**Section 250.510 Laboratory Services**

The hospital shall have a clinical laboratory, certified in accordance with 42 CFR 493, to perform services commensurate with the hospital's needs for its patients. Anatomical pathology services and blood bank services shall be available either in the hospital or by arrangement with other facilities.

a) Adequacy of Laboratory Services. Clinical laboratory services adequate for the individual hospital shall be maintained in the hospital, as determined by the following:

1) The extent and complexity of services are commensurate with size, scope and nature of the hospital, and the demands of the medical staff upon the laboratory.

2) Basic laboratory services, necessary for routine examinations as defined in subsection (b), are provided in the hospital.

b) Clinical Laboratory Examinations. Provisions shall be made to carry out basic clinical laboratory examinations including chemistry, microbiology, hematology, serology, and clinical microscopy in such depth as required by the medical staff.

1) Other laboratory examinations may be provided under arrangements by the hospital with another laboratory which is certified under CLIA regulations.

2) In the case of work performed by an outside laboratory, the original report from this laboratory shall be contained in the medical record as specified in subsection (f).

c) Availability of Facilities and Services

1) Facilities and services shall be available at all times. Adequate provision shall be made for assuring the availability of emergency laboratory services, either in the hospital or under arrangements with a laboratory which meets the requirements of subsection (b).

2) Such services shall be available 24 hours a day, 7 days a week, including holidays. Coverage of the service is permissible by having arrangements with personnel for "on call duty."

3) Where services are provided by an outside laboratory, the conditions, procedures, and availability of examinations performed are to be in writing and available in the hospital.

d) Required Examinations. The laboratory examinations required on all admissions shall be determined by the medical staff as provided in Section 250.240(c).

e) Laboratory Report.

Signed or otherwise authenticated reports shall be filed with the patient's medical record and duplicate copies are maintained in the laboratory.

1) The laboratory director shall be responsible for the laboratory reports.

2) There shall be a policy for assuring that all tests and procedures are ordered by a member of the medical staff or by others in accordance with approved policies. (See Section 250.330)

f) Pathologist Services. Services of a pathologist shall be provided as indicated by the needs of the hospital.

1) Services are to be under the supervision of a pathologist certified by the American Board of Pathology or who possesses training and experience acceptable to the Department and equivalent to such certification, and licensed to practice medicine in all its branches in Illinois, on a full-time, regular part-time or regular consultive basis. If the latter pertains, the hospital shall provide for, at a minimum, semimonthly consultive visits by a pathologist.

2) The pathologist shall participate in staff, departmental and clinicopathologic conferences.

g) Tissue Examination. All tissues removed at operation are to be submitted for examination. The extent of examination is determined by the pathologist.

1) All tissues removed from patients at surgery shall be macroscopically, and if necessary, microscopically examined by the pathologist, with the exception of the following tissues and materials, which do not need to be examined by a pathologist:

A) Foreskin, fingernails, toenails, and teeth that are removed during surgery;

B) Bone, cartilage, normal skin and scar tissue that are coincidentally removed during the course of cosmetic or corrective surgery;

C) Cataract lenses that are removed during the course of eye surgery;

D) Foreign substances (e.g., wood, glass, pieces of metal including previously inserted surgical hardware) that are removed during surgery; and

E) Placenta and placental tissue, unless requested by the delivering physician or practitioner.

2) The pathologist is responsible for verifying the receipt of tissues for examinations.

3) A list of tissues which routinely require microscopic examination shall be developed in writing by the pathologist with the approval of the medical staff.

4) A tissue file shall be maintained and include, as a minimum, reports, slides and cross-index.

5) In the absence of a pathologist, there shall be an established plan for sending to a pathologist outside the hospital all tissues requiring examination. The pathologist may refer tissues to another pathologist for consultation when he deems necessary.

h) Reports of Tissue Examination. Signed reports of tissue examinations are to be filed with the patient's medical record and duplicate copies are to be maintained.

1) All reports of macro and microscopic examinations performed shall be signed by the pathologist.

2) Provisions are to be made for the prompt filing of examination results in the patient's medical record and notification of the physician requesting the examination.

3) Duplicate copies of the examination reports are to be maintained in a manner which permits ready identification and accessibility.

(Source: Amended at 48 Ill. Reg. 450, effective December 20, 2023)