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properly cancel opt-out is an initial determination for purposes of § 498.3(b) of this chapter.

(b) A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.924.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014; 80 FR 71371, Nov. 16, 2015]

§ 405.455 Application to Medicare Advantage contracts.

An organization that has a contract with CMS to provide one or more Medicare Advantage (M + C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014]

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services

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on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health services covered by the Medicare program. Section 1861(v) sets forth the general authority under which CMS may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term “covered osteoporosis drug.” Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the “reasonable charge” for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of “reasonable cost” (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, FQHCs that are authorized to bill under a reasonable cost system, and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995; 79 FR 25473, May 2, 2014]

§ 405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians’ services, the prevailing charges adjusted to reflect economic changes as provided under § 405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians’ services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in § 405.580 in teaching and non-

teaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which CMS has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under § 415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Centers for Medicare & Medicaid Services, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Centers for Medicare & Medicaid Services. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program—(1) General.* Reason-

able charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings—(1) General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, auscultation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits—*

(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The

charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by non-specialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of payment amounts in special circumstances—*(1) *General.* (i) For purposes of this paragraph (g), a "category of items or services" may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physicians' services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital services or home health services) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS-initiated adjustments, CMS will publish in the FEDERAL REGISTER an analysis of payment adjustments that exceed \$100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing

the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier considers in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup.* Price markup is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the price markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Use.* CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities.* CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits*—(i) *National limits.* CMS publishes in the FEDERAL REGISTER proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii) *Carrier-level limits.* (A) A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section and must solicit comments. The notice must also consider the following:

(1) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(2) What entities would be affected, such as classes of providers or suppliers and beneficiaries.

(3) How significantly would these entities be affected.

(4) How would the adjustment affect beneficiary access to items or services.

(B) Before publication of a final notice, the carrier must—

(1) Evaluate the comments it receives on the proposed notice.

(2) Notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification.

(3) After receipt of CMS' acknowledgement, inform the affected suppliers and State Medicaid agencies of any final limits it establishes.

(C) The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data.* In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, valid and reliable data are used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) *Review of market prices.* If CMS or a carrier makes a payment adjustment of more than 15 percent under this paragraph (g), CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(5) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a

category of items or services within a year:

(1) *Potential impact of special limit.* CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the FEDERAL REGISTER the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Paramedic intercept ambulance services.* (1) CMS establishes its payment allowance on a carrier-wide basis by using the median allowance from all localities within an individual carrier's jurisdiction.

(2) CMS's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) CMS bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term “customary charges” will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a “customary charge” for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's “customary” charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to

individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by CMS; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to CMS, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity) was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent $((.40 \times 112) + (.60 \times 110) = 110.8)$ above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee

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screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least \$1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than \$1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to CMS, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a

relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992—*(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights ^{1 2} (percent)	Price proxy ³
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm. ⁴
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm. ⁴

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES—Continued

Expense category	1989 weights ^{1 2} (percent)	Price proxy ³
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees. ⁴
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar. ⁴
b. Office Expense	10.3	CPI-U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI-U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	CMS survey of change in average liability premiums for \$100,000/\$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI-U, private transportation.
(2) Other	5.5	CPI-U, all items less food and energy.

¹ Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990*. Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, "Practice Expenses Take the Leap of the Decade," *Medical Economics*, November 12, 1990; and CMS, OACT special study.

² Due to rounding, weights may not sum to 100.0%.

³ All price proxies are for annual percent changes for the 12 months ending June 30th.

⁴ Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, CMS publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

"Locality" is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis con-

stituting medical services areas (inter-state or otherwise), comparable in concept to "trade areas." Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The

mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(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)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from \$80 to \$100 in a certain locality.

Doctor A's bill is for \$75 although he customarily charges \$80 for the procedure.

Doctor B's bill is his customary charge of \$85

Doctor C's bill is his customary charge of \$125

Doctor D's bill is for \$100, although he customarily charges \$80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to \$75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be \$85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than \$100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be \$80, because that is his customary charge. Even though his actual charge of \$100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* "Comparable circumstances," as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Centers for Medicare & Medicaid Services. When the pertinent information has been reported, the Centers for Medicare & Medicaid Services will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of CMS generally does not vary significantly in quality from one supplier to another (and that is

identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from CMS as follows:

(1) *For items or services furnished on or before December 31, 1986.* (i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.* (i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating 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)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§ 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.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 10298, Mar. 4, 1994]

§ 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.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 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 the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 69 FR 66420, Nov. 15, 2004]

§ 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 assistants' 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.

[63 FR 58905, Nov. 2, 1998, as amended at 66 FR 49547, Sept. 28, 2001]

§ 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 screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth

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in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is \$59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bi-

lateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994; 66 FR 55328, Nov. 1, 2001]

§ 405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

The provisions in this section apply for screening mammography services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are physician services pursuant to § 414.2 of this chapter paid under the physician fee schedule. If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997; 66 FR 55328, Nov. 1, 2001]

Subparts F– G [Reserved]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1866(j), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395cc(j), and 1395hh).

SOURCE: 77 FR 29028, May 16, 2012, unless otherwise noted.