Overview of Oregon Clinical Laboratory Regulations

The Clinical Laboratory Improvement Amendments (CLIA) program, administered by the Centers for Medicare and Medicaid Services (CMS), and the Department of Human Services (DHS), Health Services (HS formerly the Oregon Health Division) regulate clinical laboratory testing performed within the state for the purpose of diagnosis and treatment or assessment of health of humans in all facility types. The performance of even a single test requires a CLIA certificate. Exempt from regulation are tests performed for pure research and home testing when performed by the patient.

Four types of CLIA certificates are issued: Certificate of Waiver, Certificate of Provider-Performed Microscopy Procedures (PPMP), Certificate of Compliance (for laboratories performing moderate and high complexity testing) and Certificate of Accreditation (for laboratories accredited by the American Association of Blood Banks (AABB), American Osteopathic Association (AOA), American Society of Histocompatibility and Immunogenetics (ASHI), College of American Pathologist (CAP), COLA, and Joint Commission on Accreditation of HealthCare Organizations (JCAHO).

All facilities will receive their applicable certificate following initial payment to CMS except non-accredited laboratories performing moderate and/or high complexity testing. The Certificate of Compliance is issued to the more complex non-accredited laboratories only after on-site CLIA survey which indicates substantial compliance to the CLIA regulations and payment of the compliance fee. All CLIA certificates are issued for a two-year period.

All laboratories must notify Laboratory Compliance & Quality Assurance within 30 days of any change of laboratory name, location, tax identification, or director. High complexity laboratories must notify DHS of changes in technical supervisor. Any change in certificate type requires the payment of appropriate fees and substantial compliance to regulations.

ALL LABORATORIES

Tests may be performed only at the written request of a MD, DO, Podiatrist, Dentist, Naturopath, Chiropractor, certified Nurse Practitioner (NP)\midwife, or Physician Assistant (PA). The exception to this required order is non-medical urine drug screening for substances of abuse and health screen testing (mall testing). Test requisitions and reports must be kept for a minimum of two years (five and six years for Medicare and Medicaid reimbursement).

Written procedures must be readily available to the testing personnel for all tests performed.

There are specific requirements for what is to be included in each procedure.

Laboratories must meet DHS standards for safety and disposal of hazardous or infectious waste. Reports of communicable diseases and other conditions shall be made to the local health department of the patient's county of residence. The laboratory collecting the specimen and reporting to the physician/clinician is responsible for reporting. A "reportable conditions" laboratory reporting poster, listing reportable organisms/tests and time frames for reporting, is available from Laboratory Compliance & Quality Assurance at (503) 229-5853.

Specimens may be referred only to laboratories operating in compliance with CLIA. CMS allows states with CLIA comparable programs to apply for and receive an exemption from CLIA. Currently the only states with a CLIA exemption are Washington and New York (partial).

Unannounced surveys may be performed at any time during routine hours of laboratory operation to investigate complaints, to validate that testing is performed according to regulations and only within the scope of the certificate issued (i.e., waived laboratories perform waived tests only; PPMP laboratories perform waived and PPMP tests only, etc.)

WAIVED LABORATORIES

A Certificate of Waiver authorizes the facility to perform only tests defined as waived. A waived laboratory is waived from personnel standards, routine on-site inspections, proficiency testing and quality assurance. Waived laboratory personnel must follow manufacturers' instructions for test performance and meet other minimal requirements. A synopsis for waived laboratories and a list of current waived tests are available from Laboratory Compliance & Quality Assurance or through the Lab Licensing web site.

PROVIDER-PERFORMED MICROSCOPY PROCEDURES (PPMP) LABORATORIES

A Certificate of PPMP authorizes the facility to perform waived and PPMP tests. Tests classified as PPMP may be performed only by a MD, DO, Podiatrist, Dentist, certified NP or PA. The director must meet the same qualifications as testing personnel. The director is responsible and legally liable for all aspects of testing. The facility must meet general requirements for quality control (if controls are available), records and reports and quality assurance. A synopsis for PPMP laboratories and a list of current PPMP tests are available from Laboratory Compliance & Quality Assurance.

CERTIFICATE OF COMPLIANCE & CERTIFICATE OF ACCREDITATION

MODERATE AND HIGH COMPLEXITY LABORATORIES

The Certificate of Compliance or Certificate of Accreditation authorizes a moderate complexity laboratory to perform tests listed as waived, PPMP or moderate. The Certificate of Compliance authorizes a high complexity laboratory to perform all levels of testing. Complexity levels may be obtained from the manufacturer of laboratory reagents/kits or equipment. In addition, the Certificate of Compliance or Certificate of Accreditation only authorizes a laboratory to perform the specific specialties and subspecialties for which application was made. [For example: microbiology (bacteriology and mycology); chemistry (routine and toxicology); hematology (routine and coagulation)]. The laboratory must inform Laboratory Compliance & Quality Assurance withing 30 days of any change in name, owner, director, location and, in the case of high complexity testing, the technical supervisor. The laboratory must inform Laboratory Compliance & Quality Assurance no later than six months after initiating any testing within a speciality or subspeciality that is not included on their current CLIA certificate.

There are personnel requirements and responsibilities specific for each level of testing ranging from the Director to testing personnel. Minimum requirements for testing personnel of a moderate complexity laboratory are a high school diploma, or equivalent, documented training and proof of competency of laboratory testing. Minimum requirements for testing personnel of a high complexity laboratory depend on when an individual began performing high complexity testing. All personnel performing high complexity testing prior to 4/24/95 can continue to perform the same types of tests. Performance of any high complexity test by an individual with only a high school diploma, or equivalent, requires *direct on-site* supervision by an individual who qualifies as a general supervisor. Anyone hired on or after 4/24/95 must have an AA degree in a laboratory science or medical technology or equivalent in order to perform high complexity tests.

The laboratory director is legally liable and responsible for all laboratory testing at the location indicated on the certificate. Minimum director requirements for moderate complexity testing are a bachelor degree in a chemical, physical, or biological science or medical technology and two years of laboratory training in non-waived testing and two years of supervisory experience in non-waived testing.

Minimum director requirements for high complexity testing are an earned degree of Doctor of Science, Doctor of Public Health, or Doctor of Philosophy or an acceptable degree as determined by DHS and one or more years of experience supervising high complexity testing.

General quality control (QC) requirements are two levels of controls, covering the full range of expected results, each day of testing. Different requirements exist for some specialties or tests, sometimes requiring more frequent QC and other times, less frequent.

Successful proficiency testing (PT) is required on "regulated" analytes. Unsuccessful participation may result in removal of a specific test/specialty or revocation of the CLIA certificate. A list of PT providers and regulated analytes is available from Laboratory Compliance & Quality Assurance. The Laboratory Compliance & Quality Assurance website also provides links to the PT providers.

The laboratory must establish and follow written policies and procedures for a comprehensive quality assurance (QA) program. It must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, post-analytic). The laboratory's QA program must evaluate the effectiveness of these policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. Monitoring and evaluation includes, but is not limited to, QC, PT, records and reports, remedial action and complaints. The assessment of employee competence must be biannual the first year of employment and annual thereafter. All QA activities and corrective action must be documented and discussed with pertinent staff.

In general, laboratory records must be kept for two years. The exceptions are immunohematology for five years, and pathology/cytology for ten years. Hospitals performing transfusion services must maintain records to enable look-back for HIV and hepatitis C for ten (10) years. Reports must identify the name and address of the laboratory performing the test. Records must identify the individual performing the test. More detailed requirements for records and reports must also be met. Note: Medicare and Medicaid require laboratories to keep the test requisition and report for five and six years respectively.

Routine surveys are performed during normal hours of operation every two years in all moderate and high complexity laboratories. Surveys may be announced or unannounced. Surveys may be performed in all types of laboratories to investigate complaints or to verify level of test complexity.

CMS has granted deemed status to specific private *laboratory* accreditation programs which

have laboratory requirements and programs equivalent to the CLIA program. The current recognized accreditation organizations are College of American Pathologists, Joint Commission on Accreditation of Health Care Organizations, American Osteopathic Association, American Association of Blood Banks, COLA, and the American Society of Histocompatibility and Immunogenetics. Laboratories accredited by the aforementioned organizations will not receive routine CLIA inspections. However, 5% of accredited laboratories will receive validation surveys each year.

Department of Human Services, Laboratory Compliance & Quality Assurance has more stringent requirements for substance of abuse testing (including urine drug screening) and health screen testing (mall testing for cholesterol, glucose, etc.). A synopsis of the Oregon Administrative Rules for such testing is available from Laboratory Compliance & Quality Assurance. Practitioners' orders are not required for tests performed by a Health Screen Testing service or substance of abuse tests performed for non-medical purposes.

The current tests which an HST service may perform include:

- Blood in feces (fecal occult blood)
- Blood glucose
- Blood hemoglobin
- Cholesterol
- High density lipoprotein (HDL) by direct method
- Human chorionic gonadotropin (pregnancy test)
- Packed red cell volume (hematocrit)
- Triglycerides following 12 to 16 hour fasting
- Low Density Lipoprotein (LDL) using an automatic calculation with the Friedenwald equation.

Routine on site surveys or a paper survey may be performed every two years in all health screen testing (HST) laboratories. Surveys are performed every two years in all substance of abuse screening (SOA) laboratories. These surveys may be announced or unannounced. Unannounced site visits may occur at any time for mobile health screen testing.

Copies of the complete Oregon Administration Law for clinical laboratories are available upon request from Laboratory Compliance & Quality Assurance, 503-229-5853 or may be downloaded from the Laboratory Compliance & Quality Assurance web site.

Copies of the CLIA regulations, 42 CFR Part 493 are available from the CMS website at http://hcfa.gov/medicaid/clia/cliahome.htm or from the Federal Bookstore in Portland, OR Phone: (503)221-6217. For additional sources, call Lab Licensing at (503)229-5853.

PENALTIES AND ENFORCEMENT FOR ALL CLINICAL LABORATORIES

Laboratory Compliance & Quality Assurance is responsible for ensuring the provisions of Oregon Revised Statute Chapter 438 and 42 CFR Part 493 are carried out. CMS may take disciplinary action against any clinical laboratory that fails to meet the requirements in the references cited. This includes laboratories that are accredited by an approved accreditation organization. All enforcement actions are handled by Region X regional office in Seattle, Washington.

If after investigation or inspection of a laboratory, Laboratory Compliance & Quality Assurance believes there is substantial evidence that a violation has occurred or is occurring, all information is forward to the CMS Regional Office which may seek by civil or judicial means to obtain appropriate remedial relief.

ENFORCEMENT ACTIONS MAY TAKE THE FORM OF ANY OF THE FOLLOWING:

- **PRINCIPLE SANCTIONS**
  1. Suspension of the CLIA certificate
  2. Limitation of the CLIA certificate
  3. Revocation of CLIA certificate
  4. Cancellation of approval to receive Medicare or Medicaid payments

- **ALTERNATIVE SANCTIONS**: may be imposed in lieu of OR in addition to a Principle Sanction
  1. Directed plan of correction (493.1832)
  2. State onsite monitoring (493.1836)
  3. Civil money penalty (493.1834)
  4. Suspension of approval to receive Medicare or Medicaid payments (493.1826)

- **CIVIL SUIT**

- **CRIMINAL SANCTIONS**