

Legal Issues in Medical Technology



April 11, 2007

Objectives

- ✓ Briefly describe how the following regulations affect the clinical laboratory
 - CLIA '88
 - HIPAA
 - Title VII of the Civil Rights Act
 - Age Discrimination in Employment Act
 - Americans with Disabilities Act

Legal Issues in the Clinical Lab

- ✓ Regulatory issues
 - CLIA '88
 - Reimbursement
 - OSHA, Accreditation
 - HIPAA
 - Confidentiality
- ✓ Personnel
- ✓ Malpractice
- ✓ Expert witness in legal cases

Regulatory

- ✓ CLIA '88
 - Classifies laboratories based on the complexity of the procedures they perform
 - Sets personnel qualifications from lab director to testing personnel
 - Sets minimum standards and requirements for laboratory practice for moderate- and high-complexity laboratories (QA, QC, inspections)
 - <http://www.vh.org/adult/provider/pathology/CLIA/ProcedureManuals.html>

Reimbursement

- ✓ Medicare will only pay for medically necessary testing
- ✓ Physician must provide ICD-9-CM diagnostic codes
- ✓ Lab provides CPT code to describe service ordered
- ✓ Advanced Beneficiary Notice (ABN) must be signed by patient if it is expected Medicare will not pay for testing ordered.

Regulations - Accreditation

- ✓ Three organizations are active in inspection and accreditation of medical laboratories
 - Joint Commission on the Accreditation of Healthcare Organizations
 - College of American Pathologists
 - American Association of Blood Banks

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- ✓ Protects health insurance coverage of workers
- ✓ Centers for Medicare and Medicaid Services (formerly Health Care Financing Administration) is responsible for implementing the various unrelated provisions of HIPAA, including the Standards for Privacy of Individually Identifiable Health Information

HIPAA

- HIPAA contained a provision that gave Congress until August 21, 1999 to pass comprehensive privacy legislation.
- Congress didn't enact privacy legislation by that date, so the law required the Department of Health & Human Services (HHS) to craft such protections by regulation.

HIPAA Privacy Rule

- ✓ HHS published the final privacy rule on December 28, 2000.
- ✓ Rule gives patients greater access to their own medical records and more control over how their personal information is used.
- ✓ The Privacy Rule also addresses the obligations of health care providers and plans to protect information.

Personnel Issues - Hiring

- ✓ Institutional Regulations
 - Vacancy announcements
 - Length of time job is posted
- ✓ Interview Regulations
 - Certain questions prohibited - Can't ask about marital status, child-care arrangements, citizenship, arrests, foreign languages, height, weight, disability, credit status, date of birth, age, religious affiliation, property ownership, type of military discharge, personal finances, memberships, unless the matter is directly related to the performance of the job.

Personnel Issues - Hiring

- ✓ Title VII of the Civil Rights Act
- ✓ Age Discrimination in Employment Act
- ✓ Rehabilitation Act of 1973
- ✓ Americans with Disabilities Act

Personnel Issues - On The Job

- ✓ Collective Bargaining
 - National Labor Relations Act of 1935
 - Laboratorians can organize as a separate unit from other areas of the hospital
- ✓ Wages and Hours
 - Fair Labor Standards Act (FLSA)(overtime)
 - Equal Pay Act (equal pay for equal work)

Personnel Issues - On The Job

- ✓ Medical, Maternity, and Family Leave
 - The Family and Medical Leave Act
 - Allows employees who have been on the job for at least one year to take 12 weeks unpaid leave
 - The manager can be held personally liable for errors made regarding FLSA and FMLA.
 - Always consult with Human Resource Office

Personnel Issues - On The Job

- ✓ Sexual Harassment
 - Institutional Policy
 - Procedural steps for employees to follow if a sexual harassment situation exists
- ✓ Termination
 - Usually three warnings, one verbal, two written
 - If employee's presence is a danger to other employees or patients, the employee may be removed immediately.

Malpractice

Malpractice is defined as incorrect performance or improper conduct on the part of a purveyor, especially a professional, either through negligence or by violating ethical and professional standards.

Malpractice

- Good records are a major element of sound management and good legal defense
- “If it isn't written down,
it is not done.”

James L. Griffith, J.D.
Medical Laboratory Observer, November, 1986

“Communication and documentation, rather than testing proficiency, are the key areas of legal risk for a laboratory.”

Expert Witness

- ✓ Obtaining counsel and practicing for testimony are especially crucial in preparing to be a witness or giving a disposition.

When an attorney calls the lab:

- ✓ **Never give out any information!**
- ✓ Get his name, firm, phone number, and all patient details (names, dates, tests). Tell him you'll look into it and someone will contact them
- ✓ Do not answer questions, no matter how innocent they sound
- ✓ Notify the lab director and risk management
- ✓ Keep copy of conversation details

Hospital Rules and Policies

- ✓ Maintain patient confidentiality - you can be sued if you release this information
- ✓ Any worksheets, results or computer printouts must have patient information blanked out before turning them over
- ✓ Get approval from hospital attorney for any and all documents
- ✓ Compare lab results with medical record to verify that all information is the same.

Chain of Custody

- ✓ Who drew sample and when
- ✓ Who delivered it to the lab and when
- ✓ Who received the sample and what did they do with it
- ✓ Who ran the tests on the sample and when it was tested
- ✓ Exactly what was done with the sample during testing
- ✓ What was done with sample after testing (storage)

Subpoena

- ✓ **Subpoena Duces Tecum**
 - Issued by judge requesting detailed information or **actual testing equipment!** Lab policies should have policy in place to deal with this in advance
 - Testing devices cannot be removed - biohazards
 - Lab manuals - copyrighted, cannot be copied and distributed, but can be reviewed during normal lab hours

In Court

- ✓ May need to prove qualified people ran the tests
- ✓ Don't take attorneys personally
- ✓ Know COLD the theory and procedure of the test in question. Study in advance
- ✓ Meet with the lawyers ahead of time

References

- Griffith, James L. "How to defuse Legal Dynamite in the Lab" Medical Laboratory Observer, November, 1986.
- Labowitz, Daniel I. "Getting Involved in the Legal System: Choice or Chance?" Clinical Chemistry 34/2, 460-463 (1988)