by these systems and regulatory needs
- Various technologies included
- How laboratories can achieve compliance

Building a Safe, Compliant LIS

Clinical laboratories first came under scrutiny by the Office of the Inspector General (OIG) in 1992. The OIG had embarked on project Lab Scam to investigate fraudulent billing practices by clinical laboratories. The OIG Model Compliance plan (1998) emphasizes that each laboratory organization should develop and implement its own compliance plan taking into consideration its unique compliance requirements and operational complexities. The plan recommended seven elements in the compliance plan at a minimum[1] :

1. A Code of Conduct for adhering to laboratory-wide principles of compliance and ethics in day-to-day activities, as well as standard operating procedures designed to provide direction and guidance to every member of the work force
2. A Compliance Officer and Compliance Committee with defined charter, composition, roles, and responsibilities
3. Effective staff training and education on a regular basis, including as a part of new hire orientation programs
4. Assuring effective lines of communication, including a confidential hotline available to all work force members
5. Implementing effective disciplinary processes to assure adherence to applicable rules and regulations and documented actions in response to demonstrated violations
6. Regular auditing and monitoring practices
7. Establishing protocols for prompt responses to detected violations and effective remediation

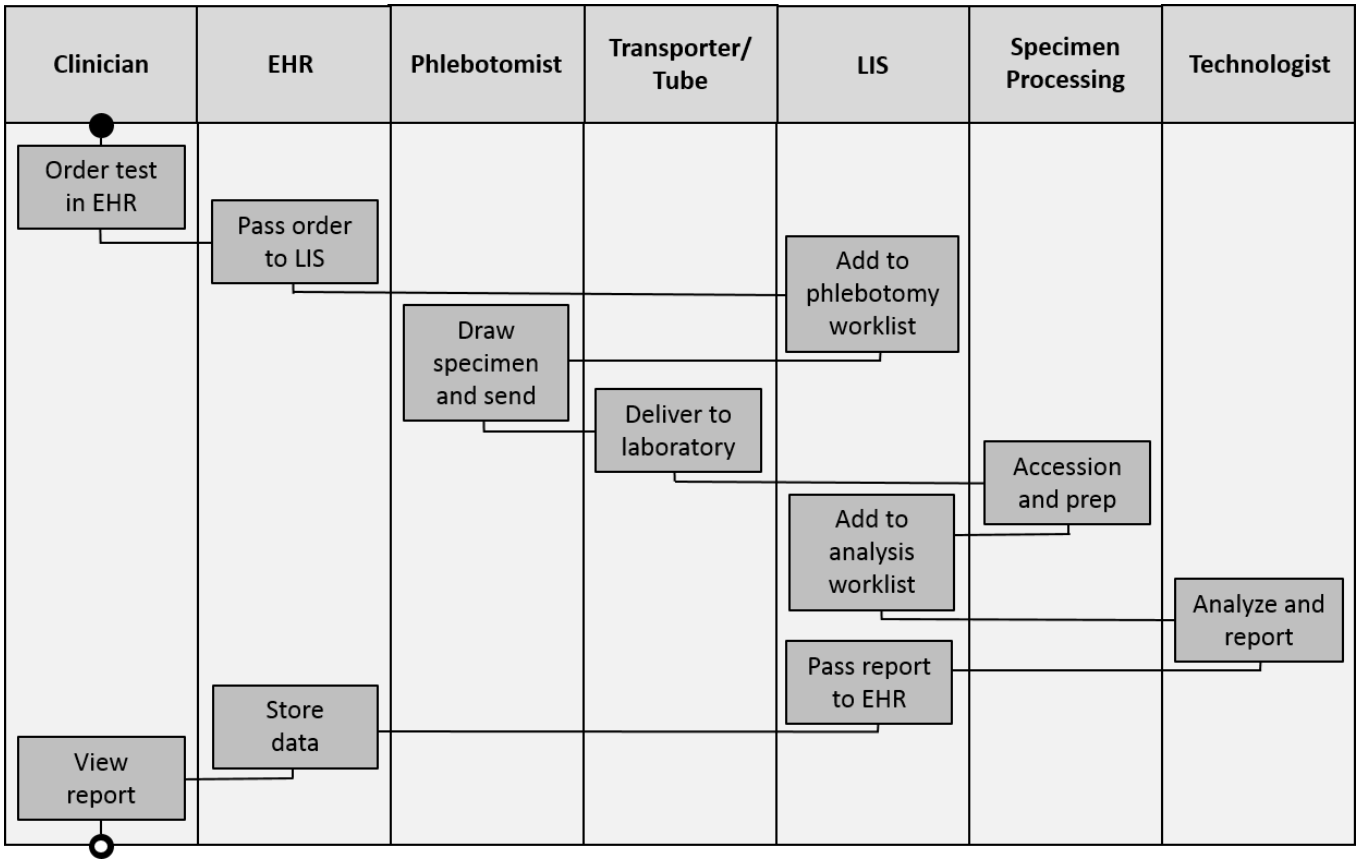
The Government is aware of the fraud, abuse, and waste that exist in the healthcare industry because of the cases it has prosecuted and settled. There are several laws, regulations and agencies that govern laboratories.

- FDA (US Food and Drug Administration)
- CLIA (Clinical Laboratory Improvement Amendments)
- CAP (College of American Pathologists)
- AABB (American Association of Blood Banks)
- HIPAA (Health Insurance Portability and Accountability Act)

These regulations ensure accuracy, reliability, completeness and timeliness of patients test results. They improve the quality of testing services provided to patients and support quality clinical data flow through the different interfaces and health information exchanges.

Laboratory Departments

A clinical laboratory, also known as a medical laboratory, is an area where tests are done on clinical specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the assessment of the health of human beings.



A typical laboratory workflow, including processes and key players.
http://www.captodayonline.com/Archives/0312/0312_newsbytes_fig2.pdf

Depending on the size or specialization of a hospital there can be a number of labs in a single facility. For example, a hospital may have a flow cytometry lab or a genetics/cytogenetics lab and a main laboratory. Laboratory tests that are not performed on site at the hospital are sent to a Reference Laboratory. A reference laboratory is usually a large independent lab that has contracts with other facilities to perform routine high volume or specialty tests. Once a facility decides to outsource some or all of its testing to a reference laboratory, the referring lab must exercise considerable due diligence in selecting the reference laboratory, making sure they are licensed and accredited by the federal and state regulatory agencies.

While clinical laboratories are obligated to perform only tests requested by a physician, care provider or other authorized individual, they must ensure the ordering practitioner has not been debarred, delicensed, or otherwise excluded from participation in federally-funded health care programs.

The general function of the Clinical Laboratory is to perform qualitative and quantitative analyses on blood, urine and other body fluids and secretions.

- A Qualitative Analysis is a test designed to identify the components of a substance or mixture, i.e. what is in it? This is a test that may be resulted as positive or negative. If positive this test may reflex to a Quantitative test.
- A Quantitative Analysis is a test designed to determine the amounts or proportions of the components of a substance, i.e. how many or how much is in it? These tests usually give discreet results, for example Glucose = 147 mg/dl.

Microbiology

Microbiology is the study of microorganisms that cause infectious diseases in humans. Any bodily fluid or tissue can be cultured for infectious disease. The specimen may include samples from wounds, noses/throats, blood and body fluids, and many other body sites. The agents that are detected may be bacteria (aerobic, anaerobic, acid fast), fungi (molds and yeasts), parasites, or viruses. Once the microorganism grows in culture, it can be tested against many different antibiotics to find the most effective for fighting the infection while limiting opportunities for antibiotic resistance. Microbiology lab services can have other sub-divisions such as bacteriology and mycology, parasitology, virology, and serology. [2, 3, 4, 5, 6]

Chemistry

Chemistry is usually the largest and most automated of all lab departments. Chemistry performs a wide variety of tests using the most current technology. It is defined as the scientific study of matter and the various compounds of the elements as it relates to the human body. Common tests include glucose (blood sugar), cholesterol and fats, thyroid function studies, hormone assays, vitamin assays, drug screens and drug assays. Testing can be performed on blood or other body fluids, like cerebral spinal fluid and joint fluids. [2, 3, 4, 5, 6]

Hematology

In the hematology laboratory, the clinical lab scientists primarily focus on the cellular components of blood. Each cellular component in the blood is present in predictable numbers when humans are in good health, so any imbalance can be symptoms of disease. The blood cells are classified into erythrocytes (red blood cells), leukocytes (white blood cells), and platelets. Other body fluids such as urine and cerebral spinal fluid are also routinely examined in hematology.

In a large institution, hematology can be classified into different subspecialties such as routine hematology, special hematology, flow cytometry, hemostasis, and urinalysis. [2, 3, 4, 5, 6]

Transfusion Services/Immunohematology

Often called blood banks, there are actually two distinct types of facilities that handle blood: donor centers and transfusion services. Donor centers collect blood from donors after doing multiple tests and Transfusion Services is the subspecialty of the laboratory that prepares and cross-matches blood specimens for transfusion of red blood cells, platelets and plasma. Testing is performed on the patient's blood specimen prior to transfusing to make sure compatible blood is given. Immunohematology is the laboratory process of establishing the compatibility of blood and its components given by donor with the blood of recipients for transfusion purposes. Transfusion services are closely involved with emergency services and surgery where blood transfusion on a given patient may be necessary at a moment's notice. This is also the only area of the laboratory which prepares products that will be administered directly to patients. [2, 3, 4, 5, 6]

Laboratory Stakeholders

The three key stakeholders here are providers, clinical laboratories, and patients, but there are a range of other stakeholders who drive or benefit from integration with clinical laboratories. First, at the "nuts and bolts" level, clinicians' participation in an HIE is dictated by the Electronic Health Record (EHR) application they have selected and this greatly influences how the specific installation participates in an HIE. Similarly, clinical laboratories' ability to participate in an HIE is dictated by their LIS and the vendors that develop and support these systems. Other key stakeholders include public health officials who could derive benefit from systems designed to allow electronic notification of reportable conditions and population-based surveillance. Finally, public and private payers and purchasers stand to benefit from increased cost-effectiveness of care.

In recent years all laboratories have been required to adapt their information management focus and use laboratory information systems (LIS) to automate the routine steps in the daily workflow. These steps include test ordering, specimen labeling, analytical interfaces between instruments and information systems reporting results, quality control, efficiency, productivity management, financial services (billing, inventory, forecasting and analysis), reference testing, and regulatory compliance. The extent of LIS adoption and their capabilities vary widely among the laboratories.

Physicians and Nurses

Physicians and nurses rely on the critical information generated from the clinical laboratories primarily because this information helps them in reaching the diagnosis. Because they enter the orders and review the results in EMR/EHR, the LIS and EMR/EHR workflows are constantly revised to improve the usability for this set of stakeholders. Their acceptance of the LIS and EMR/EHR system is one of the key deciding factors of success for the information systems implementation and usage.

Laboratory Directors

Laboratory directors are usually pathologists in hospital-based laboratories. A pathologist is a physician who is board certified in anatomic and clinical pathology. Pathologists serve other physicians by consulting on matters of cytologic as well as clinical correlation of laboratory

information relevant to their medical practices. In other instances, directors may have non-medical degrees, but have advanced degrees and/or training in administration and/or other scientific areas.

Administrative Technologists

Administrative technologists are medical technologists (laboratory scientists) with the required training or experience to govern the day-to-day operation of the laboratory, including making decisions in matters of finance, personnel, and other key functions. In today's highly competitive laboratory services marketplace, individuals with clinical laboratory science training coupled with marketing/finance backgrounds are in high demand.

Compliance Officer

The compliance officer heads the compliance department which oversees protocols that are set internally or by other regulatory accreditation agencies such as CAP, CLIA etc. The compliance officer also monitors activity to ensure adherence in the different departments of the clinical laboratory. He or she develops, initiates, maintains, and revises policies and procedures for the general operation of the compliance program. Other key responsibilities include making efforts to prevent illegal, unethical, or improper conduct by the personnel, medical devices, equipment, and information systems employed in a clinical laboratory.

Technologies Included

Health Information Technology (HIT) enables all types of healthcare institutions to generate, use, store, organize, transfer and analyze healthcare data. This is a trend consistent with the wide availability of computing. Use of HIT has been accelerated through the multiple laws and regulations with incentives to increase the adoption of HIT at all levels.

Reports of automation to support clinical data management dates back to 1950s[7]. Over the years, information systems have been designed to optimize clinical workflows, processes and most of the healthcare business practices. The primary focus of implementing all these systems is increasing patient safety and quality improvement. They also promote better communication with the patient and other care providers. The most common systems include:

- Electronic Medical Record (EMR)
- Electronic Health Record (EHR)
- Master Patient Index (MPI)
- Laboratory Information Systems (LIS)
- Radiology Information Systems (RIS)
- Picture Archiving Systems (PACS)
- Hospital Information System (HIS)
- Practice Management System

Laboratory Information System

A Laboratory Information System (LIS) is a software program that provides automation functionality within a clinical laboratory. This system should have basic features like patient registration, order entry, result entry, specimen collection, specimen tracking, and reporting. In addition to these, the LIS system should be able to interface with the institution's EMR system and the medical devices interfaces (MDI).

Some advanced LIS systems also offer non-clinical functionality such as workflow monitoring and billing services. The functionality needs of an LIS may vary widely based on the institution whether it is a small physician office, clinic, single hospital, multiple hospital system, commercial laboratory or and an integrated delivery network (IDN).

While most laboratories process test orders and perform lab tests efficiently and with a quick turn-around time, there is no dearth for errors and issues related to communication of test orders and results between the providers and laboratories. These issues are addressed through integration of LIS with EMR / EHR systems and making the clinical data readily available to the care providers at point of care. In the current era, electronic exchange of lab test results is being adopted, though slowly, by a number of hospitals and physicians.

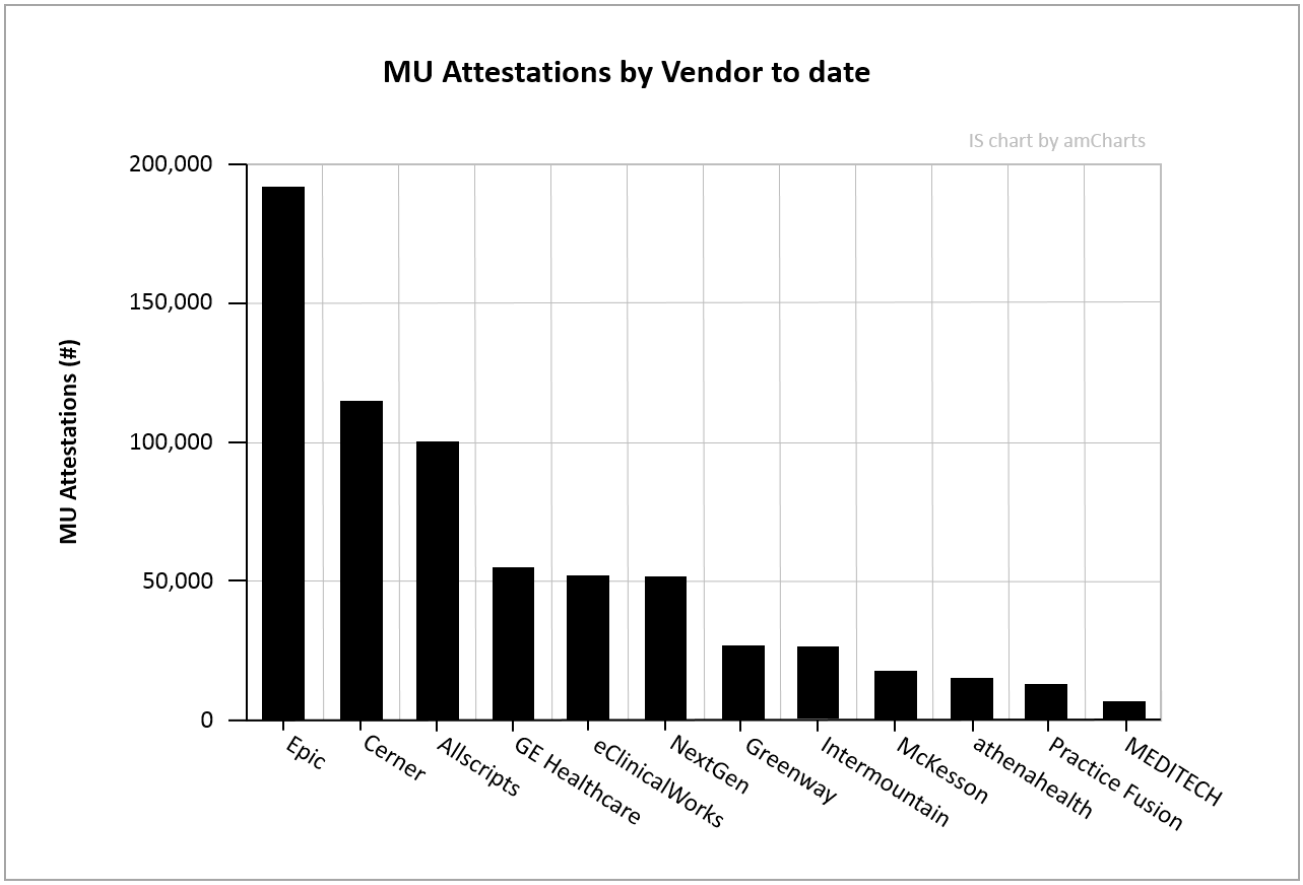
Electronic Medical Record and Electronic Health Record

An electronic medical record (EMR) is a computerized system allowing real-time access to the history of a patient's care within a single practice. The content of an EMR consists of both structured and unstructured data and is analogous to the paper record, but the electronic format creates usable data in medical outcome studies, improves the efficiency of care, and makes for more efficient communication among providers and easier management of health plans. This also forms the legal health record. A good example of an EMR is a patient record in an outpatient setting that shows the patient data from their multiple encounters. This data is mostly internal only and is not easily interoperable, i.e. cannot be shared with other care providers outside of the hospital/patient in real time.

An electronic health record (EHR) differs from and EMR because it is the longitudinal collection of electronic health information that includes data from the multiple sources of care that the patient has used. Since EHRs are interoperable they can be accessed at any authorized point of care. EHR aims to be the current and most complete view of patient data. A standard example is an enterprise wide EHR implemented in a hospital system that operates in multiple states. An EHR is usually integrated with all the other information systems in the enterprise and any update made on the patient's record whether it is lab, billing, or registration can be accessed in real time by authorized personnel.

There are a multitude of EMR/EHR systems available in the market today with built-in LIS capabilities. These work great for normal workflows but may not be sufficient to address the complexities of specialty clinical diagnostic laboratories. In this case, integrating a best-of-breed LIS system that supports their complex workflows with the EMR/EHR systems becomes the need of the hour.

HealthcareIT News published the chart below to show the number of meaningful use (MU) attestations by vendor[8]. According to CMS data, Epic Systems accounts for nearly 186,000 of those attestations, Cerner is second with 120,331 attestations, and Allscripts is close behind at 99,091 as of the charts publication.



http://www.healthcareitnews.com/news/ehr-vendor-marketshare-mu-attestations-vendor-chart

Basic features of an EMR:

- Electronic Clinical Information
  - Patient demographics
  - Physician notes
  - Nursing assessments
  - Problem lists
  - Medication lists
  - Discharge summaries
  - Advance directives

- Computerized Provider Order Entry
    - Lab reports
    - Radiology tests
    - Medications
    - Consultation requests
    - Nursing orders
- Results Management
    - Lab reports
    - Radiology reports
    - Radiology images
    - Diagnostic test results
    - Diagnostic test images
    - Referral/consultant report
- Decision Support
    - Clinical guidelines
    - Clinical reminders / alerts
    - Drug allergy results
    - Drug-drug interactions
    - Drug-lab interactions
    - Drug dosing support

There are several agencies that publish EMR/EHR/Health IT adoption rates by state, by vendor etc. According to HHS:[9]

> "78% of office-based physicians reported they adopted some type of EHR system. About half of all physicians (48%) had an EHR system with advanced functionalities in 2013, a doubling of the adoption rate in 2009. About 6 in 10 (59%) of hospitals had adopted an EHR system with certain advanced functionalities in 2013, quadruple the percentage for 2010."

One of the standard metrics used to measure EMR adoption is the HIMSS EMR Adoption Model (EMRAM)[10]. EMRAM is an eight-step process that allows healthcare organizations to analyze their level of EMR adoption, chart their accomplishments, and track their progress against other healthcare organizations across the country. Each of the stages is measured by cumulative capabilities and all capabilities within each stage must be reached before moving to the next stage. The table below gives us a quick view how well the US hospitals and ambulatory clinics are employing the use of health IT systems.

United States EMR Adoption Model [SM]			
Stage	**Cumulative Capabilities**	**2014 Q3**	**2014 Q4**
Stage 7	Complete EMR; CCD transactions to share data: Data warehousing: Data continuity with ED, ambulatory, OP	3.4%	3.6%
Stage 6	Physician documentation (structured templates), full CDSS (variance & compliance, full R-PACS	16.5%	17.9%
Stage 5	Closed loop medication administration	29.5%	32.8%
Stage 4	CPOE, Clinical Decision Support (clinical protocols)	14.5%	14.0%
Stage 3	Nursing/clinical documentation (flow sheets), CDSS (error checking), PACS available outside Radiology	23.9%	21.0%
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable	5.3%	5.1%
Stage 1	Ancillaries – Lab, Rad, Pharmacy – All Installed	2.5%	2.0%
Stage 0	All Three Ancillaries Not Installed	4.4%	3.7%
Data from HIMSS Analytics® Database ©2014		N = 5453	N = 5467

http://www.healthcareitnews.com/news/benchmarks-stage-7-success-stories?single-page=true

Health Information Exchange

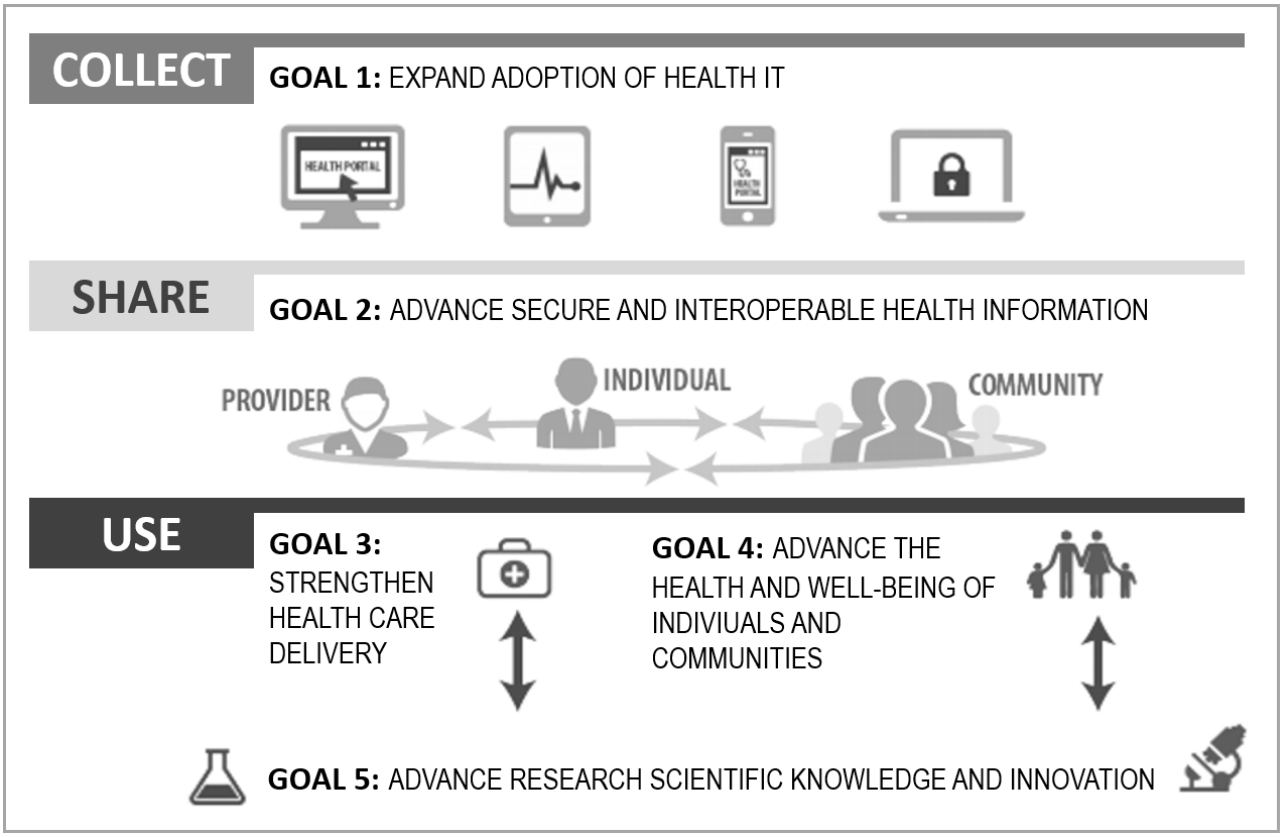
According to HIMSS and HealthIT.gov, Health Information Exchange (HIE) is a term used to describe both the sharing of health information electronically among two or more entities and also an organization which provides services that enable the sharing electronically of health information. HIE allows providers across the care continuum to access and securely communicate patients vital medical information in real time, thus improving quality, safety, cost and speed of patient care. This medical information can range from medical history, lab results to images and allergies. There are multiple standards in play today that enable this level of exchange in the most secure form while taking into consideration patient privacy.

Two HIE architectures are popular – Centralized and Decentralized/Federated. In a centralized model, patient data is collected from local sources but stored in a central repository. With a request from entities for patient data, the transaction is routed through the central repository. Such

architecture permits local entities to maintain autonomy but through cooperation provide data at a local or regional level. Since all the data exists in a single repository, it is very quick and easy to perform queries against it. In the centralized model, all providers send their data periodically to the central repository, usually on a daily basis. The decentralized or federated model provides organizational control of the healthcare record and provides the framework for data sharing capability to enterprises in a widely distributed region. The local entity owns their data and the record locator services manage the pointers to the information. Updates and access to the healthcare record are only provided when needed to authorized personnel.

Today there are several incentive programs, penalties and laws that promote EHR and HIE adoption. These include the American Recovery and Reinvestment Act (ARRA, 2009), the HITECH (Health Information Technology for Economic and Clinical Health Act, 2010), meaningful use incentives, and new regulations passed by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC).

While it is evident that integration of LIS with EMR/EHR systems is vital, this is not without its challenges. Large laboratories have to implement hundreds of interfaces, each unique and customized based on the host EHR systems and provider preferences. It is preferred by many to have one interface for every vendor product, but due to the unique environment of each vendor and lack of national standards, the lab typically ends up having multiple interfaces for every EHR product and is constantly developing new ones. It is also important to have interface verification procedures to ensure that the existing interfaces are not affected, and to ensure new interfaces adhere to the company standards and regulatory requirements. Generally the implementation and verification of a bi-directional interface takes approximately twice as long as that of a unidirectional interface.



U.S. healthcare goals regarding interoperability and integration

http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf

Meaningful Use

As defined by HealthIT.gov[11], meaningful use is using certified electronic health record technology to:

- Improve quality, safety, efficiency, and reduce health disparities
- Engage patients and family
- Improve care coordination, and population and public health
- Maintain privacy and security of patient health information

Meaningful use sets specific objectives that eligible professionals (EPs) and hospitals must achieve to qualify for Centers for Medicare and Medicaid Services (CMS) incentive programs. These objectives are being rolled out in stages. Hospitals, EPs and Health IT products are currently working towards MU Stage 2.

- Stage 1(2011 – 2012)
    - Data Capture and sharing
    - Promotes basic EHR adoption
- Stage 2 (2014)
    - Advance clinical processes
    - Emphasizes care coordination and exchange of patient information
- Stage 3 (2016)
    - Improved healthcare outcomes

Ultimately, it is hoped that the meaningful use compliance will result in:

- Better clinical outcomes
- Improved population health outcomes
- Increased transparency and efficiency
- Empowered individuals
- More robust research data on health systems

Standards and Coding

There are a number of standards applicable for integration and interoperability:

- Data Exchange
    - HL7, DICOM, X12, IEEE 1073, XML
- Terminology
    - CPT, ICD, SNOMED, LOINC, NDC, NIC, NOC
- Document
    - CCR, CDA, UACDS, UHDDS
- Infrastructure
    - ASTM E: 1762, 1985, 2084, 2147
- Identification
    - UPIN, NPI
- Composite standards
    - IHE
    - HITSP

Some of the major data exchange and coding standards applicable to LIS Integration are described below.

HL7 - Health Level Seven

Health Level Seven, abbreviated as HL7, is the most widely used standard to facilitate communication between disparate clinical applications. HL7 and its members provide a framework for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure, and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services.

HL7 is the one of the several American National Standards Institute (ANSI) accredited Standards Developments Organizations (SDO). HL7 describes both the SDO and a group of standards. It mainly focuses on clinical and administrative data. HL7 has three primary types of users: clinical interface specialists, government entities and medical informatics. While the use of HL7 V2.3 messages is widespread, HL7 V3 is being introduced through newer applications such as CDA (Clinical Document Architecture), CCD (Continuity of Care Document), and CCR (Continuity of Care Record). Each of these have a very specific role in data transmission in an HIE.

HL7 contains messages for every single healthcare application area. Common HL7 message types include ADT (Patient Registration), ORU (Results), ORM (Orders), and ACK (Acknowledgement). These messages are used to communicate between disparate systems irrespective of the vendor and product type. By employing an HL7 interface engine, providers and hospitals can reap the benefits of existing information systems without major reinvestments in new technology. To establish an HL7 Interface, providers usually implement either a point-to-point interfacing approach or utilize an interface engine.

The HL7 standard is often called the “non-standard standard.” While it can be challenging to implement, it allows for some flexibility and customization according to the needs of the sending and receiving facilities.

ICD - International Classification of Disease

The International Classification of Disease (ICD)[12] is a widely recognized international standard for reporting diagnoses. It is developed, monitored, and copyrighted by the World Health Organization

(WHO). The ICD is designed as a health care classification system, providing a system of diagnostic codes for classifying diseases, including nuanced classifications of a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease. This system is designed to map health conditions to corresponding generic categories together with specific variations, and assigning them a designated code up to six characters long. Thus, major categories are designed to include a set of similar diseases. ICD-9 codes have been in use for a long period of time and the switch to ICD-10 codes is currently on-going. The target date for conversion is set for October 2015.

CPT - Current Procedural Terminology

Current Procedural Terminology (CPT)[12] is a U.S. standard for coding medical procedures, maintained and copyrighted by the American Medical Association (AMA). Similar to ICD coding, CPT is used to standardize medical communication across the board. But where ICD-9 and ICD-10 focus on the diagnosis, CPT codes identify the services provided, and are used by insurance companies to determine how much physicians will be paid for their services.

LOINC - Logical Observation Identifiers Names and Codes

Logical Observation Identifiers Names and Codes (LOINC)[12] was created in 1994 by the Regenstrief Institute to be used as the universal standard for laboratory and clinical observations, and to enable exchange of health information across different systems. Where ICD records diagnoses and CPT identifies services, LOINC is a code system used to identify test observations. LOINC codes are often more specific than CPT, and one CPT code can have multiple LOINC codes associated with it. LOINC is the preferred standard for coding testing and observations in HL7.

SNOMED CT - Systematized Nomenclature of Medicine

SNOMED Clinical Terms (SNOMED CT)[12] is a comprehensive, computerized healthcare terminology containing more than 311,000 active concepts, with the purpose of providing a common language across different providers and sites of care. SNOMED CT is essential for recording clinical data such as patient problem lists and family, medical, and social histories in electronic health records in a consistent, reproducible manner. SNOMED CT can be mapped to other coding systems such as ICD-9 and ICD-10, which helps facilitate semantic interoperability.

IHE – Integrating the Health Enterprise

IHE isn't a single standard or even a set of standards. It's a nonprofit organization that brings together the multitude of stakeholders in healthcare to promote sharing of health information. IHE is a multi-year initiative under the leadership of Healthcare Information Management & Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE technical committees develop integration profiles to assure that health information transmits seamlessly across the entire healthcare enterprise.

IHE fills an important gap between the development of health IT standards and their implementation in real-world health IT systems. IHE assembled experts worldwide in all the clinical and operational domains to develop guidelines for the use of established standards to make health IT systems interoperable and achieve effective use of EHRs.

Interface Engines

Healthcare facilities typically use a wide range of complex software applications for different functions, supplied by different vendors. These applications have to "talk" to each other in order to transmit clinical and administrative data with the use of interfaces. HL7 is generally used as the data exchange standard for implementing interfaces. HL7 interfaces require sending and receiving modules which are parts of the sending and receiving applications. While the HL7 standard is the same, no two facilities have to use the same HL7 message format and there can be some manipulation needed to ensure seamless data exchange. HL7 interfaces can be built point-to-point or an interface engine can be employed.

Implementing and monitoring point to point interfaces in a healthcare facility can become cumbersome, given the number of applications. Because of this, interface engines play an increasingly critical role in facilitating the growing demand for patient data exchange in HIEs. Some of the benefits of using an interface engine include:

- Reducing the required number of export and import endpoints
- Allowing for reuse of data between applications
- Providing an easier method to interface a new or replaced application
- Providing the ability to monitor the entire system at one time

Some of the more advanced interface engines also function as a healthcare integration platform that supports the operations of a care delivery organization. From interfaces to workflow to operational decisions, interface engines assist in modernizing the healthcare system. Current market leaders for integration engines include:

- BizTalk [Microsoft]
- Cloverleaf [Lawson (Quovadx)]
- Corepoint, NeoTool [Corepoint Health]
- Ensemble [Intersystems]
- Epic Bridges [Epic]
- Fusion Middleware [Oracle]
- Mirth Connect [Mirth Corporation]
- Open Engine [Cerner]
- OPENLink [Siemens]
- Pathways [McKesson]
- Rhapsody [Orion Health]

Specimen Management

A specimen management system helps automate collection and processing of specimens before testing is performed in the laboratories. Its functions may include accession assignment, printing collection lists and labels, logging specimens into the lab, tracking specimens as they are transferred within or between labs, and storage of specimens.

Patient identification and specimen labeling are two key specimen management processes which are under constant scrutiny. Any errors in these steps can have serious consequences in terms of high lab costs and risk to patient health. All labs are required to meet the Joint Commission's national patient-safety goal (NSPG.01.01.01), which stipulates use of at least two identifiers when providing care, treatment, and services.

The Clinical and Laboratory Standards Institute (CLSI) recently published "Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard (AUTO12-A)," which identifies the required human-readable elements that must appear on specimen labels, while specifying their exact locations, fonts, and font sizes[13]. The standard also dictates the location and size of the bar code, while allowing adequate space for other label elements frequently used by laboratories, such as collection priority (e.g. routine, stat), source of specimen (e.g. nasal swab) and

space for special instructions. The development of AUTO12 was prompted by published data that reveal an unacceptably high rate of mislabeled specimens in U.S. laboratories. Compliance with AUTO12-A is expected to be considered for CAP and The Joint Commission accreditation for labs.

Computerized Provider Order Entry (CPOE)

CPOE is the software program that allows a healthcare provider to enter orders electronically and to manage the results of those orders. The benefits of using a CPOE system are significant and range from improving order accuracy, to support for clinical decision support at the point of care, to improved medication safety.

The MU2 core measure related to CPOE states, "Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines."[14]

Billing / Revenue Cycle Management

Medical billing is the process of submitting and following up on claims with health insurance companies in order to receive payment for services rendered by a healthcare provider or laboratory[15]. The same process is used for most insurance companies, whether they are private companies or government sponsored programs such as Medicare or Medicaid. Billing software programs automate the medical billing workflow, which includes insurance verification, coding for services, charge entry, claims processing, authorization management, payment entry, denial management, accounts receivable, and reporting.

Electronic data interchange (EDI) is the computer-to-computer exchange of data or information in a standardized format. Medical EDI refers to the electronic transmission of detailed medical bill payment information. The older standard for EDI is X12 version 4010. CMS has mandated that the industry upgrade to X12 version 5010. The implementation of ANSI 5010 is a requirement for implementing ICD-10 codes.

Medical Device Interfaces (MDI)

MDI is software that provides electronic communication between the clinical/medical devices and LIS. MDI reformats the data from the device into a common internal structure that can be understood by the LIS. The devices can be connected to the MDI though serial RS232 connection or a standard TCP/IP Ethernet connection.

The common classifications of MDIs are:

- Unidirectional
- Bidirectional
- Multiplexer
- Point of care

CEN ISO/IEEE 11073 standards enable communication between medical, health care and wellness devices and with external computer systems[16]. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data.

Laboratory Governing Bodies, Regulations, Applicable Laws

There is a profound need for compliance in the healthcare arena as a whole, and laboratories are one of the most regulated entities in the field. Compliance with government regulations and laws is mandatory for all clinical laboratories, and there are multiple federal and state laws that apply to them. While pursuing accreditation is voluntary, it is considered a must-have to run a successful business entity. This ensures optimal compliance and fiscal health in a highly competitive and intensely regulated environment. . It is important to have a clear understanding of the differences between regulation and accreditation[17].

- Regulation is a government's oversight and control of a non-government entity's operations and practices through the enactment and enforcement of laws. Failure to comply with governmental regulations may result in civil and criminal penalties.
- Accreditation is a mechanism by which an organization's or an industry's practices are surveyed and formally approved by a private agency that promotes standards of practice for a specific industry or profession. In contrast to regulation, the accreditation process is voluntary and failure to comply is not grounds for civil or criminal action.

AABB

Established in 1947, AABB (formerly known as the American Association of Blood Banks) is an international, not-for-profit association dedicated to the advancement of science and the practice of transfusion medicine and related biological therapies. The association is committed to improving health by developing and delivering standards, accreditation, and educational programs and services to optimize patient and donor care and safety.

AABB accreditation is voluntary. Accreditation requires an intensive on-site assessment by specially-trained AABB assessors and establishes that the level of technical and administrative performance within the facility that meets or exceeds the standards set by AABB. AABB's accreditation program contributes to the quality and safety of collecting, processing, testing, distributing, and administering blood and cellular therapy products. Furthermore, the program assesses the quality and operational systems in place within a facility. The basis for assessment is compliance with AABB standards, Code of Federal Regulations (CFR), and other federal guidance

documents. Various standards may apply depending on the laboratory's activities[18].AABB was granted "deemed status" as an accrediting organization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) program in 1995. This granting of "deemed status" confirms that the Centers for Medicare and Medicaid (CMS) finds the AABB accreditation process to provide reasonable assurance that the facilities accredited by it meet or exceed the conditions required by federal law and regulations.

AABB grants accreditation for [18]:

- Transfusion Services
- Blood Banks
- Cellular Therapy Clinical Activities
- Donor Centers
- Donor Testing
- Cord Blood Services
- Somatic Cell Services
- Relationship Testing Facilities
- Immunohematology Reference Laboratories
- Perioperative Services

Detailed steps on becoming a AABB accredited facility is available here:
http://www.aabb.org/sa/becomeaccredited/Pages/default.aspx

CLIA

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) (42 CFR 493) in 1988 to establish standards for all laboratory testing and ensure the accuracy and reliability of patient test results. CLIA has served as the primary regulatory program governing U.S. clinical laboratory testing since its implementation, and its regulations apply to all laboratories performing testing of human specimens for health assessment[19]. CLIA regulations apply to laboratory testing in all settings including commercial, hospital, and physician office laboratories. The only exceptions are facilities that perform testing for forensic purposes, research laboratories that do not report patient results, and facilities that are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to perform urine drug testing only.

CLIA standards are national and are not Medicare-exclusive, meaning that CLIA applies to all providers rendering clinical laboratory services, whether or not Medicare claims are filed. The Centers for Medicare and Medicaid Services (CMS) administers the CLIA laboratory certification program in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC)[20].

FDA

- Categorizes tests based on complexity
- Reviews requests for waiver by application
- Develops rules/guidance for CLIA complexity categorization

CMS

- Issues laboratory certificates
- Collects user fees
- Conducts inspections and enforces regulatory compliance
- Approves private accreditation organizations for performing inspections, and approves state exemptions
- Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs
- Publishes CLIA rules and regulations

CDC

- Provides analysis, research, and technical assistance
- Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducts laboratory quality improvement studies
- Monitors proficiency testing practices
- Develops and distributes professional information and educational resources
- Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

CLIA regulations place the responsibility of accurate and timely reporting and the privacy of laboratory information on the laboratories performing the tests. Although CLIA regulations originated in a paper-based environment, they are written in a manner that would apply to both electronic and paper-based exchange[18]. CLIA has helped to improve the quality of testing in the United States, as the number of quality deficiencies decreased approximately 40% between the first and second set of laboratory surveys under CLIA[19].

CLIA regulations are based on the complexity of the test method. Test methods are categorized into three levels of complexity: waived, moderate, and high. The more complicated the test, the more stringent the requirements.

CLIA has standards for:[19]

- Quality Assurance - preanalytic, analytic, and postanalytic processes
- Preparing a procedure manual for facility administration
- Proficiency Testing (PT)
- General laboratory systems
- Personnel qualifications and responsibilities
- Recordkeeping requirements
- Quality assessment and quality control
- Specific cytology provisions for laboratories performing moderate and/or high complexity tests.

CLIA grants five types of laboratory certificates [19]:

- Certificate of Waiver
- Certificate of Registration
- Certificate of Compliance
- Certificate of Accreditation
- Certificate of Provider Performed Microscopy Procedures

Information on how to apply for a CLIA Certificate can be found here:

http://www.cms.gov/RegulationsandGuidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html

CLIA and EHR

Clinical laboratories originally developed interfaces through their own systems to meet CLIA requirements and are now facing increasing pressures as the number of EHRs on the market continues to grow. CLIA also requires that, unless otherwise specified by state law, laboratories send test results only to authorized persons as identified.

In the context of a health information exchange, results are sent to a central switch and this information is then routed to multiple end points. This creates risks for labs, as they will not be aware of all uses and displays of data. Hence, labs must trust another organization to ensure that all

the lab data is transmitted and that test results are displayed accurately in a manner compliant with both CLIA and state laws[18].

Although CLIA regulates the timely delivery of test results, there are no current standards or requirements with respect to how, in an EHR or in the context of a HIE, information is passed back to the lab that the provider has viewed a result. Technically, the EHR can send an HL7 message to inform the laboratory's LIS that a message has been received.

Some of the issues that arise with transmitting laboratory data through EHR have been addressed by CLIA and CMS. According to them, an authorized person can designate an agent as one of the additional individuals/entities on the test requisition. Information necessary for the electronic transmission of laboratory results can be included on the test requisition by the authorized person. The final report destination for CLIA purposes is considered to be the authorized person or their designated agent where an agent is an individual or entity legally acting on behalf of the authorized person to receive test results. The laboratory's CLIA responsibility ends when the patient, agent or if applicable, the individual(s) responsible for using the laboratory results receive the results.

CLIA does not regulate EHR systems or vendors and EHR companies are not required to develop products that are CLIA compliant. The laboratory determines if the EHR product meets all applicable facility needs and regulatory requirements. If a laboratory uses an EHR system, the laboratory (not the vendor) makes sure their staff are trained on EHR systems

In this scenario where EHR is involved, the laboratory must ensure the test requisition solicits the name and address or other suitable identifiers of the authorized person requesting the test. The individual responsible for using the test results, or the name and address of the laboratory submitting the specimen should also be noted on the requisition. This will enable speedy reporting of imminently life threatening, critical, or high priority result values.

CAP

The College of American Pathologists (CAP) is a medical society that serves more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient

care[21]. The U.S. federal government recognizes the CAP Laboratory Accreditation Program, begun in the early 1960s, as being equal-to or more-stringent-than the government's own inspection program. CMS has granted the CAP Laboratory Accreditation Program deeming authority, which allows CAP inspection in lieu of a CMS inspection. It is also recognized by The Joint Commission, and can be used to meet many state certification requirements.

CAP accreditation helps laboratories meet CLIA requirements and ensure compliance through the guidance of the most comprehensive scientifically endorsed laboratory standards. This includes maintaining accuracy of test results and ensuring accurate patient diagnosis. The accreditation also brings value to organizations, customers, and patients. CAP's accreditation program uses a peer-based inspection model and uses teams of practicing professionals qualified through a CAP training program. If a laboratory is CAP accredited, it can have a "deemed status" and is exempt from other surveys like The Joint Commission (TJC).

The CAP checklists, based on the standards, are key tools used by inspectors to ensure that each inspection is consistent and thorough, and the checklist items enable CAP to determine if the laboratory meets the standards for accreditation. Each checklist contains questions specific to a particular discipline[22]. Questions in each checklist cover proficiency testing, quality control, and quality improvement activities including supervision, the procedure manual, specimen collection and handling, reporting of results, reagents, instruments and equipment, individual tests performed in that laboratory section, personnel requirements, physical facilities, and safety. These questions can be classified as Phase I and Phase II. A deficiency of a Phase I question does not seriously affect the quality of patient care or significantly endanger the health or safety of a laboratory or hospital worker or a patient. If a laboratory is cited with a deficiency in a Phase I question, it must provide a written response to CAP. However, in this case documentation showing a plan of corrective action has been implemented is not required. A deficiency in a Phase II question, on the other hand, may seriously affect the quality of patient care or endanger the health or safety of a laboratory or hospital worker or a patient. If a laboratory is cited with a deficiency in a Phase II question, it must provide a written plan of corrective action and submit evidence demonstrating implementation of the plan of corrective action.

The CAP accreditation process is designed to ensure the highest standard of care for all laboratory patients, Inspectors examine the laboratory's records and quality control of procedures for the preceding two years. They also examine laboratory staff qualifications, equipment, facilities, safety

program and record, and overall management[22]. At the core of the accreditation process is the on-site inspection which is conducted every other year in accordance with regulations contained in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Inspectors are to be observers and reporters, not judges. The inspection process is collaborative and consultative, the intent of the inspection is to identify opportunities for improvement in the quality of laboratory. Sometimes a deficiency may be identified that can be corrected even as the balance of the inspection is being conducted. In such a case, the deficiency will be cited and become a part of the laboratory's record. However, if the inspector notes that the deficiency has been corrected, further action on the part of the laboratory may not be required. At the end of the inspection, the summation conference provides a time for wrap-up and discussion of any remaining issues.

During the post-inspection phase, the laboratory has 30 days from the date of the summation conference in which to respond to the deficiencies cited. A laboratory would typically respond with plans of corrective action and evidence of their implementation, if necessary. Conversely, the laboratory could also respond with a request for expungements, if it believes that a deficiency should not have been cited. When CAP receives these responses, a staff medical technologist reviews them first for completeness and then to ensure that the deficiencies have been corrected. During this review, the reviewer may request the laboratory to provide additional information to support its corrective actions. Once this review is completed, the information is forwarded to the regional commissioner (a pathologist), who performs the final review of the assembled material and makes a determination of its adequacy. These review processes are generally completed in less than 90 days. Once the commissioner determines that the laboratory's responses are adequate or grants the request for expungements, the laboratory is accredited. If the laboratory fails to address deficiencies appropriately, the commissioner may recommend denial of accreditation[22].

In alternate years, the laboratory is required to conduct a thorough self-inspection, using materials provided by CAP. If deficiencies are discovered, the laboratory should correct them and retain the records of the corrective actions for review by the inspectors at the time of the next on-site inspection [22].

For each analyte for which proficiency testing is available, accredited laboratories must perform CAP-approved proficiency testing and request that the provider forward all scores to CAP[22]. These results are received and reviewed on a continuous basis. The initial review may identify three sorts of problems: scores received for tests not known by CAP to be on the laboratory's test menu, scores

not received for tests known to be on the laboratory's test menu, and scores received that are either unacceptable or unsatisfactory.

Apart from CAP checklists, there are other important resources such as CAP's comprehensive collection of Quality Management Tools (QMT) that strengthen our knowledge of key laboratory processes, identify quality improvement opportunities, and provide the information needed for effective laboratory management[23, 24]. The QMTs are:

- Q-Probes - In-Depth Quality Assessment Program
- Q-Tracks - Continuous Quality Monitoring Program
- Q-Monitors - Customized Quality Monitors Program
- LMIP - Laboratory Management Index Program
- CAP LINKS - The Laboratory Integrated Knowledge Source

FDA

In the context of a laboratory with a blood collection center or transfusion services, the Food and Drug Administration (FDA) protects and enhances the public health through regulation of biological products including vaccines, therapeutics, and related drugs and medical devices. FDA also ensures the safety, purity, and potency of blood products, as blood is subject to both biologics and drug regulatory oversight.

The FDA has been inspecting blood collection agencies and blood banks since 1946. While similar in scope to the AABB inspection, the FDA is primarily concerned with assuring the application of current good manufacturing practice regulations (cGMP) to the biologic product blood. The inspector is a government employee who scrutinizes all aspects of donor suitability, collection methods, product preparation, infectious disease testing, donor records, and product disposition. Donor collection records, testing logs, and transfusion records are thoroughly reviewed. In addition, there is direct observation of donor center and blood bank personnel. The final report includes any deficiencies, all of which must be corrected (with documentation) to the satisfaction of the agency. Deficiencies can result in a range of enforcement actions by the FDA as well as loss of license. These include orders to cease blood collection and component preparation, seizure of current blood inventory, monetary fines, and criminal sanctions.

A blood establishment has to collect and process licensed products, provide transfusion services, or perform certain actions within the facility to warrant the attention of the FDA such as, pooling, using a sterile connector device, irradiating blood products, or use of a computer system. The FDA sends a field investigator to each blood center at least every two years to perform a routine investigation. Facilities with noted deficiencies from previous inspections could be inspected more frequently. Each visit is unscheduled and the investigation concludes within four to five days. While blood and blood products carry an inherent risk of infectious agents, the FDA strives to keep this risk at the lowest level reasonably achievable without unduly decreasing the availability of this life saving resource[25]. Blood establishments are now held to quality standards comparable to those expected of pharmaceutical manufacturers.

The world of FDA regulations is vast. The FDA is organized into offices that manage and direct FDA operations. For all FDA regulated products and industries, the Office of Regulatory Affairs (ORA) serves as the lead office for compliance assurance. The two FDA offices specifically concerned with laboratory operations are the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH).

CBER regulates the collection of blood and blood components used for transfusion and establishes standards for the manufacture of pharmaceutical products derived from blood products. CBER publishes guidance documents that provide background, explanation, interpretation, and recommendations for various specific industry processes and procedures[25]. Although not legally binding, these guidance documents are considered to be the standards for the blood industry and cGMP.

The inspection of a blood establishment is based on a multi-layered set of safeguards referred to as the "five layers of safety" related to blood and blood component collection, manufacturing and distribution. The inspection options provide coverage of the following five layers of safety[26]:

- Donor Screening – procedures to identify donors who have defined risk factors for communicable diseases or who are otherwise unsuitable to donate.
- Donor Deferral – procedures to identify unsuitable donors and prevent the distribution of blood products collected from these donors.
- Product Testing – procedures to properly test blood for required infectious diseases and antigens and antibodies that may cause a hemolytic transfusion reaction.
- Quarantining – procedures to ensure that blood products are quarantined until all tests and control procedures are acceptable and unsuitable products are removed from inventory.

- Monitoring and Investigating Problems – procedures to identify system problems, biologic product deviations, and blood donor and recipient adverse reactions and to ensure that adequate corrective action is implemented.

In order to operate legally in the United States, a blood establishment must comply with the specific blood manufacturing regulations outlined in the Title 21, Code of Federal Regulations (21 CFR), which is published by the FDA. Key parts related to laboratory operations are:

- 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- 600 – Biological Products: General
- 601 - Licensing
- 606 – Current Good Manufacturing Practice for Blood and Blood Components
- 607 – Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products
- 610 – General Biological Products Standards
- 640 – Additional Standards for Human Blood and Blood Products

Blood Establishment Computer Software (BECS) is software designed to be used in a blood establishment and is used for prevention of diseases or other conditions in donors by stopping the release of unsuitable blood and blood components[27]. Software used in both blood centers and transfusion services is highly regulated. The software is considered a Class II medical device requiring 510(k) premarket notification. There are recommendations for BECS validation listed in various guidance documents, and these are strictly followed by the medical devices and IT departments within hospitals.

When it comes to software validation, verification and validation are very distinct terms as used in the guidance documents. Validation of BECS in the user's facility should assure that the software is suitable for specific operations and workload, and can accurately and repeatedly meet the needs as defined in the requirements document. When it comes to verification, it provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase.

Software validation is also described in terms of installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). According to the below documents, activities in a typical software life cycle model include the following:

- Quality Planning
- System Requirements Definition
- Detailed Software Requirements Specification
- Software Design Specification
- Construction or Coding
- Testing
- Installation
- Operation and Support
- Maintenance
- Retirement

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States[28]. Medical devices are classified as Class I, II, or III based on their design, the intended use, and the potential for harm to the user/patient. Class I devices are generally simple in design, manufacture, have a history of safe use, and are the least regulated. A Class I device example is a hemostat. Class II medical devices are devices where general controls are not sufficient to assure safety and effectiveness. For Class II devices, existing methods, standards, and guidance documents are available to provide assurances of safety and effectiveness. In addition to compliance with general controls, Class II devices are required to comply with special controls. Special controls include special labeling requirements, mandatory performance standards, both internationally and domestically post-market surveillance, and FDA medical device specific guidance. A Class II device example is a glucometer. Class III devices are high risk, the most complex, and have no predicate to compare with and hence most regulated. Class III devices can have tragic consequences in the event of failure and these do not have comparable devices existing in the marketplace. A Class III device example is a prosthetic heart valve[29].

The majority of Class II medical devices are cleared to market by submission and FDA review of a 510(k) pre-market notification submission[30]. This helps establish that a given device is similar in safety and effectiveness to another lawfully marketed comparable device "predicate" or to a standard recognized by the FDA, when used for the same intended purpose(s). The nature of

comparison depends on the complexity and degree of risk to the patient or the user, associated with the use of the new device.

Some of the key FDA guidance documents referred to frequently are:

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm078815.pdf

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm337001.pdf

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM164981.pdf

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf

TJC

The Joint Commission (TJC) is an independent, not-for-profit organization that serves as the nation's predominant standard-setting and accrediting body for health care organizations. It was established in 1951, and has been accrediting laboratories since 1979. Until 2007, they were known as The Joint Commission on Accreditation of Healthcare Organizations (JCAHO). TJC was created collaboratively by the American College of Surgeons (ACS), American Medical Association (AMA), American Hospital Association (AHA), American College of Physicians (ACP) and American Dental Association (ADA). Only hospitals that provide the highest level of quality choose to be evaluated by TJC, because their standards are regarded as the most rigorous in the industry[31].

TJC's Gold Seal of Approval is a clear sign that the accredited organization has demonstrated compliance with the most stringent standards of performance. CMS officially recognizes the TJC Laboratory Accreditation Program to be meeting the requirements of CLIA. TJC standards and CLIA regulations require that a laboratory be enrolled in a CMS-approved proficiency testing program for all regulated tests conducted by the laboratory.

Laboratories eligible for TJC accreditation include[32]:

- Hospital laboratories
- Reference laboratories
- Physician office laboratories
- Assisted reproductive technology laboratories
- Clinics
- Long term care facilities
- Home care organizations
- Behavioral health organizations
- Public health laboratories, including Indian health services
- Ambulatory sites
- Blood transfusion facilities
- Federally owned laboratories

TJC lab accreditation focuses on operational systems critical to the safety and quality of patient care. To attain Joint Commission accreditation, a health care organization and/or clinical laboratory must undergo an on-site survey. The objective of the survey is not just to evaluate the laboratory but also to serve as good practice guidance and education to promote continuous performance improvement. Surveys are conducted by TJC employed medical technologists, RNs, and MDs who must meet very high academic and clinical experience requirements. They also receive comprehensive, continuing education throughout the year[31]. Laboratories are surveyed every two years and other organizations' survey cycle is three years.

From a cost, time, and resource perspective, a key advantage of the TJC laboratory survey process is that all laboratories within an organization can be reviewed during the course of one survey. The Joint Commission survey covers not only laboratories within the hospital, but also laboratories serving different organizational elements even if services are provided off-campus or in a neighboring state. The accreditation process does not end when the on-site survey is completed. The Joint Commission requires ongoing self-assessment and corrective actions. The Comprehensive Standards Manual for Laboratories (CAMLAB) is designed for use in self-assessment activities and includes the requirements that form the basis of the accreditation survey. TJC standards meet or exceed the CMS Conditions of Participation (often referred to as CoPs) which must be met in order to participate in federal healthcare programs[33]. Organizations seeking Medicare/Medicaid approval may choose to be surveyed either by an accrediting body, such as TJC or by any other state surveyors on behalf of CMS.

The TJC survey follows tracer methodology. In a laboratory setting, tracer methodology does the following, as outlined in the Lab Accreditation Overview Guide[34]:

- The surveyor(s) will follow the patient's experience, looking at services provided by various individuals and service areas within the laboratory, as well as 'handoffs' between them.
- It follows the experience of care of individuals through the pre-analytical, analytical, and post-analytical laboratory processes.
- It allows the surveyor to identify performance issues in one or more steps of the process, or in the interfaces between processes

The Joint Commission has been the American healthcare quality advocate for more than half a century with ongoing initiatives such as "Speak Up," National Patient Safety Goals, Office of Quality Monitoring, Quality Check, Public Advisory Group, Business Advisory Group, board representation, and public policy initiatives to help consumers and providers of healthcare. The Joint Commission has a proven record of helping thousands of organizations address their patient safety problems.

The National Patient Safety Goals for Laboratory, published by TJC in 2015, include:[35]

- Improve the accuracy of patient identification by use of two patient identifiers, to help ensure each patient receives the correct treatment and medications
- Improve the effectiveness of communication among caregivers and timely reporting of critical results
- Reduce the risk of healthcare delivery associated infections by meeting hand hygiene guidelines that are published by Centers for Disease Control and Prevention or the World Health Organization

Useful TJC Lab Accreditation Resources:
http://www.jointcommission.org/assets/1/6/2013_Lab_Overview.pdf
http://www.jointcommission.org/facts_about_laboratory_accreditation/default.aspx
http://www.jointcommission.org/assets/1/18/Acreditation_Process_Overview.pdf

HIPAA

Originally referred to as the Kennedy-Kassebaum Bill, the Health Insurance Portability and Accountability Act (HIPAA) was passed by Congress in 1996[36]. Compliance with the HIPAA law is mandatory for all laboratories and other healthcare organizations. HIPAA law has five Titles (parts), out of which Title II is the most relevant in this context as applied to Protected Health Information (PHI).

HIPAA Title II contains what are known as the Administrative Simplification Provisions. These provisions apply to three types of entities known as covered entities. They are health care providers who conduct healthcare data transactions electronically, health plans, and health care clearinghouses[37]. Nearly all laboratories use LIS and other various integrated systems such as EMR, EHR, and electronic billing to create, store, and transmit electronic healthcare data, and are therefore regulated by HIPAA laws. Each covered entity can evaluate its own business functions and needs, the business risks, and the types and amounts of PHI it collects, uses, and discloses to determine adequate safeguards for its particular circumstances. HIPAA requires that the covered entities use designated standard transaction formats and code sets for the electronic transmission of health information. HIPAA also establishes standards for the privacy and security of individually identifiable health information and provides penalties for its wrongful disclosure. These standards are meant to encourage widespread electronic data interchange for day to day healthcare delivery activities.

Administrative Simplification Provisions include:[38]

- Transactions and Code Set Standards
- Identifier Standards
- Privacy Rule
- Security Rule
- Enforcement Rule
- Breach Notification Rule

These are contained in 45 CFR Part 160, Part 162, and Part 164.

The HIPAA Privacy Rule and HIPAA Security Rule cover data exchange both inside and outside laboratories. The Privacy Rule applies to PHI in any form whether it is electronic, paper, or verbal whereas the Security Rule applies only to the electronically transmitted PHI. The Privacy Rule lists

18 patient identifiers that constitute individually identifiable health information. It allows only six scenarios of PHI "use or disclosure". These are treatment, payment and healthcare operations, by operation of law, with written patient authorization from patient, and waiver of patient authorization from internal review board or privacy committee. Any healthcare worker not directly part of the organization's workforce should be covered under a Business Associate Agreement before having access to PHI. "Minimum necessary" standard should always be applied so that PHI that is being shared is kept to a minimum, and is just enough to accomplish the purpose of disclosure. HIPAA laws are not applicable on de-identified PHI.

The Security Rule sets national standards for the security of electronic PHI (ePHI). This requires covered entities to have "reasonable and appropriate administrative, technical, and physical safeguards" to ensure the confidentiality, integrity, and availability of all ePHI which the covered entity creates, receives, maintains, or transmits. Required electronic healthcare data security safeguards include[39]:

- Administrative safeguards – application of appropriate policies and procedures
- Technical safeguards – ensuring that technical security measures are in place to protect networks, computers, and other electronic devices
- Physical safeguards – safeguarding physical access to ePHI

HIPAA ePHI security safeguards require covered entities to protect against any reasonably anticipated threats or hazards to the security or integrity of ePHI. The safeguards should also protect against any reasonably anticipated uses or disclosures of ePHI that are not permitted or required by the Privacy Rule, and ensure compliance by the covered entity's workforce through continued training and auditing.

Here is a recommended list of safeguards to follow:[39]

- Administrative Safeguards
    - Security management process
    - Assigned security responsibility
    - Workforce security
    - Information access management
    - Security awareness and training
    - Security incident procedures
    - Contingency plan
    - Evaluation
    - Business Associate contracts and other arrangements

- Physical Safeguards
    - Facility access controls
    - Workstation use
    - Workstation security
    - Device and media controls

- Technical Safeguards
    - Access control
    - Audit controls
    - Integrity
    - Person or entity authentication
    - Transmission security

Protecting patient information confidentiality is a legal and ethical responsibility of utmost importance. HIPAA mandates necessary administrative, technical, and physical safeguards to ensure the confidentiality, integrity, and availability of PHI. These safeguards are to be followed through all stages of patient information from creation to transmission. This includes release of information in person, through telephone, fax, emails or any other media in all of the above quoted 6 scenarios for PHI use or disclose. An ongoing challenge for all the care providers is the act of balancing HIPAA Compliance and delivering convenient access to the patient information whether it is for physician, clinician, patient interaction or for billing purposes. Centralization of patient data, encryption of communications and reduction of data exposure on client devices are some of the technology related security guidelines. Other challenging areas include security for shared workstations/kiosks in laboratories, minimizing cache or saved information on distributed devices, encrypting communications over the different networks, and protecting the organization's software systems from malicious code and hackers. When an organization is using web hosted or cloud based software from a vendor, where all the PHI resides in the vendor's servers, additional steps must be taken to ensure security of the same. HIPAA compliant cloud providers are the recent rage in the healthcare software market.

HIPAA compliance is an ongoing process. According to HealthcareITNews[40], since 2009, when the HIPAA breach notification requirement took effect, nearly 31.4 million people have had their protected health information compromised in privacy and security breaches. The Office for Civil Rights, the HHS division responsible for enforcing HIPAA, has levied more than $25.1 million in fines against healthcare organizations responsible for violating the privacy and security rules. Penalties

have been raised with the introduction of the HITECH Act. Previously, monetary penalties were limited to $100 per violation to a maximum of $25,000 per year. The penalties are now broken into four tiers based on the knowledge and willfulness of the violation. The highest tier of penalty is a minimum of $50,000 to a maximum of $1.5million per year when the HIPAA violation has resulted due to willful neglect that the organization did not correct.

Other useful resources related to HIPAA:

http://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/security101.pdf

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html

Steps to Achieve Compliance

Clinical laboratories are committed to provide consistent quality results to the patients as well as ensure compliance with all applicable federal statutes, laws, and regulations. The 1998 OIG guidance document[40] emphasized that each laboratory organization should develop and implement its own compliance plan that addresses their unique compliance obligations and operational complexities. It recommends each compliance program must include the essential elements described in the original OIG guidelines and rely on written standards of conduct, policies and procedures, and education to instill a culture of compliance and ethics organization-wide. These seven essential compliance elements are listed below[41, 42]:

1. The development and distribution of written standards of conduct, as well as written policies and procedures that promote the clinical laboratory's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as marketing schemes, CPT/HCPCs coding issues, improper ICD–9 coding, and improper claims submission;
2. The designation of a chief compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;
3. The development and implementation of regular, effective education and training programs for all affected employees;
4. The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
5. The development of a system to respond to allegations of improper/ illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or requirements of Federal, State or private health plans;
6. The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
7. The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

Implementing written policies, procedures and standards of conduct

Laboratories should develop and distribute written compliance policies as part of their compliance programs. These policies should be created under the supervision of the compliance committee or chief compliance officer. They should be amended and revised as necessary and a clear revision history should be maintained. These policies and procedures should be made accessible to all laboratory stakeholders and personnel.

The written policies can be broken down in the following sections:[41]

- Standards of Conduct and Standard Operating Procedures
- Ensure Understanding of "Medical Necessity" While Ordering Tests
- Billing Policies and Procedures
- Reliance on Standing Orders
- Compliance with Fraud Alerts
- Marketing
- Prices Charged to Physicians
- Retention of Records
- Compliance as an Element of a Performance Plan

The written policies and procedures should address marketing, self-referral, Stark and Anti-kickback statute (AKS) violations, HIPAA and HITECH protection, CLIA requirements, documenting medical necessity, and accuracy in billing. Risks specific to laboratories should be addressed, e.g. correct identification of services and selection of proper CPT or HCPCS codes[43].

Designating a Compliance Officer and Compliance Committee

The OIG recommends that a compliance committee be established to advise and assist the compliance officer. The compliance officer oversees the corporate compliance program, functioning as an independent and objective body that reviews and evaluates compliance issues and concerns within the organization. This position ensures the board of directors, management, and employees are in compliance with the rules and regulations of the various applicable regulatory bodies and laws. This position is also key in upholding standards of conduct and standard operating procedures across the organization.

The role and responsibilities of a compliance officer or committee can be summarized as below: [44]

- Develop, initiate, maintain, and revise standards of conduct and other policies and procedures for the general operation of the compliance program and its related activities to prevent illegal, unethical, or improper conduct; Manage day-to-day operation of the program
- Collaborate with other departments (e.g. risk management, internal audit, employee services, legal) to direct compliance issues to appropriate channels for investigation and resolution
- Investigate and respond to alleged violations of rules, regulations, policies, procedures, fraud, and breaches
- Identify potential areas of compliance vulnerability and risk; develop/implement corrective action plans for resolution
- Develop an effective compliance training program, including appropriate introductory training for new employees as well as ongoing training for all employees and managers

The compliance committee is also responsible to ensure inspection readiness. These steps are listed below:[45]

- Identify the entities that will be inspecting the laboratory and the anticipated frequency of the audit/inspection
- Know the criteria the regulatory bodies will use to judge acceptability and compliance
- List the inspection criteria in an easy-to-use format
- Assign responsibility for meeting each criterion to appropriate departments and staff
- Verify the inspection criteria are being met
- Educate the laboratory staff about the significance of continuous inspection readiness
- Verify that an inspector/audit team is legitimate

Conducting Effective Training and Education

Proper education and training of the personnel form very significant elements of a compliance program. It is essential to mandate compliance training when employees are newly hired and then on a periodic basis thereafter as determined by the compliance committee/chief compliance officer to meet the requirements of the various regulations and laws. These trainings should address federal and state statutes, regulations, program requirements, the policies of private payers, and corporate ethics. The training should emphasize the organization's commitment to compliance with the legal requirements and policies.

Managers of specific departments can assist in identifying areas that require training. Training delivery methods can range from classroom to web based delivery. Training attendance and

competency are documented for audit purposes. Apart from training on compliance policies, targeted training should also be provided to corporate officers, managers, and other employees whose actions affect the accuracy of the claims submitted to government and private payers, such as employees involved in the coding, billing, and marketing processes.[41]

Developing Effective Lines of Communication

All lab personnel should have free access to the compliance officer/committee and are encouraged to approach the coordinator to seek additional information or clarification regarding the compliance plan or to report and discuss suspected misconduct. It must be a lab policy to protect employees who communicate with the coordinator from disclosure of their identity and from any retribution for this communication. The compliance committee should also establish various independent reporting paths for employees to freely report or seek clarification when there is suspected fraud, waste, or abuse.[41]

Conducting Internal Monitoring and Auditing

A successful compliance program requires consistent monitoring and reporting to the compliance officer and committee. Such monitoring should detect any non-compliance, fraud, and abuse. These reports should be kept confidential and maintained by the compliance committee. Although many monitoring tools are available, one of the most effective and widely used techniques is a regular audit of the different departments for any outlier. An effective compliance program should also incorporate periodic reviews of whether all of its compliance elements are being satisfied.

In the current age, most of the LIS systems have in-built audit trails that can show which user has accessed the systems and what steps have been performed. These also form an important resource for monitoring. When it comes to protected health information (PHI), access on any system or interface should be in adherence to HIPAA.[41]

Enforcing Standards through Well-Publicized Disciplinary Guidelines

The compliance plan should be enforced through appropriate performance incentives and disciplinary measures. Compliance breaches should be dealt with fairly without regard to internal hierarchy. Specific penalties for non-compliance must be clearly articulated, approved by legal counsel, communicated to the human resources department, and consistently enforced. Actual disciplinary measures should be publicized.[43]

Swift Action against Offenses and Breaches

Failure to comply with federal or state laws, and other violations of a lab's compliance program, should be handled with utmost seriousness. Detected but uncorrected misconduct, fraud, or data breach can seriously endanger the mission, reputation, and legal status of the laboratory. Investigation into these incidents must be initiated promptly.

Depending on the nature of the offense, the investigation may involve internal interviews, referral to law enforcement authorities, corrective action plans, a report to the government, and reimbursement of overpayments, if any. While any action taken as the result of an investigation could vary depending on the lab and the particular situation, the compliance committee should strive for consistency by utilizing sound practices and disciplinary protocols.[41]

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