5160-11-02 **Laboratory-related services: general provisions.**

(A) A specialized provider of laboratory services must fulfill specific requirements.

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

(a) It must meet all the applicable standards of compliance listed at 42 C.F.R. 493.3 (October 1, 2014).

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

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

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

(iii) A provider possessing a certificate of registration, a certificate of compliance, or a certificate of accreditation may receive payment for the following procedures:

(a) Waived procedures;

(b) PPM procedures;

(c) Tests of moderate complexity, if the provider fulfills the applicable requirements set forth in 42 C.F.R. 493.20 (October 1, 2014); and

(d) Tests of high complexity, if the provider fulfills the applicable requirements set forth in 42 C.F.R. 493.25 (October 1, 2014).

(2) A portable x-ray supplier must meet the following criteria:

(a) It must comply with the conditions set forth in 42 C.F.R. part 486 subpart C (October 1, 2014).

(b) It must be enrolled in medicare as a supplier of portable x-ray services.

(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 (October 1, 2014).

(b) It must be enrolled in medicare as an 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 works for the facility either as an employee (full-time or part-time) or under contract and has responsibilities that 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 rule 5160-1-17.2 of the Administrative Code.

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

(a) It must participate in medicaid as an IDTF.

(b) It must comply with the conditions set forth in 42 C.F.R. 410.34 (October 1, 2014).

(B) Payment can be made for a laboratory-related service only if all of the following conditions are satisfied:

(1) The procedure is medically necessary in accordance with Chapter 5160-1 of the Administrative Code, or the procedure is medically indicated when performed in conjunction with a covered preventive health service defined in Chapter 5160-4 of the Administrative Code.

(2) Although the service may be rendered on the verbal order of a qualified practitioner, the laboratory provider must obtain a written order before submitting a claim.

(a) A written order may consist of an entry in a person's medical records (e.g., in an individual physician's office, a group practice, a clinic, or a

hospital).

(b) A necessary follow-up procedure (e.g., a quantitative test performed in response to a positive qualitative test result) does not require a separate written order so long as the procedure follows appropriate standard practices and is included in the laboratory provider's written protocols. A laboratory provider, however, must not submit a claim for any additional procedure that is based solely on internal protocols without first obtaining a written order.

(3) A written order must include the following information:

(a) The name of the medicaid-eligible individual;

(b) Contact information for the practitioner ordering the service;

(c) Specification of the service (e.g., procedure code, description, number of units);

(d) At least one appropriate diagnosis code;

(e) The date of the order;

(f) The names of the relevant persons or entities involved in providing the service (e.g., referring laboratory, reference laboratory, interpreting practitioner, radiographer); and

(g) Any additional information necessary to ensure accurate and timely testing or reporting (e.g., for a Pap test, the beginning date of the individual's last menstrual period, her age or date of birth, an indication of previous abnormal results and subsequent actions).

(4) A laboratory provider must keep a copy of each written order for the period of time specified in rule 5160-1-17.2 of the Administrative Code and must make it available to the department on request.

(C) Certain laboratory-related services are excluded from medicaid payment.

(1) In general, no payment is made for the following services:

(a) Laboratory-related services exceeding the provisions set forth in this chapter;

(b) Routine laboratory or screening procedures;

(c) Laboratory-related services requiring CLIA certification for which a laboratory provider is not appropriately certified under CLIA;

(d) Laboratory-related services rendered in conjunction with non-covered services, which are delineated in rule 5160-1-61 of the Administrative Code; and

(e) Laboratory-related services rendered for forensic investigation, autopsy, or paternity testing.

(2) Although certain provisions in Chapter 5160-1 of the Administrative Code allow an eligible provider to seek payment directly from a medicaid-eligible individual for services that are not covered by the medicaid program, no laboratory provider may seek payment for any laboratory-related service for which it lacks the necessary CLIA certification.

(D) Payment is made in accordance with Chapter 5160-2 of the Administrative Code for the following services, which in a hospital setting are treated not as laboratory-related services but rather as hospital services:

(1) Clinical diagnostic procedures performed for hospital inpatients;

(2) The technical component of physician pathology procedures performed for hospital inpatients; and

(3) The technical component of other laboratory-related services performed for hospital patients.

(E) Payment may be made to a qualified practitioner or a clinic only for the following laboratory-related services:

(1) A clinical diagnostic procedure or specimen collection actually performed in the practitioner's office, group practice, or clinic;

(2) The professional component of a physician pathology procedure or other laboratory-related service;

(3) A global physician pathology procedure if the following conditions are satisfied:

(a) The practitioner operates a full-service, in-office laboratory certified for the performance of the technical component; and

(b) The procedure was not performed for a hospital patient;

(4) A clinical pathology consultative service; or

(5) The professional administration of a testing device, isotope, or other material.

(F) When submitting a claim to the department, laboratory providers must use the code that describes the procedure in the most detail.

(1) Analytic procedures can be listed by analyte (the substance or material being measured), by method, by both analyte and method, or by specimen type (e.g., urine, blood). Many laboratory procedures, especially drug tests, have synonyms. Care must therefore be taken in the selection of the most appropriate procedure code.

(2) A "not otherwise specified," "miscellaneous," or "unlisted" procedure code in the appropriate area of specialty may be used only if no other code accurately corresponds to a procedure. The laboratory provider must submit a claim for such a service "by report" in accordance with rule 5160-4-02.1 of the Administrative Code. The analyte, the specimen type, and the method must be noted in the claim. The department may deny a claim that omits necessary information or that includes a "not otherwise specified," "miscellaneous," or "unlisted" procedure code when an appropriate procedure-specific code is available.

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