Kansas Administrative Regulations

Department of Health and Environment

Article 34.—Hospitals—Part 1. General.

28-34-11. Laboratory.

(a) Definitions.

(1) "CLIA" means Public Law 100-578 implemented by 42 CFR 493 issued Feb. 28, 1992, as in effect on Sept. 1, 1992; changes in subparts H, R and preamble to the Feb. 28, 1992 final rule issued Aug. 11, 1992, as in effect on Sept. 1, 1992; technical corrections made in subparts T, F, A, K, C, Q, M and R issued Jan. 19, 1993, as in effect on Sept. 1, 1992; and changes in subparts M and K issued July 22, 1993, as in effect on Jan. 19, 1993.

(2) "Clinical consultant" means the individual or individuals in the laboratory defined by 42 CFR 493.1417(b), as in effect on Sept. 1, 1992 or 493.1455(b), as in effect on Sept. 1, 1992.

(b) The laboratory or laboratories performing analytical tests within the hospital shall hold a valid CLIA certificate for the type and complexity of all tests performed.

(c) Clinical laboratory services shall be available on the hospital premises or provided by a CLIA certified laboratory.

(d) An "authorized individual" shall, through written or electronic means, request all tests performed by the laboratory. The individual or individuals serving as the laboratory's clinical consultant or consultants, defined by 42 CFR 493.1417(b), as in effect on Sept. 1, 1992 or 493. 1455(b), as in effect on Sept. 1, 1992, shall clearly define in writing an "authorized individual."

(e) All tissues removed shall be macroscopically examined. If deemed necessary, by written hospital policies and procedures, tissues shall then be microscopically examined. A list of all tissues which routinely do not require microscopic examination shall be developed in writing by a pathologist and approved by the medical staff of each hospital.

(f) The original report or duplicate copies of written tests reports and supporting records shall be retained in a readily retrievable form by the laboratory for a period of at least:

(1) two years for routine test reports;

(2) five years for blood banking test reports; and

(3) ten years for histologic or cytologic test reports.

(g) Facilities for procurement, safekeeping, and transfusion of blood, blood products or both shall be provided or readily available. If blood products or transfusion services are provided by sources outside the hospital, they shall be provided by a CLIA certified laboratory. The source shall be certified for the scope of testing performed or products provided.

(h) Laboratories shall release all proficiency test results to KDHE within seven days of a written request.

(Authorized by and implementing K.S.A. 65-431; effective Jan. 1, 1969; amended Jan. 1, 1974; amended May 3, 1996.)

***** Authenticated Kansas Administrative Regulation *****