5160-11-01 **Laboratory-related services: definitions and explanations.**

(A) The following definitions apply to this chapter.

(1) "CLIA" is an abbreviation for the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578; 42 U.S.C. 263a, as in effect on December 1, 2014).

(2) "Clinical consultation" is the formal evaluation by a qualified practitioner, performed on the written order of a treating practitioner, of test results that appear to be abnormal. Payment for the clinical consultation is based on the physician fee schedule relative value file published by the centers for medicare and medicaid services (CMS). (The procedure code used for clinical consultation is different and separate from the procedure code for the test whose results are being evaluated.)

(3) "Clinical pathology interpretation" is the interpretation, performed on the written order of a treating practitioner by another practitioner, of the results of any of a certain group of clinical diagnostic procedures that are distinguished by three shared traits:

(a) Separate payment may be made for interpretation;

(b) Payment for the clinical diagnostic procedures themselves is based on the clinical laboratory fee schedule published by CMS; and

(c) Payment for the clinical pathology interpretation is based on the physician fee schedule relative value file published by CMS. (The procedure code for the clinical pathology interpretation consists of a professional component modifier appended to the relevant clinical diagnostic procedure code.)

(4) "Cost-based clinic" is a collective term for a federally qualified health center, an outpatient health facility, or a rural health clinic.

(5) "Current procedural terminology (CPT)" is a uniform numeric code set maintained by the American medical association (AMA) that is used primarily to report medical procedures and services.

(6) "Global procedure" is a procedure, in its entirety, that comprises both a professional component and a technical component.

(7) "Healthcare common procedure coding system (HCPCS)" is a standard code set maintained by CMS that is used for claims processing. Level I of the HCPCS is the set of five-digit CPT codes. Level II of the HCPCS is a standardized set of alphanumeric codes used primarily to report products, supplies, and services not included in the CPT.

(8) "Hospital patient" is a collective term for a hospital inpatient, a hospital outpatient, or a hospital emergency department patient.

(9) "Laboratory-related services" is a collective term encompassing the following procedures:

(a) Laboratory procedures;

(b) Nonroutine specimen collection procedures;

(c) Neonatal diagnostic screening performed with a prefabricated kit;

(d) Diagnostic radiology services (e.g., x-ray procedures, mammography procedures); and

(e) Other diagnostic procedures (e.g., imaging procedures such as MRI or ultrasound, imaging-related procedures such as the placement of catheters or the administration of contrast media, electrocardiography services, electrocardiogram monitoring and analysis, stress tests, sleep studies).

(10) "Neonatal diagnostic screening kit" is a prefabricated laboratory kit used for screening a newborn infant for genetic, endocrine, or metabolic disorders listed in Chapter 3701-55 of the Administrative Code.

(11) "Reference laboratory" is a laboratory that receives a specimen from another laboratory for testing.

(12) "Referring laboratory" is a laboratory that sends a specimen to another laboratory for testing.

(13) "Routine procedure" is a procedure for which no separate payment is made for either of two reasons:

(a) It is very common and is performed only in connection with another procedure (e.g., the collection of a clean-catch urine sample or a throat swab); or

(b) It is included in a treatment protocol for which a composite payment amount has been established (e.g., a specific laboratory test performed for an individual receiving dialysis).

(14) "Written order" is a directive that authorizes the performance of a procedure or service. The order must be produced either in writing or by electronic means.

(B) A provider of laboratory-related services may be either specialized or nonspecialized.

(1) "Specialized provider of laboratory-related services" is a collective term for any of the following providers:

(a) "Independent diagnostic testing facility (IDTF)" is a facility or an entity established for the performance of diagnostic tests that are conducted by licensed or certified nonphysician personnel under appropriate physician supervision. An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is separate from an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. A diagnostic testing facility under the ownership and direction of a physician or physician group is considered to be an independent diagnostic testing facility if it is represented to other practitioners that both the physician-owners and -directors and the facility are available for the performance of diagnostic tests.

(b) "Independent laboratory" is a laboratory that is separate from an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. A laboratory under the ownership and direction of a physician or physician group is considered to be an independent laboratory if it is represented to other practitioners that both the physician-owners and -directors and the facility are available for the performance of laboratory procedures. Facilities that only collect or prepare specimens or that function only as a mailing service and do not perform testing are not considered to be laboratories.

(c) "Mammography supplier" is a facility or an entity established solely for the provision of mammography services. For claim-payment purposes within medicaid, a mammography supplier is treated as an independent diagnostic testing facility.

(d) "Portable x-ray supplier" is an entity established for the provision of diagnostic x-ray services in an individual's place of residence.

(2) "Nonspecialized provider of laboratory-related services" is a collective term for any of the following providers:

(a) An ambulatory surgery center (ASC);

(b) A cost-based clinic;

(c) A fee-for-service clinic;

(d) A hospital eligible for participation in medicaid in accordance with Chapter 5160-2 of the Administrative Code insofar as it is providing services to outpatients (because clinical diagnostic procedures and the

technical components of other laboratory-related services provided to hospital inpatients are paid for in the form of a facility fee under an all-inclusive prospective payment system usually based on diagnosis-related groups, or DRGs);

(e) A physician or physician group practice;

(f) A podiatrist or podiatric group practice; or

(g) Another eligible medicaid provider holding appropriate certification under CLIA to perform laboratory procedures.

(C) For purposes of medicaid, most laboratory procedures are divided into two broad categories.

(1) Clinical diagnostic procedures do not require the specialized skills or knowledge of a physician.

(a) Clinical diagnostic procedures have no separate professional and technical components.

(b) Performance of these procedures generally requires CLIA certification of the laboratory provider.

(c) Payment for these procedures is based on the clinical laboratory fee schedule published by CMS.

(2) Professional procedures require the involvement of a qualified practitioner, usually a pathologist or a hematologist.

(a) Physician pathology procedures have both a professional component and a technical component. In most instances, these components are distinguished on claims by the inclusion of a modifier along with the procedure code. (The professional and technical components of a few procedures may be represented by separate procedure codes.) The professional component of a physician pathology procedure represents the professional services a practitioner renders in the performance of the procedure. It does not represent the simple reading of test results, which is included in the associated originating service (e.g., office visit or surgery).

(b) Some procedures are exclusively professional in nature and have no technical component.

(c) Only an eligible practitioner or an independent laboratory submitting claims on behalf of its physicians (e.g., physician-owners, staff physicians, or physicians under contract with the laboratory) may

receive payment for a professional procedure (or a professional component of a procedure).

(d) Payment for physician pathology procedures and for other professional procedures or components of procedures is based on the physician fee schedule relative value file published by CMS. (There are a very few exclusively technical procedures for which payment is also based on the physician fee schedule relative value file.)

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