

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the Amer-

ican Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship*. Transfer of title and property to another party.

(3) *Corporation*. The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41098, June 23, 2016; 83 FR 60074, Nov. 23, 2018; 84 FR 61490, Nov. 12, 2019; 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023]

§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2024.

(2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

(3) For new ADLTs—

(i) Initially, no later than the last day of the second quarter of the new ADLT initial period; and

(ii) Thereafter, every year.

(b) Applicable information must be reported in the form and manner specified by CMS.

(c) A laboratory seeking new ADLT status for its test must, in its new ADLT application, attest to the actual list charge.

(d) To certify data integrity, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters described in this section.

(e) If the Secretary determines that a reporting entity has failed to report applicable information for its applicable laboratories, or made a misrepresentation or omission in reporting applicable information for its applicable laboratories, the Secretary may apply a civil monetary penalty to a reporting entity in an amount of up to \$10,000 per day, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114-74, November 2, 2015), for each failure to report or each such misrepresentation or omission. The provisions for civil monetary penalties that apply in general to the Medicare program under 42 U.S.C. 1320a-7b apply in the same manner to the laboratory data reporting process under this section.

(f) CMS or its contractors will not disclose applicable information reported to CMS under this section in a manner that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except to permit the Comptroller General, the Director of the Congressional Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement this subpart,

such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities.

(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLTs, the applicable information of its CDLTs that are not ADLTs may not be reported.

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022; 88 FR 79531, Nov. 16, 2023]

§414.506 Procedures for public consultation for payment for a new clinical diagnostic laboratory test.

For a new CDLT, CMS determines the basis for and amount of payment after performance of the following:

(a) CMS makes available to the public (through CMS's Internet Web site) a list that includes codes for which establishment of a payment amount is being considered for the next calendar year.

(b) CMS publishes a FEDERAL REGISTER notice of a meeting to receive public comments and recommendations (and data on which recommendations are based) on the appropriate basis, as specified in §414.508, for establishing payment amounts for the list of codes made available to the public.

(c) Not fewer than 30 days after publication of the notice in the FEDERAL REGISTER, CMS convenes a meeting that includes representatives of CMS officials involved in determining payment amounts, to receive public comments and recommendations (and data on which the recommendations are based).

(d) Considering the comments and recommendations (and accompanying data) received at the public meeting, CMS develops and makes available to the public (through an Internet Web site and other appropriate mechanisms) a list of—

(1) Proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, with an explanation of the reasons for each determination, the data on which the determinations are based,