BC SOLUTIONS

AN EXPLANATION OF LABORATORY GOVERNING BODIES, REGULATIONS, & APPLICABLE LAWS

AUTHOR: SUDHA POOSA

BC SOLUTIONS, LLC.

Laboratory Governing Bodies, Regulations & Applicable Laws

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'Understanding Laboratory Information Systems Compliance'

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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 fully 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.

Presented by:

BC SOLUTIONS

16815 S. Desert Foothills Pkwy, #130 ● Phoenix, AZ 85048

480.346.7011 ● www.bcsolutionsrfn.com

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

References

Difference between Regulation and Accreditation

17 Blood Banking and Transfusion Medicine: Basic Principles & Practice; Page 223, Google Books

AABB Program Overview

18 http://www.aabb.org/sa/overview/Pages/program.aspx

Lab Electronic Exchange White Paper

19 http://aspe.hhs.gov/sp/reports/2009/informationissues/report.pdf

CLIA Brochure

20 http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CLIABrochure.pdf

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