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 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