

907 KAR 1:575. Compliance with laboratory certification requirements.

RELATES TO: KRS 205.520, 42 C.F.R. 493, 42 U.S.C. 1396a-d

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), EO 2004-726

NECESSITY, FUNCTION, AND CONFORMITY: EO 2004-726, effective July 9, 2004, reorganized the Cabinet for Health Services and placed the Department for Medicaid Services and the Medicaid Program under the Cabinet for Health and Family Services. The Cabinet for Health and Family Services has responsibility to administer the program of medical assistance. KRS 205.520(3) empowers the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law for the provision of medical assistance to Kentucky's indigent citizenry. This administrative regulation sets forth provisions relating to compliance by Medicaid providers with requirements for certification for performance of laboratory testing and implements the Clinical Laboratory Improvement Amendments of 1988.

Section 1. Definitions.

- (1) "Certificate" means the appropriate certificate of waiver, certificate of registration, or certificate of accreditation issued by the United States Department of Health and Human Services (HHS) which authorizes the performance of laboratory testing by a provider of medical services.
- (2) "Medicaid provider" means a participating provider of medical services under the Medicaid Program.
- (3) "State-exempt" means the state laboratory licensing program has been approved by HHS.

Section 2. Requirement for Certification. Any provider of laboratory testing services participating in the Medicaid Program shall comply with certification requirements specified in 42 CFR Part 493 unless the state's licensure program has been approved by the HHS and the provider is appropriately licensed or certified under the state-exempt licensing program.

Section 3. Issues Related to Certification Requirements.

- (1) A provider must have a current, valid certificate in order to provide laboratory testing under the Medicaid Program.
- (2) A Medicaid provider may perform Medicaid covered laboratory services for Medicaid eligible individuals only to the extent authorized by the provider's certificate.
- (3) Any service not covered by the Medicaid provider's certificate shall not be considered a covered Medicaid service.
- (4) Any services not considered a covered Medicaid service shall not be paid for by the Medicaid Program.
- (5) Payments for laboratory testing shall be made without proof of certification for the period December 1, 1992 through December 31, 1992, with payments subject to recovery if the provider does not subsequently receive and show proof of certification for that period of time. Claims for laboratory testing performed after December 31, 1992, shall be denied unless the appropriate certification has been obtained. If a request for certification is not made, is rejected, or when approved does not cover the provision of the laboratory test(s) for which payment has been made, the provider shall immediately refund all payments for the noncovered laboratory service(s).
- (6) The provisions of this administrative regulation relate to covered laboratory testing which is otherwise provided for by Medicaid administrative regulations.

Section 4. State-exempt Laboratory Licensing Program.

(1) If the state has a state-exempt laboratory licensing program, the requirements contained in this administrative regulation shall apply with regard to certifications from the state's licensing program.

(2) Providers licensed under a state-exempt program are not required to obtain a certificate issued by HHS.

Section 5. Effective Date. The provisions of this administrative regulation shall be effective with regard to services provided on or after December 1, 1992.

(19 Ky.R. 1505; eff. 1-27-1993; Crt eff. 12-6-2019.)