5101:3-11-02 **Provider requirements: independent laboratory, portable x-ray supplier, independent diagnostic testing facility (IDTF), mammography supplier, and other providers of laboratory services.**

(A) General requirements for participation.

(1) An entity is eligible to participate in the medicaid program as an independent laboratory, a portable x-ray supplier, or an independent diagnostic testing facility (IDTF) and to provide covered services if it satisfies the following requirements:

(a) It must conform to the appropriate definition set forth in rule 5101:3-11-01 of the Administrative Code;

(b) It must have executed the standard Ohio medicaid provider agreement in accordance with rule 5101:3-1-17.2 of the Administrative Code; and

(c) It must comply with all applicable state laws.

(2) Any eligible medicaid provider included in the following list or otherwise certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) may provide and be reimbursed for covered laboratory procedures appropriate to its level of certification.

(a) Ambulatory health care clinic;

(b) Ambulatory surgery center (ASC);

(c) Federally qualified health center (FQHC);

(d) Outpatient health facility (OHF);

(e) Outpatient hospital laboratory;

(f) Physician or physician group practice;

(g) Podiatrist or podiatric group practice; or

(h) Rural health clinic (RHC).

(B) Specific requirements for reimbursement.

A participating entity is eligible for reimbursement if it satisfies additional requirements.

(1) An independent laboratory must meet the following criteria:

(a) It must meet the standards of compliance listed at 42 C.F.R. 493.3 (effective April 24, 2003).

(b) It must perform covered procedures that are appropriate to its level of certification.

(i) A provider possessing only a certificate of waiver may be reimbursed only for waived procedures.

(ii) A provider possessing only a certificate for provider-performed microscopy (PPM) procedures may be reimbursed only for waived and PPM procedures.

(iii) A provider possessing a certificate of registration, a certificate of compliance, or a certificate of accreditation may be reimbursed for:

(a) Waived procedures;

(b) PPM procedures;

(c) Tests of moderate complexity, if the provider meets the applicable requirements set forth in 42 C.F.R. 493.20 (effective September 22, 2003); and

(d) Tests of high complexity, if the provider meets the applicable requirements set forth in 42 C.F.R. 493.25 (effective September 22, 2003).

(2) A portable x-ray supplier must comply with the conditions for coverage set forth in 42 C.F.R. part 486, subpart C (sections 486.100, 486.102, 486.104, 486.106, and 486.108 effective February 8, 1995; section 486.110 effective September 29, 1995).

(3) An independent diagnostic testing facility (IDTF) must meet the following criteria:

(a) It must meet all standards set forth in and provide services in accordance with 42 C.F.R. 410.33 (effective January 15, 2008).

(b) It must be a party to a current, unrevoked, and unsuspended agreement to participate in medicare as an independent diagnostic testing facility (IDTF).

(c) It must take the following measures to establish accountability:

(i) It must ensure that each supervising physician certifies in writing, at the time of the initial application and at each renewal of the Ohio medicaid provider agreement, that one of two statements is true:

(a) The physician owns the facility, in whole or in part, and employs the operating personnel; or

(b) The physician is an employee of the facility (full-time, part-time, or under contract) whose responsibilities include checking the procedure and quality control manuals; observing the performance of operators or technicians; verifying that the equipment and personnel meet applicable federal, state, and local licensure and registration requirements; and ensuring that safe operating procedures and quality control procedures are used.

(ii) It must maintain and update procedure and quality control manuals. All records of quality control must be kept for the period of time specified in paragraph (D) of rule 5101:3-1-17.2 of the Administrative Code.

(4) A mammography supplier must meet the following criteria:

(a) It must participate in the medicaid program as an independent diagnostic testing facility (IDTF).

(b) It must comply with the conditions for coverage set forth in 42 C.F.R. 410.34 (effective October 31, 1997).

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