the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1))


§ 405.512 Carriers' procedural terminology and coding systems.

(a) General. Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) Modification of terminology and/or coding systems. A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Centers for Medicare & Medicaid Services with all pertinent data and information for approval before the revision is implemented. The Centers for Medicare & Medicaid Services will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Centers for Medicare & Medicaid Services will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) Guidelines. The following considerations and guidelines are taken into account in evaluating a carrier’s proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier’s area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier’s or Professional Standards Review Organizations’ review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier’s processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians’ services for services which are identified by a single element of terminology but which may vary in content.


§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician’s bill, or a request for payment for a physician’s services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as
§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) Applicability—(1) Payment for drugs and biologicals before January 1, 2004. Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician’s service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in §413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(2) Payment for drugs and biologicals on or after January 1, 2004. Effective January 1, 2004, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with Part 414, subpart I of this chapter.

(3) Payment for drugs and biologicals on or after January 1, 2005. Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with Part 414, subpart K of this chapter.

(b) Methodology. Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) Multiple-source drugs. For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of...