**Section 518.2000 Laboratory Services**

The freestanding emergency center shall have a clinical laboratory to perform services commensurate with the FEC's needs for its patients, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and 42 CFR 493. Anatomical pathology services shall be available either in the FEC or by arrangement with other facilities.

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

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

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

b) Clinical Laboratory Examinations. Basic clinical laboratory examinations, including chemistry, microbiology, hematology, serology and clinical microscopy, shall be carried out as required by the medical staff.

1) Other laboratory examinations may be provided under arrangements by the FEC with another laboratory that is certified under CLIA 88.

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

c) Availability of Facilities and Services

1) Facilities and services shall be available at all times.

2) 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 FEC.

d) Laboratory Report

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

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

2) All tests and procedures shall be ordered by a member of the medical staff or by others in accordance with approved policies.

e) Pathologist Services. Services of a pathologist shall be provided as indicated by the needs of the FEC.

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 who is licensed to practice medicine in all of its branches in Illinois, on a full-time, regular part-time or regular consultive basis. If the latter pertains, the FEC shall provide for, at a minimum, semimonthly consultive visits by a pathologist.

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

(Source: Amended at 33 Ill. Reg. 8317, effective June 4, 2009)