

## § 414.426

(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations.* (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination.* The CBIC must mail the Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

## § 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes

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is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

## Subpart G—Payment for Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

### § 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

### § 414.502 Definitions.

For purposes of this subpart—

*Actual list charge* means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

*Advanced diagnostic laboratory test (ADLT)* means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of

that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

*Applicable information*, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

*Applicable laboratory* means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least \$12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this \$12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

*Blood bank or center* means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

*Data collection period* is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2024 through March 31, 2024, the data collection period is January 1, 2019 through June 30, 2019.

*Data reporting period* is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2024 through March 31, 2024.

*National Provider Identifier* (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

*New advanced diagnostic laboratory test* (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

*New ADLT initial period* means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

*New clinical diagnostic laboratory test* (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

*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,

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including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and § 414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in § 414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under § 414.508 and provide recommendations to CMS under this subpart.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41099, June 23, 2016]

#### § 414.507 Payment for clinical diagnostic laboratory tests.

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§ 414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology.* For each test under paragraph (a) of this section for which

applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions.* For years 2018 through 2026, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—0.0 percent of the payment rate established in 2020.

(5) 2022—0.0 percent of the payment rate established in 2021.

(6) 2023—0.0 percent of the payment rate established in 2022.

(7) 2024—15 percent of the payment rate established in 2023.

(8) 2025—15 percent of the payment rate established in 2024.

(9) 2026—15 percent of the payment rate established in 2025.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2).

(g) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in § 414.508(a).

[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]

#### § 414.508 Payment for a new clinical diagnostic laboratory test.

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment

amount based on either of the following:

(1) *Crosswalking*. Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling*. Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in §414.507(b):

(1) *Crosswalking*. Crosswalking is used if it is determined that a new CDLT is

comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under §414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under §414.507.

(2) *Gapfilling*. Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

[81 FR 41100, June 23, 2016]

**§414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.**

For a new CDLT, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment*. (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under §414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this

section may also present its reconsideration request at the public meeting convened under § 414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (a)(1) of this section.

(ii) If the requestor presents its reconsideration request at the public meeting convened under § 414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(3) Considering reconsideration requests and other comments received, CMS may reconsider its determination of the basis for payment. As the result of such a reconsideration, CMS may change the basis for payment from crosswalking to gapfilling or from gapfilling to crosswalking.

(4) If the basis for payment is revised as the result of a reconsideration, the new basis for payment is final and is not subject to further reconsideration.

(b) *Reconsideration of amount of payment*—(1) *Crosswalking*. (i) For 60 days after making a determination under § 414.506(d)(2) of the code or codes to which a new test will be crosswalked, CMS receives reconsideration requests in written format regarding whether CMS should reconsider its determination and the recommended code or codes to which to crosswalk the new test.

(ii)(A) A requestor that submitted a request under paragraph (b)(1)(i) of this section may also present its reconsideration request at the public meeting convened under § 414.506(c), provided that the requestor requests an opportunity to present at the public meeting as part of its written submission under paragraph (b)(1)(i) of this section.

(B) If a requestor presents its reconsideration request at the public meeting convened under § 414.506(c), members of the public may comment on the reconsideration request verbally at the public meeting and may submit written comments after the public meeting (within the timeframe for public comments established by CMS).

(iii) Considering comments received, CMS may reconsider its determination

of the amount of payment. As the result of such a reconsideration, CMS may change the code or codes to which the new test is crosswalked.

(iv) If CMS changes the basis for payment from gapfilling to crosswalking as a result of a reconsideration, the crosswalked amount of payment is not subject to reconsideration.

(2) *Gapfilling*. (i) By April 30 of the year after CMS makes a determination under § 414.506(d)(2) or paragraph (a)(3) of this section that the basis for payment for a CDLT will be gapfilling, CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site.

(ii) For 60 days after CMS posts interim Medicare Administrative Contractor-specific amounts on the CMS Web site, CMS will receive public comments in written format regarding the interim Medicare Administrative Contractor-specific amounts.

(iii) After considering the public comments, CMS will post final Medicare Administrative Contractor-specific amounts on the CMS Web site.

(iv) For 30 days after CMS posts final Medicare Administrative Contractor-specific payment amounts on the CMS Web site, CMS will receive reconsideration requests in written format regarding whether CMS should reconsider the final Medicare Administrative Contractor-specific payment amount and median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(v) Considering reconsideration requests received, CMS may reconsider its determination of the amount of payment. As the result of a reconsideration, CMS may revise the median of the Medicare Administrative Contractor-specific payment amount for the CDLT.

(3) For both gapfilled and crosswalked new tests, if CMS revises the amount of payment as the result of a reconsideration, the new amount of payment is final and is not subject to further reconsideration.

(c) *Effective date*. If CMS changes a determination as the result of a reconsideration, the new determination regarding the basis for or amount of payment is effective January 1 of the year following reconsideration. Claims for

services with dates of service prior to the effective date will not be reopened or otherwise reprocessed.

(d) *Jurisdiction for reconsideration decisions.* Jurisdiction for reconsidering a determination rests exclusively with the Secretary. A decision whether to reconsider a determination is committed to the discretion of the Secretary. A decision not to reconsider an initial determination is not subject to administrative or judicial review.

[72 FR 66401, Nov. 27, 2007, as amended at 73 FR 2432, Jan. 15, 2008; 81 FR 41100, June 23, 2016]

**§414.510 Laboratory date of service for clinical laboratory and pathology specimens.**

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of

service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, “chemotherapy sensitivity test” means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in §414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, the date of service of the test must be the date the test was performed only if—

(i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

(ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in §410.2 of this chapter);

(iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and



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(v) The test was reasonable and medically necessary for the treatment of an illness.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007; 82 FR 52636, Nov. 13, 2017; 82 FR 59496, Dec. 14, 2017; 84 FR 61490, Nov. 12, 2019; 85 FR 86301, Dec. 29, 2020]

### § 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking method as described in § 414.508(b)(1) and (2).

[81 FR 41100, June 23, 2016]

### § 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) *Specimen collection fee and travel allowance.* In addition to the payment amounts provided under this subpart for CDLTs, new CDLTs, and new ADLTs, CMS pays a specimen collection fee, as set forth in paragraph (a)(1) of this section, and a travel allowance, as set forth in paragraph (a)(2) of this section.

(1) *Payment for specimen collection.* Except as provided in paragraph (a)(1)(v) of this section and subject to the an-

nual update in paragraph (a)(1)(iv) of this section, beginning January 1, 2023, CMS pays \$8.57 for all specimens collected in one patient encounter, where the specimen(s) is:

(i) Used to perform a CDLT paid under this subpart G;

(ii) Collected by a trained technician from a Medicare beneficiary who is—

(A) Homebound as described in 42 CFR 424.22(a)(1)(ii).

(B) A non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen;

(iii) Of the following type—

(A) Blood specimen collected through venipuncture.

(B) A urine sample collected by catheterization.

(iv) Beginning January 1, 2024, CMS updates the specimen collection fee amount under paragraph (a)(1) of this section for each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year.

(v) For a specimen collected from a Medicare beneficiary.

(2) *Payment for travel allowance—(i) General requirement.* CMS pays a travel allowance, as calculated under paragraph (a)(2)(iii) of this section, where the specimen is one for which a specimen collection fee is paid under paragraph (a)(1) of this section.

(ii) *Travel allowance basis.* CMS pays a travel allowance on the following bases:

(A) *Flat-rate travel allowance.* The flat-rate travel allowance applies when the trained technician travels 20 eligible miles or less (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(B) *Per-mile travel allowance.* The per-mile travel allowance applies when:

(1) The trained technician travels more than 20 eligible miles (calculated in accordance with paragraph (a)(2)(iii)(A) of this section) to and from one location for specimen collection from one or more Medicare beneficiaries; or

(2) The trained technician travels to more than one location for specimen collection from more than one Medicare beneficiary.

(iii) *Travel allowance amount*—(A) *Eligible miles*. Eligible miles begin at the laboratory or the starting point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section, and end at the laboratory or the ending point of the technician's travel for specimen collection as specified in paragraph (a)(1) of this section. Eligible miles do not include miles traveled for any purpose unrelated to specimen collection as specified in paragraph (a)(1) of this section, such as collecting specimens from non-Medicare beneficiaries or for personal reasons.

(B) *Travel allowance mileage rate*. The travel allowance mileage rate is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician equal to the most recent median hourly wage for phlebotomists, as published by the United States Bureau of Labor Statistics, divided by 40 to represent an average miles-per-hour driving speed.

(C) *Travel allowance amount calculation*. (1) For the flat-rate travel allowance basis specified in paragraph (a)(2)(ii)(A) of this section, the travel allowance amount is the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section multiplied by ten, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(2) For the per-mile travel allowance basis specified in paragraph (a)(2)(ii)(B) of this section, the travel allowance amount is the number of eligible miles multiplied by the travel allowance mileage rate specified in paragraph (a)(2)(iii)(B) of this section, divided by the number of beneficiaries for whom a specimen collection fee is paid under paragraph (a)(1) of this section.

(b) [Reserved]

[87 FR 70225, Nov. 18, 2022]

## Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

### § 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule. Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

[67 FR 9132, Feb. 27, 2002, as amended at 84 FR 63193, Nov. 15, 2019]

### § 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as “ground”) ambulance services and to air ambulance services unless otherwise specified:

*Advanced life support (ALS) assessment* is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

*Advanced life support (ALS) intervention* means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

*Advanced life support, level 1 (ALS1)* means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.