

§ 414.508

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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, and a request for public written 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.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

§ 414.508 Payment for a new clinical diagnostic laboratory test.

For a new clinical diagnostic laboratory test that is assigned a new or substantially revised code on or after January 1, 2005, CMS determines the payment amount based on either of the following:

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

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

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

(b) *Gapfilling*. Gapfilling is used when no comparable existing test is available.

(1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:

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

(ii) Resources required to perform the test;

(iii) Payment amounts determined by other payers; and

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

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

(3) For a new test 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 carrier-specific amounts will pay for the test appropriately. If CMS determines that the carrier-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007]

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

For a new test for which a new or substantially revised HCPCS code was assigned on or after January 1, 2008, 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.