§ 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 follows (subject to the coinsurance and deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician’s reasonable charge for the test (as determined in accordance with §405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

1. The laboratory’s reasonable charge for the service (as determined in accordance with §405.502), or
2. The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician’s locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier’s area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier’s service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with §405.511, in the carrier’s service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this

section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.


§ 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 brand name forms of the drug or biological.


§ 405.520 Payment for a physician assistant’s, nurse practitioner’s, and clinical nurse specialists’ services and services furnished incident to their professional services.

(a) General rule. A physician assistant’s, nurse practitioner’s, and clinical nurse specialists’ services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistant’s services may not exceed the limits at §414.52 of this chapter. The payment for a nurse practitioners’ and clinical nurse specialists’ services may not exceed the limits at §414.56 of this chapter.

(b) Requirements. Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with §424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants’ services, nurse practitioners’ services and clinical nurse specialists’ services, and services and supplies furnished incident to their professional services.

(c) Civil money penalties. Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.


§ 405.534 Limitation on payment for screening mammography services.

The provisions in paragraphs (a), (b), and (c) of this section apply for services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are paid under the physician fee schedule in accordance with §414.2 of this chapter.

(a) Basis and scope. This section implements section 1834(c) of the Act by establishing a limit on payment for