#### EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by sections 154(c) and 341(c) of Pub. L. 98–21 effective Apr. 20, 1983, see sections 154(e) and 341(d) of Pub. L. 98–21, set out as notes under section 401 of this title.

#### EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility's or provider's first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as a note under section 426 of this title.

#### EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 132(e) of Pub. L. 92–603 applicable with respect to gifts and bequests received after Oct. 30, 1972, see section 132(f) of Pub. L. 92–603, set out as a note under section 401 of this title.

Amendment by section 263(d)(4), (e) of Pub. L. 92–603 with respect to collection of premiums applicable to premiums becoming due and payable after the fourth month following the month of enactment of Pub. L. 92–603 which was approved on Oct. 30, 1972, see section 263(f) of Pub. L. 92–603, set out as a note under section 1395s of this title.

### DISPOSAL OF FUNDS IN FEDERAL HOSPITAL INSURANCE CATASTROPHIC COVERAGE RESERVE FUND

Pub. L. 101–234, title I, §102(c), Dec. 13, 1989, 103 Stat. 1981, provided that: "Any balance in the Federal Hospital Insurance Catastrophic Coverage Reserve Fund (created under section 1817A(a) of the Social Security Act [former 42 U.S.C. 1395i–1a(a)], as inserted by section 112(a) of MCCA [Pub. L. 100–360]) as of January 1, 1990, shall be transferred into the Federal Supplementary Medical Insurance Trust Fund and any amounts payable due to overpayments into such Trust Fund shall be payable from the Federal Supplementary Medical Insurance Trust Fund."

### Due Date for 1983 Report on Operation and Status of Trust Fund

Notwithstanding subsec. (b)(2) of this section, the annual report of the Board of Trustees of the Trust Fund required for calendar year 1983 under this section may be filed at any time not later than forty-five days after Apr. 20, 1983, see section 154(d) of Pub. L. 98–21, set out as a note under section 401 of this title.

## §§ 1395t-1, 1395t-2. Repealed. Pub. L. 101-234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 1981

Section 1395t–1, act Aug. 14, 1935, ch. 531, title XVIII,  $\S$ 1841A, as added July 1, 1988, Pub. L. 100–360, title II,  $\S$ 212(a), 102 Stat. 739; amended Oct. 13, 1988, Pub. L. 100–485, title VI,  $\S$ 608(d)(10)(A), 102 Stat. 2415, provided for the creation of the Federal Catastrophic Drug Insurance Trust Fund.

Section 1395t-2, act Aug. 14, 1935, ch. 531, title XVIII, §1841B, as added July 1, 1988, Pub. L. 100-360, title II, §213, formerly §213(a), 102 Stat. 741, as redesignated Oct. 13, 1988, Pub. L. 100-485, title VI, §608(d)(11), 102 Stat. 2415, provided for the creation of the Medicare Catastrophic Coverage Account.

#### Statutory Notes and Related Subsidiaries

#### EFFECTIVE DATE OF REPEAL

Repeal effective Jan. 1, 1990, see section 202(b) of Pub. L. 101-234, set out as an Effective Date of 1989 Amendment note under section 401 of this title.

### \$ 1395u. Provisions relating to the administration of part B

#### (a) In general

The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk-1 of this title.

#### (b) Determination of reasonable charges

- (1) Repealed. Pub. L. 108-173, title IX, §911(c)(3)(A), Dec. 8, 2003, 117 Stat. 2384.
- (2)(A), (B) Repealed. Pub. L. 108-173, title IX, §911(c)(3)(B)(i), Dec. 8, 2003, 117 Stat. 2384.
- (C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1395x(s)(2)(K) of this title performed by a member of a team, the Secretary shall instruct medicare administrative contractors to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.
  - (3) The Secretary—
  - (A) shall take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1395x(v) of this title);
  - (B) shall take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1395gg(f) of this title) be made—
    - (i) on the basis of an itemized bill; or
  - (ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this subchapter is denied under section 1320c-3(a)(2) of this title by reason of a determination under section 1320c-3(a)(1)(B) of this title, and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1395y(a) of this title, and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this

subchapter (except in the case of physicians' services and ambulance service furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title);

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the period ending 1 calendar year after the date of service.

(C) to (E) Repealed. Pub. L. 108-173, title IX, §911(c)(3)(C)(iv), Dec. 8, 2003, 117 Stat. 2384;

(F) shall take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) shall, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1395w-4(g) of this title—

(i) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1395w-4(g)(2) of this title;

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

#### (H) shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians; <sup>1</sup>

(I) Repealed. Pub. L. 108-173, title IX, §911(c)(3)(C)(vi), Dec. 8, 2003, 117 Stat. 2384;

(J), (K) Repealed. Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981;

(L) shall monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality.

In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by yearto-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1395x(s)(6) of this title, charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, medicare administrative contractor, or agent of the Department of Health and Human Services performing functions under this subchapter and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pur-

<sup>&</sup>lt;sup>1</sup>So in original. Probably should be followed by "and".

suant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1395x(v)(1)(K) of this title, and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility. In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii)(I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a nonparticipating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge

level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4)) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3)) for each year shall be the same for nonparticipating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services—

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4)) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section

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for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1)) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1)) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a nonparticipating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (i)(1)(C).

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is—

(I) 3.6 percent for primary care services (as defined in subsection (i)(4)), and

(II) 1 percent for other physicians' services.

- (iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is—
  - (I) 3.0 percent for primary care services, and (II) 1 percent for other physicians' services.
- (iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is—
  - (I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)).

- (v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is—
  - (I) 0 percent for services (other than primary care services), and
  - (II) 2 percent for primary care services (as defined in subsection (i)(4)).
- (5) Repealed. Pub. L. 108–173, title IX,  $\S 911(c)(3)(D)$ , Dec. 8, 2003, 117 Stat. 2384.

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1395gg of this title) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part. (C) in the case of services described in clause (i) of section 1395x(s)(2)(K) of this title, for such services furnished before January 1, 2022, payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1395x(aa)(2) of this title) for a continuous period beginning prior to August 5, 1997, and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1395x(aa)(2) of this title, payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident

to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services: (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the medicare administrative contractor for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1395yy(e)(2)(A)(ii) of this title) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), (G) in the case of services in a hospital or clinic to which section 1395qq(e) of this title applies, payment shall be made to such hospital or clinic, (H) in the case of services described in section 1395x(aa)(3) of this title that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this subchapter is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed, (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier or, in the case of items and services described in clause (i) of section 1395m(u)(7)(A) of this title furnished to an individual during the period described in clause (ii) of such section, payment shall be made to the eligible home infusion therapy supplier, and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 254e(a)(1)(A) of this title), a medically underserved area (as designated pursuant to section 254b(b)(3)(A) of this title), or a rural area (as defined in section 1395ww(d)(2)(D) of this title), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians' services furnished by physicians.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, the Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) unless—

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this

subchapter, and

(III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), the Secretary shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

- (ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, the Secretary shall base payment under this subchapter on the greatest of—
  - (I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),

(II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such

patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

- (iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.
- (C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, the Secretary shall provide for payment for such services under this part on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).
- (D)(i) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the
  - (I) are required due to exceptional medical circumstances,
  - (II) are performed by team physicians needed to perform complex medical procedures, or
  - (III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

- (ii) For purposes of this subparagraph, the term "assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.
- (iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(8)(A)(i) The Secretary shall by regulation—

- (I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this subchapter to payment under this part (other than to physicians' services paid under section 1395w-4 of this title) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and
- (II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.
- (ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).
- (B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if—
  - (i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,
  - (ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and
  - (iii) the Secretary complies with the procedural requirements of paragraph (9).
- (C) The factors described in this subparagraph are as follows:
  - (i) The programs established under this subchapter and subchapter XIX are the sole or primary sources of payment for an item or service.
  - (ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.
  - (iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.
- (D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.
- (9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.
- (B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register—
- (i) specifying the payment amount proposed to be established with respect to an item or service.

- (ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and
- (iii) explaining the potential impacts described in paragraph (8)(D).
- (C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.
- (D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.
- (ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.
- (10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987—
  - (I) subject to clause (iii), reduced by 2.0 percent, and
  - (II) further reduced by the applicable percentage specified in clause (ii).
- (ii) For purposes of clause (i), the applicable percentage specified in this clause is—
- (I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;
- (II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and
- (III) in the case of any other prevailing charge, a percent determined on the basis of a straight-line sliding scale, equal to 3/13 of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.
- (iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).
- (B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.
- (C) In the case of a reduction in the reasonable charge for a physicians' service under subpara-

- graph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).
- (D) There shall be no administrative or judicial review under section 1395ff of this title or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).
- (11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall—
  - (i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1395x(r) of this title), and
  - (ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.
- (B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.
- (ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.
- (C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.
- (ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).
- (D) In the case of a reduction in the reasonable charge for a physicians' service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (i)(1)(D).
- under subsection (j)(1)(D).

  (12) Repealed. Pub. L. 105–33, title IV, § 4512(b)(2), Aug. 5, 1997, 111 Stat. 444.
- (13)(A) In determining payments under section 1395l(l) of this title and section 1395w-4 of this title for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of August 10, 1993.

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(A)(i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, ½ of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

- (ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.
  - (B) For purposes of this paragraph:
  - (i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of—
    - (I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and
    - (II) the adjustment factor (specified under clause (iii)) for the locality.
  - (ii) The "reduced national weighted average prevailing charge" for a physicians' service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.
  - (iii) The "adjustment factor", for a physicians' service for a locality, is the sum of—
  - (I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101–M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and
  - (II) 1 minus the practice expense component (percent), divided by 100.
  - (C) For purposes of this paragraph:
  - (i) The physicians' services specified in this clause are the procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specifica-

tion is of physicians' services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part.

(ii) The "national weighted average prevailing charge" specified in this clause, for a physicians' service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

the Secretary using the best data available.

(iii) The "percentage change" specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians' services which the Secretary shall designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(16)(A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4), hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

- (iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; femoral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.
- (17) With respect to payment under this part for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable x-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

- (B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) shall apply in this subparagraph in the same manner as such paragraph applies to such section.
- (C) A practitioner described in this subparagraph is any of the following:
  - (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1395x(aa)(5) of this title).
  - (ii) A certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title).
  - (iii) A certified nurse-midwife (as defined in section 1395x(gg)(2) of this title).
  - (iv) A clinical social worker (as defined in section 1395x(hh)(1) of this title).
  - (v) A clinical psychologist (as defined by the Secretary for purposes of section 1395x(ii) of this title).
  - (vi) A registered dietitian or nutrition professional.
- (D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1395l(a)(1) of this title, the reasonable charge for ambulance serv-

ices (as described in section 1395x(s)(7) of this title) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.

#### (c) Prompt payment of claims

(1) Repealed. Pub. L. 108–173, title IX, §911(c)(4)(A), Dec. 8, 2003, 117 Stat. 2384.

(2)(A) Each contract under section 1395kk-1 of this title that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

- (i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.
- (ii) The term "applicable number of calendar days" means—
  - (I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,
- (II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),
- (III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians).
- (IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and
- (V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.
- (C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31 (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

- (3)(A) Each contract under this section which provides for the disbursement of funds, as described in section 1395kk-1(a)(3)(B) of this title, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this subchapter within the applicable number of calendar days after the date on which the claim is received.
- (B) In this paragraph, the term "applicable number of calendar days" means—
  - (i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and
  - (ii) with respect to claims submitted otherwise, 28 days.
- (4) Neither a medicare administrative contractor nor the Secretary may impose a fee under this subchapter—
  - (A) for the filing of claims related to physicians' services.
  - (B) for an error in filing a claim relating to physicians' services or for such a claim which is denied,
  - (C) for any appeal under this subchapter with respect to physicians' services,
  - (D) for applying for (or obtaining) a unique identifier under subsection (r), or
  - (E) for responding to inquiries respecting physicians' services or for providing information with respect to medical review of such services.
- (d) to (f). Repealed. Pub. L. 108-173, title IX, § 911(c)(5), Dec. 8, 2003, 117 Stat. 2384

#### (g) Authority of Railroad Retirement Board to enter into contracts with medicare administrative contractors

The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a medicare administrative contractor or contractors to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 426(a) of this title and section 231f(d) of title 45.

# (h) Participating physician or supplier; agreement with Secretary; publication of directories; availability; inclusion of program in explanation of benefits; payment of claims on assignment-related basis

(1) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term "participating physician or supplier" means a physician or supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such

an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) The Secretary shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). The Secretary shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which 2 medicare administrative contractor having a contract under section 1395kk-1 of this title that provides for making payments under this part is able to develop a system for the electronic transmission to such contractor of bills for services, such contractor shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1395ss(g)(1) of this title) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by a medicare administrative contractor with a contract under this section, the contractor shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by a medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories

<sup>&</sup>lt;sup>2</sup>So in original. Probably should be followed by "a".

available in each district and branch office of the Social Security Administration, in the offices of medicare administrative contractors, and to senior citizen organizations.

- (B) The annual notice provided under subparagraph (A) shall include—
  - (i) a description of the participation program,
  - (ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,
  - (iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and
  - (iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.
- (6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.
- (7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1395l(a)(1) of this title (made other than on an assignment-related basis), shall include—
- (A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),
- (B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,
- (C)(i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and
- (D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1395w-4(g) of this title, information regarding such applicable limiting charge (including information concerning the right to a refund under section 1395w-4(g)(1)(A)(iv) of this title).
- (8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.
- (9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section

1395cc(j) of this title if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this subchapter, as specified by the Secretary.

#### (i) Definitions

For purposes of this subchapter:

- (1) A claim is considered to be paid on an "assignment-related basis" if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii), in accordance with subsection (b)(6)(B), or under the procedure described in section 1395gg(f)(1) of this title.
- (2) The term "participating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (h)(1)); the term "non-participating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term "nonparticipating supplier or other person" means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1)).
- (3) The term "percentage increase in the MEI" means, with respect to physicians' services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)) applicable to such services furnished as of the first day of that year.
- (4) The term "primary care services" means physicians' services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

### (j) Monitoring of charges of nonparticipating physicians; sanctions; restitution

- (1)(A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician's actual charges to individuals enrolled under this part for physicians' services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician's actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).
- (B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of each such physician for physicians' services furnished to individuals enrolled under this part. If such physician knowingly and willfully bills on a repeated basis for

such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians' service furnished by a nonparticipating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician's maximum allowable actual charge for that service in the previous year was—

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician's maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians' service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is—

(I) for 1987, ½,

(II) for 1988, ½,

(III) for 1989, ½, and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) ½ of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply

(I) an adjustment under subsection (b)(8)(B) (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) (relating to certain overprised procedures).

(III) a reduction under subsection (b)(11)(B) (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A),

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii) of this section, and

(VI) an adjustment under section 1395l(l)(3)(B) of this title (relating to physician

supervision of certified registered nurse anesthetists).

- (iii) In clause (i), the term "reduced payment allowance" means, with respect to an action—
- (I) under subsection (b)(8)(B), the inherently reasonable charge established under subsection (b)(8);
- (II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) or under section 1395l(l)(3)(B) of this title, the prevailing charge for the service after the action; or
- (III) under subsection (b)(11)(C)(ii), the payment allowance established under such subsection.
- (iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).
- (v) Clause (i) shall not apply to items and services furnished after December 31, 1990.
- (2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are—
  - (A) excluding a physician from participation in the programs under this chapter for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1320a-7 of this title, or
  - (B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1320a–7a(a) of this title,

or both. The provisions of section 1320a–7a of this title (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1320a–7a(a) of this title, except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

- (3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community
- (B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).
- (4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

### (k) Sanctions for billing for services of assistant at cataract operations

(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason

of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1.1987.

#### (l) Prohibition of unassigned billing of services determined to be medically unnecessary by carrier

- (1)(A) Subject to subparagraph (C), if—
- (i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,
- (ii) payment for such services is not accepted on an assignment-related basis,
- (iii)(I) a medicare administrative contractor determines under this part or a quality improvement organization determines under part B of subchapter XI that payment may not be made by reason of section 1395y(a)(1) of this title because a service otherwise covered under this subchapter is not reasonable and necessary under the standards described in that section or (II) payment under this subchapter for such services is denied under section 1320c-3(a)(2) of this title by reason of a determination under section 1320c-3(a)(1)(B) of this title, and
- (iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

- (B) A refund under subparagraph (A) is considered to be on a timely basis only if—
  - (i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or
  - (ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse determination on reconsideration or appeal.
- (C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(iii)(I) if—
  - (i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1395y(a)(1) of this title, or
- (ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service.
- (2) Each medicare administrative contractor with a contract in effect under this section with

respect to physicians and each quality improvement organization with a contract under part B of subchapter XI shall send any notice of denial of payment for physicians' services based on section 1395y(a)(1) of this title and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

### (m) Disclosure of information of unassigned claims for certain physicians' services

- (1) In the case of a nonparticipating physician who—  $\,$
- (A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician's actual charge is at least \$500, and
- (B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

- (2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.
- (3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).
- (4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

### (n) Elimination of markup for certain purchased

- (1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1395x(s)(3) of this title (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:
  - (A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs

(net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

- (B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.
- (2) A physician may not bill an individual enrolled under this part—
- (A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or
- (B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).
- (3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

#### (o) Reimbursement for drugs and biologicals

- (1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:
  - (A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:
  - (i) A drug or biological furnished before January 1, 2004.
  - (ii) Blood clotting factors furnished during 2004
  - (iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.
  - (iv) A vaccine described in subparagraph (A) or (B) of section 1395x(s)(10) of this title furnished on or after January 1, 2004.
  - (v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.
  - (B) In the case of a drug or biological furnished during 2004 that is not described in—  $\,$
  - (i) clause (ii), (iii), (iv), or (v) of subparagraph (A).
    - (ii) subparagraph (D)(i), or
    - (iii) subparagraph (F),

the amount determined under paragraph (4).

- (C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005 (and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017), the amount provided under section 1395w-3 of this title, section 1395w-3a of this title, section 1395r(b)(13) of this title, as the case may be for the drug or biological.
- (D)(i) Except as provided in clause (ii), in the case of infusion drugs or biologicals furnished

through an item of durable medical equipment covered under section 1395x(n) of this title on or after January 1, 2004, and before January 1, 2017, 95 percent of the average wholesale price in effect on October 1, 2003.

(ii) In the case of such infusion drugs or biologicals furnished in a competitive acquisition area under section 1395w-3 of this title on or after January 1, 2007, and before December 13, 2016.<sup>3</sup>, the amount provided under section 1395w-3 of this title.

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1395w-3a of this title.

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1395x(n) of this title that are furnished—

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and (ii) in 2005 and subsequent years, the amount provided under section 1395w-3a of this title for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).

(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled "Average of GAO and OIG data (percent)" in the table entitled "Table 3.—Medicare Part B Drugs in the Most Recent GAO and OIG Studies" published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled "Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost", provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1395x(s)(2) of this title and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

### (p) Requiring submission of diagnostic informa-

(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection

 $<sup>^3\,\</sup>mathrm{So}$  in original. The period probably should not appear.

(b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in subsection (j)(2)(A).

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1395x(s) of this title ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

### (q) Anesthesia services; counting actual time units

- (1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this subchapter for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.
- (B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:
  - (i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

- (ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.
- (iii) The adjusted prevailing charge conversion factor for a locality is the sum of—
- (I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and
- (II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in subsection (b)(14)(C)(iv) for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

- (iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).
- (2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

### (r) Establishment of physician identification system

The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this subchapter. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

#### (s) Application of fee schedule

- (1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.
- (B) Any fee schedule established under this paragraph for such item or service shall be updated—
  - (i) for years before 2011—
  - (I) subject to subclause (II), by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year; and
  - (II) for items and services described in paragraph (2)(D) for 2009, section 1395m(a)(14)(J) of this title shall apply under this paragraph instead of the percentage increase otherwise applicable; and
  - (ii) for 2011 and subsequent years—

- (I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—
- (II) the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title.

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year, and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

- (2) The items and services described in this paragraph are as follows:
  - (A) Medical supplies.
  - (B) Home dialysis supplies and equipment (as defined in section 1395rr(b)(8) of this title).
  - (C) Repealed. Pub. L. 108-173, title VI, §627(b)(2), Dec. 8, 2003, 117 Stat. 2321.
  - (D) Parenteral and enteral nutrients, equipment, and supplies.
    - (E) Electromyogram devices.
    - (F) Salivation devices.
    - (G) Blood products.
    - (H) Transfusion medicine.
- (3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1395w-3(a) of this title—
- (A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and
- (B) subject to section 1395m(a)(1)(G) of this title, the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1395w–3 of this title, and in the case of such adjustment, paragraphs (8) and (9) of subsection (b) shall not be applied.

#### (t) Facility provider number required on claims

- (1) Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility for which payment may be made under this part shall include the facility's medicare provider number.
- (2) Each request for payment, or bill submitted, for therapy services described in paragraph (1) or (3) of section 1395l(g) of this title, including services described in section 1395l(a)(8)(B) of this title, furnished on or after October 1, 2012, for which payment may be made under this part shall include the national provider identifier of the physician who periodically reviews the plan for such services under section 1395x(p)(2) of this title.

### (u) Reporting of anemia quality indicators for cancer anti-anemia drugs

Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and

manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.

(Aug. 14, 1935, ch. 531, title XVIII, § 1842, as added Pub. L. 89-97, title I, §102(a), July 30, 1965, 79 Stat. 309; amended Pub. L. 90-248, title I, §§ 125(a), 154(d), Jan. 2, 1968, 81 Stat. 845, 863; Pub. L. 92-603, title II, §§ 211(c)(3), 224(a), 227(e)(3), 236(a), 258(a), 262(a), 263(d)(5), 281(d), Oct. 30, 1972, 86 Stat. 1384, 1395, 1407, 1414, 1447–1449, 1455; Pub. L. 93–445, title III, §307, Oct. 16, 1974, 88 Stat. 1358; Pub. L. 94–182, title I, §101(a), Dec. 31, 1975, 89 Stat. 1051; Pub. L. 94-368, §§ 2, 3(a), (b), July 16, 1976, 90 Stat. 997; Pub. L. 95-142, §2(a)(1), Oct. 25, 1977, 91 Stat. 1175; Pub. L. 95–216, title V, §501(b), Dec. 20, 1977, 91 Stat. 1565; Pub. L. 96-499, title IX, §§ 918(a)(1), 946(a), (b), 948(b), Dec. 5, 1980, 94 Stat. 2625, 2642, 2643; Pub. L. 97–35, title XXI, §2142(b), Aug. 13, 1981, 95 Stat. 798; Pub. L. 97-248, title I, §§104(a), 113(a), 128(d)(1), Sept. 3, 1982, 96 Stat. 336, 340, 367; Pub. L. 98-369, div. B, title III,  $\S 2303(e)$ , 2306(a), (b)(1), (c), 2307(a)(1), (2), 2326(c)(2), (d)(2), 2339, 2354(b)(13), (14), title VI, 2663(j)(2)(F)(iv), July 18, 1984, 98 Stat. 1066, 1070, 1071, 1073, 1087, 1088, 1093, 1101, 1170; Pub. L. 98-617, §3(a)(1), (b)(5), (6), Nov. 8, 1984, 98 Stat. 3295, 3296; Pub. L. 99-272, title IX, §§ 9219(b)(1)(A), (2)(A), 9301(b)(1), (2), (c)(2)-(4), (d)(1)-(3), 9304(a), 9306(a), 9307(c), Apr. 7, 1986, 100 Stat. 182–188, 190, 193, 194; Pub. L. 99-509, title IX, §§ 9307(c)(2)(A), 9320(e)(3),9331(a)(1)-(3), 9311(c), (b)(1)-(3), (c)(3)(A), 9332(a)(1), (b)(1), (2), (c)(1), (d)(1),9333(a), (b), 9334(a), 9338(b), (c), 9341(a)(2), Oct. 21, 1986, 100 Stat. 1995, 1998, 2015, 2018–2026, 2028, 2035, 2038; Pub. L. 99-514, title XVIII, §1895(b)(14)(A), (15), (16)(A), Oct. 22, 1986, 100 Stat. 2934; Pub. L. 100-93, §8(c)(2), Aug. 18, 1987, 101 Stat. 692; Pub. L. 100-203, title IV,  $\S 4031(a)(2)$ , 4035(a)(2), 4041(a)(1), (3)(A), 4042(a), (b)(1), (2)(A), (c), 4044(a), 4045(a), (c)(1), (2)(B), (D), 4046(a), 4047(a), 4048(a), (e), 4051(a), 4053(a), formerly 4052(a), 4054(a), formerly 4053(a), 4063(a), 4081(a), 4082(c), 4085(g)(1), (i)(5)-(7), (22)(C), (24)-(27), 4096(a)(1), Dec. 22, 1987, 101 Stat. 1330-76, 1330-78, 1330-83 to 1330-89, 1330-93, 1330-97, 1330-109, 1330-126, 1330-128, 1330-131, 1330-132, 1330-139, as amended Pub. L. 100–360, title IV, §411(f)(1)(A), (2)(C), (D), (F), (3)(A), (4)(B), (7)(B), (11)(A), (14), (g)(2)(C), (i)(2),(4)(C)(vi), (j)(4)(A), July 1, 1988, 102 Stat. 776–779, 781, 783, 788, 789, 791; Pub. L. 100–360, title II,  $\S 201(c), 202(c)(1), (e)(1)-(3)(A), (C), (4)(A), (5), (g),$ 223(b), (c), title IV, §411(a)(3)(A), (C)(i), (f)(1)(B), (2)(A), (B), (E), (3)(B), (4)(A), (C), (5), (6)(B),(F)-(H), (17), (21)(A), (B), (D), (24)(B), Oct. 13, 1988, 102 Stat. 2414, 2418, 2420, 2421; Pub. L. 101-234, title II, §201(a), title III, §301(b)(2), (6), (c)(2), (d)(3), Dec. 13, 1989, 103 Stat. 1981, 1985, 1986; Pub. L. 101-239, title VI, §§ 6003(g)(3)(D)(ix), 19, 1989, 103 Stat. 2153, 2184, 2187, 2188, 2208, 2210, 2212, 2213, 2218, 2234; Pub. L. 101-508, title IV,  $\S 4101(a)$ , (b)(1), 4103, 4105(a)(1), (2), (b)(1), 4106(a)(1), (b)(2), 4108(a), 4110(a), 4118(a)(1), (2), (f)(2)(A)-(C), (i)(1), (j)(2), 4155(c), Nov. 5, 1990, 104 Stat. 1388-54, 1388-58 to 1388-63, 1388-66, 1388-67, 1388-69 to 1388-71, 1388-87; Pub. L. 101-597, title IV, §401(c)(2), Nov. 16, 1990, 104 Stat. 3035; Pub. L.

103-66, title XIII, §§ 13515(a)(2), 13516(a)(2),13517(b), 13568(a), (b), Aug. 10, 1993, 107 Stat. 583-585, 608; Pub. L. 103-432, title I, §§ 123(b)(1), (2)(B), (c), 125(a), (b)(1), 126(a)(1), (c), (e), (g)(9), (h)(2), 135(b)(2), 151(b)(1)(B), (2)(B), Oct. 31, 1994, 108 Stat. 4411-4416, 4423, 4434; Pub. L. 104-191, title II,  $\S\S 202(b)(2)$ , 221(b), Aug. 21, 1996, 110 Stat. 1998, 2011; Pub. L. 105-33, title IV, §§ 4201(c)(1), 4205(d)(3)(B), 4302(b), 4315(a), 4316(a), 4317(a), (b),4432(b)(2), (4), 4512(b)(2), (c), 4531(a)(2), 4556(a), 4603(c)(2)(B)(i), 4611(d), Aug. 5, 1997, 111 Stat. 373, 377, 382, 390, 392, 421, 444, 450, 462, 471, 473; Pub. L. 106-113, div. B, §1000(a)(6) [title II, §223(c), title III, §§ 305(a), 321(k)(4)], Nov. 29, 1999, 113 Stat. 1536, 1501A-353, 1501A-361, 1501A-366; Pub. L. 106-554, §1(a)(6) [title I, §§105(d), 114(a), title II, §222(a), title III, §313(b)(1), (2), title IV, §432(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A-472, 2763A-473, 2763A-487, 2763A-499, 2763A-526; Pub. L. 108-173, title III,  $\S 302(d)(3)$ , 303(b), (e), (g)(1), (i)(1), 305(a), title VI, §627(b)(2), title VII, §736(b)(8), (9), title IX, §§911(c), 952(a), (b), Dec. 8, 2003, 117 Stat. 2233, 2238, 2252-2255, 2321, 2356, 2383, 2427; Pub. L. 109–171, title V, §§5114(a)(2), 5202(a)(2), Feb. 8, 2006, 120 Stat. 45, 47; Pub. L. 109-432, div. B, title I, §110(a), title II, §205(b)(2), title IV,  $\S405(c)(2)(A)(i)$ , Dec. 20, 2006, 120 Stat. 2985, 2989, 2999; Pub. L. 110-54, §1(a), Aug. 3, 2007, 121 Stat. 551; Pub. L. 110-173, title I, §116, Dec. 29, 2007, 121 Stat. 2507; Pub. L. 110-275, title I, §§ 137, 154(a)(2)(B), July 15, 2008, 122 Stat. 2540, 2563; Pub. L. 111-148, title III, §3401(o), title VI, §§ 6404(a)(2)(A), 6406(a), Mar. 23, 2010, 124 Stat. 488, 767, 769; Pub. L. 112–40, title II, §261(a)(3)(C), Oct. 21, 2011, 125 Stat. 423; Pub. L. 112-96, title III, §3005(c), Feb. 22, 2012, 126 Stat. 188; Pub. L. 114-255, div. A, title V, §§ 5004(a), (b)(2), 5012(c)(2), div. C, title XVI, §§ 16006(a), 16008(b)(2), Dec. 13, 2016, 130 Stat. 1190, 1191, 1202, 1328, 1329; Pub. L. 115-123, div. E, title IV, §50401(b)(1), Feb. 9, 2018, 132 Stat. 217; Pub. L. 116-260, div. CC, title IV, § 403, Dec. 27, 2020, 134 Stat. 3002.)

#### **Editorial Notes**

#### References in Text

The Omnibus Budget Reconciliation Act of 1990, referred to in subsec. (b)(14)(A)(ii), is Pub. L. 101-508, Nov. 5, 1990, 104 Stat. 1388. For complete classification of this Act to the Code, see Tables.

Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (0)(5)(B), is section 303 of Pub. L. 108-173, which enacted sections 1395w-3a and 1395w-3b of this title, amended this section and sections 1395l, 1395w-4, 1395x, 1395y, and 1396r-8 of this title, enacted provisions set out as notes under this section and sections 1395w-3a, 1395w-3b, and 1395w-4 of this title, and repealed provisions set out as a note under this section.

2020—Subsec. (b)(6)(C). Pub. L. 116–260 inserted "for such services furnished before January 1, 2022," after "section 1395x(s)(2)(K) of this title,"

2018—Subsec. (b)(6)(I). Pub. L. 115-123 inserted "or, in the case of items and services described in clause (i) of section 1395m(u)(7)(A) of this title furnished to an individual during the period described in clause (ii) of such section, payment shall be made to the eligible home infusion therapy supplier" after "payment shall be made to the qualified home infusion therapy supplier'

2016—Subsec. (b)(6)(I). Pub. L. 114-255, §5012(c)(2), added subpar. (I).

Subsec. (b)(6)(J). Pub. L. 114-255, §16006(a), added subpar. (J).

Subsec. (o)(1)(C). Pub. L. 114–255, §5004(a)(1), inserted "(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)" after "2005"

Subsec. (o)(1)(D)(i). Pub. L. 114–255, \$5004(a)(2), substituted "infusion drugs or biologicals" for "infusion drugs" and "2004, and before January 1, 2017" for "2004" and struck out "for such drug" after "average whole-

Subsec. (o)(1)(D)(ii). Pub. L. 114–255, §5004(a)(2)(A), (b)(2), substituted "infusion drugs or biologicals" for 'infusion drugs" and "2007, and before December 13, 2016." for "2007"

Subsec. (s)(3)(B). Pub. L. 114-255, \$16008(b)(2), substituted "subject to section 1395m(a)(1)(G) of this title, the Secretary" for "the Secretary".

2012—Subsec. (t). Pub. L. 112–96 designated existing provisions as par. (1) and added par. (2).
2011—Subsec. (l)(1)(A)(iii)(I), (2). Pub. L. 112–40 substituted "quality improvement organization" for "peer review organization"

2010—Subsec. (b)(3). Pub. L. 111–148, §6404(a)(2)(A)(ii), at end of concluding provisions, inserted "In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph."

Subsec. (b)(3)(B). Pub. L. 111-148, §6404(a)(2)(A)(i), substituted "period ending 1 calendar year after the date of service" for "close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year)" in concluding provisions.

Subsec. (h)(9). Pub. L. 111–148, §6406(a), added par. (9). Subsec. (s)(1). Pub. L. 111–148, §3401(o), designated existing provisions as subpar. (A), added subpar. (B) and concluding provisions, and struck out former second sentence, which read as follows: "Any fee schedule established under this paragraph for such item or service shall be updated each year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, except that for items and services described in paragraph (2)(D)

"(A) for 2009 section 1395m(a)(14)(J)(i) of this title shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(B) for 2014, if subparagraph (A) is applied to the items and services and there has not been a payment adjustment under paragraph (3)(B) for the items and services for any previous year, the percentage increase computed under section 1395m(a)(14)(L)(i) of this title shall apply instead of the percentage in-

crease otherwise applicable."
2008—Subsec. (b)(6)(D)(iii). Pub. L. 110–275, §137, struck out "(before July 1, 2008)" after "or are provided"

Subsec. (s)(1). Pub. L. 110-275, \$154(a)(2)(B), substituted "except that for items and services described in paragraph (2)(D)—" for "except that in no event shall a fee schedule for an item described in paragraph (2)(D) be updated before 2003." and added subpars. (A) and (B).

2007—Subsec. (b)(6)(D)(iii). Pub. L. 110–173 substituted 'July 1, 2008" for "January 1, 2008".

Pub. L. 110-54 inserted "or are provided (before January 1, 2008) over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces' after "of more than 60 days".

2006—Subsec. (b)(6)(H). Pub. L. 109–432, §§ 205(b)(2),

405(c)(2)(A)(i), amended directory language of Pub. L. 109-171, §5114(a)(2), identically, making technical correction. See below.

Pub. L. 109-171, §5114(a)(2), as amended by Pub. L. 109-432, §§ 205(b)(2), 405(c)(2)(A)(i), added subpar. (H).

Subsec. (c)(3)(B)(ii). Pub. L. 109-171, §5202(a)(2), sub-

stituted "28 days" for "26 days". Subsec. (u). Pub. L. 109–432, §110(a), added subsec. (u). 2003—Pub. L. 108–173,  $\S911(c)(1)$ , substituted "Provisions relating to the administration of part B" for "Use of carriers for administration of benefits" in section

Subsec. (a). Pub. L. 108-173, §911(c)(2), amended subsec. (a) generally. Prior to amendment, subsec. (a) authorized the Secretary to enter into contracts with carriers for the administration of benefits under this part.

Subsec. (b)(1). Pub. L. 108-173, §911(c)(3)(A), struck out par. (1), which provided that contracts with carriers under subsection (a) could be entered into without regard to section 5 of title 41 or any other provision of

law requiring competitive bidding. Subsec. (b)(2)(A), (B). Pub. L. 108-173, §911(c)(3)(B)(i), struck out subpars. (A) and (B), which conditioned entering into contract on Secretary's finding that carrier would perform obligations efficiently and effectively, provided for establishment and publication of standards and criteria for efficient and effective performance, and directed Secretary to establish standards for evaluating carriers' performance of reviews of initial carrier determinations and of fair hearings under former paragraph (3)(C).

Subsec. (b)(2)(C). Pub. L. 108–173, §911(c)(3)(B)(ii), substituted "medicare administrative contractors" for 'carriers'

Subsec. (b)(2)(D), (E). Pub. L. 108-173, §911(c)(3)(B)(iii), struck out subpars. (D) and (E), which directed that carrier be subject to standards and criteria relating to the carrier's success in recovering payments for items or services for which payment has been or could be made under a primary plan and that Secretary could continue administration of claims for certain home health services through fiscal intermediaries under sec-

tion 1395h of this title. Subsec. (b)(3). Pub. L. 108–173,  $\S911(c)(3)(C)(ix)$ , inserted "medicare administrative contractor," after 'carrier," in seventh sentence in concluding provisions.

Pub. L. 108-173, §911(c)(3)(C)(viii), struck out "and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate." before "In determining" in concluding provisions.

Pub. L. 108-173, §911(c)(3)(C)(i), substituted "The Secretary" for "Each such contract shall provide that the carrier" in introductory provisions.

Subsec. (b)(3)(A). Pub. L. 108-173, §911(c)(3)(C)(ii), substituted "shall take such action" for "will take such action"

Subsec. (b)(3)(B). Pub. L. 108–173, §911(c)(3)(C)(iii), substituted "to the policyholders and subscribers of the medicare administrative contractor" for "to the policyholders and subscribers of the carrier" in introductory provisions.

Pub. L. 108–173, §911(c)(3)(C)(ii), substituted "shall take such action" for "will take such action" in introductory provisions.

(b)(3)(C) to (E). Pub. 911(c)(3)(C)(iv), struck out subpars. (C) to (E), which directed that each contract provide that the carrier would establish and maintain procedures for a fair hearing in any case where the amount in controversy was between \$100 and \$500, that the carrier would furnish to the Secretary such information and reports as he would find necessary in performing his functions under this part, and that the carrier would maintain such records and afford such access thereto as the Secretary would find necessary to assure the correctness and verification of the information and reports under former subpar. (D) and otherwise to carry out the pur-

poses of this part.
Subsec. (b)(3)(F). Pub. L. 108–173, §911(c)(3)(C)(ii), substituted "shall take such action" for "will take such action"

Subsec. (b)(3)(G). Pub. L. 108-173, §911(c)(3)(C)(ii), substituted "shall, for a service" for "will, for a service" in introductory provisions.

Subsec. (b)(3)(H). Pub. L. 108-173, §911(c)(3)(C)(v)(I), struck out "if it makes determinations or payments with respect to physicians' services," before "shall im-' in introductory provisions.

Pub. L. 108-173, §911(c)(3)(C)(ii), substituted "shall implement" for "will implement" in introductory provisions.

Subsec. (b)(3)(H)(i). Pub. L. 108-173, 911(c)(3)(C)(v)(II), substituted "medicare administrative contractor" for

Subsec. (b)(3)(I). Pub. L. 108-173, §911(c)(3)(C)(vi), struck out subpar. (I), which directed that each contract would require the carrier to submit annual reports to the Secretary describing steps taken to recover payments made under this part for items or services for which payment had been or could have been made under a primary plan.

Subsec. (b)(3)(L). Pub. L. 108-173, §911(c)(3)(C)(vii), substituted period for semicolon at end.

Pub. L. 108-173, §911(c)(3)(C)(ii), substituted "shall monitor" for "will monitor"

Subsec. (b)(5). Pub. L. 108-173, §911(c)(3)(D), struck out par. (5), which provided that each contract under this section would be for a term of at least one year and could be made automatically renewable and authorized Secretary to terminate any contract where carrier had failed substantially to carry out the contract or was carrying out the contract in a manner inconsistent with the efficient and effective administration of the insurance program established by this part.

Subsec. (b)(6). Pub. L. 108-173, §952(b), substituted "except to an employer or entity as described in subparagraph (A)" for "except to an employer or facility as described in clause (A)" in second sentence.

Subsec. (b)(6)(A)(ii). Pub. L. 108-173, §952(a), added cl. (ii) and struck out former cl. (ii) which read as follows: '(where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service,".

Subsec. (b)(6)(D)(iv). Pub. L. 108–173, §911(c)(3)(E),

substituted "medicare administrative contractor" for

Subsec. (b)(7). Pub. L. 108-173, §911(c)(3)(F), substituted "the Secretary" for "the carrier" in introductory provisions of subpar. (A), before "shall take into account" in subpar. (B)(i), in introductory provisions of subpar. (B)(ii), and before "shall provide" in subpar. (C).

Subsec. (c)(1). Pub. L. 108-173, §911(c)(4)(A), struck out par. (1), which provided that any contract entered into with a carrier under this section would provide for advances of funds for the making of payments and for payment for necessary and proper cost of administration, and directed the Secretary to cause to have published in the Federal Register, by not later than Sept. 1 each year, data, standards, and methodology to be used to establish budgets for carriers and to cause to be published in the Federal Register for public comment, at least 90 days before Sept. 1, the data, standards, and methodology proposed to be used.

Subsec. (c)(2)(A). Pub. L. 108–173, §911(c)(4)(B), substituted "contract under section 1395kk-1 of this title that provides for making payments under this part" for 'contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B) of this section," in introductory provisions. Subsec. (c)(2)(B)(ii)(III). Pub. L. 108–173,  $\S736(b)(8)(A)$ ,

struck out "and" at end.

Subsec. (c)(2)(B)(ii)(IV). Pub. L. 108–173, §736(b)(8)(B), substituted ", and" for period at end.

Subsec. (c)(3)(A). Pub. L. 108–173, §911(c)(4)(C), sub-

stituted "section 1395kk-1(a)(3)(B) of this title" for 'subsection (a)(1)(B) of this section'

Subsec. (c)(4). Pub. L. 108-173, §911(c)(4)(D), substituted "medicare administrative contractor" for 'carrier' in introductory provisions.

Subsec. (c)(5), (6). Pub. L. 108-173, §911(c)(4)(E), struck out pars. (5) and (6), which provided that each contract would require the carrier to meet criteria to measure the timeliness of responses to requests for payment of items described in section 1395m(a)(15)(C) of this title and prohibited any carrier from carrying out any activity pursuant to a contract under the Medicare Integrity Program under section 1395ddd of this title.

Subsec. (d) to (f). Pub. L. 108-173, §911(c)(5), struck out subsecs. (d) to (f), which provided that contracts under this section could require surety bonds and that certifying or disbursing officers or carriers would not be liable with respect to payments in the absence of gross negligence or intent to defraud and defined "carrier" for purposes of this part.

Subsec. (g). Pub. L. 108-173, §911(c)(6), substituted "medicare administrative contractor or contractors" for "carrier or carriers".

Subsec. (h)(2). Pub. L. 108-173, §911(c)(7)(A), substituted "The Secretary" for "Each carrier having an agreement with the Secretary under subsection (a) of this section" in first sentence and for "Each such carrier" in last sentence.

Subsec. (h)(3)(A). Pub. L. 108-173, §911(c)(7)(B)(ii), which directed substitution of "such contractor" for "such carrier", was executed by making the substitution in two places to reflect the probable intent of Congress.

Pub. L. 108-173, §911(c)(7)(B)(i), substituted "medicare administrative contractor having a contract under section 1395kk-1 of this title that provides for making payments under this part" for "a carrier having an agreement with the Secretary under subsection (a) of this section".

Subsec. (h)(3)(B). Pub. L. 108-173, §911(c)(7)(C), substituted "a medicare administrative contractor" for "a carrier" in two places and "the contractor" for "the carrier" in two places.

Subsec. (B)(iii). Pub. L. (h)(5)(A),§911(c)(7)(D), substituted contractors" for "carriers". "medicare administrative

Subsec. (i)(2). Pub. L. 108-173, §736(b)(9), substituted "services, to a physician" for "services, a physician"

Subsec. (l)(1)(A)(iii), (2). Pub. L. 108–173, §911(c)(8), substituted "medicare administrative contractor" for

Subsec. (o)(1). Pub. L. 108–173, §303(b)(1), substituted "equal to the following:" for "equal to 95 percent of the average wholesale price." and added subpars. (A) to (G).

Subsec. (o)(1)(G). Pub. L. 108-173, §305(a), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: "The provisions of subparagraphs (A) through (F) of this paragraph shall not apply to an inhalation drug or biological furnished through durable medical equipment covered under section 1395x(n) of this title.

Subsec. (0)(2). Pub. L. 108-173, §303(i)(1), inserted at end "This paragraph shall not apply in the case of payment under paragraph (1)(C).

Subsec. (0)(4). Pub. L. 108-173, §303(b)(2), added par.

Subsec. (0)(5), (6). Pub. L. 108-173, §303(e), added pars. (5) and (6).

Subsec. (0)(7). Pub. L. 108-173, §303(g)(1), added par.

Subsec. (p)(3)(A). Pub. L. 108-173, §911(c)(9), substituted "medicare administrative contractor" for "carrier"

Subsec. (q)(1)(A). Pub. L. 108-173, §911(c)(10), struck out "carrier" before "localities"

Subsec. (s)(1). Pub. L. 108–173, §302(d)(3)(A), substituted "Subject to paragraph (3), the Secretary" for "The Secretary

Subsec. (s)(2)(C). Pub. L. 108–173, §627(b)(2), struck out subpar. (C) which read as follows: "Therapeutic shoes." Subsec. (s)(3). Pub. L. 108-173, §302(d)(3)(B), added par.

2000—Subsec. (b)(6)(C). Pub. L. 106-554, §1(a)(6) [title II, §222(a)], struck out "for such services provided before January 1, 2003," before "payment may be made" and substituted comma for semicolon at end.

Subsec. (b)(6)(E). Pub. L. 106-554, 1(a)(6) [title III, 313(b)(1)], inserted "by, or under arrangements made by, a skilled nursing facility" before "to an individual who" and struck out "or of a part of a facility that includes a skilled nursing facility (as determined under regulations)" before ", payment shall be made" and "(without regard to whether or not the item or service

was furnished by the facility, by others under arrangement with them made by the facility, under any other contracting or consulting arrangement, or otherwise)"

after "to the facility". Subsec. (b)(6)(G). Pub. L. 106-554, §1(a)(6) [title IV, \[ \frac{\pmatrix}{\pmatrix} \frac{\pmatrix}

§105(d)], added cl. (vi).

Subsec. (0)(3). Pub. L. 106–554, §1(a)(6) [title I, §114(a)], added par. (3).

Subsec. (t). Pub. L. 106-554, \$1(a)(6) [title III, \$313(b)(2)], struck out "by a physician" before "to an individual" and "or of a part of a facility that includes a skilled nursing facility (as determined under regulations)," before "for which payment may be made"

1999—Subsec. (b)(6)(F). Pub. L. 106-113,  $\S 1000(a)(6)$ [title III, §305(a)], inserted "(including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section)" after "home health services"

Subsec. (b)(8)(A)(i)(I). Pub. L. 106-113, §1000(a)(6) [title II, §223(c)], substituted "the application of this subchapter to payment under this part" for "the application of this part"

Subsec. (s)(2)(E). Pub. L. 106-113, §1000(a)(6) [title III, §321(k)(4)], inserted period at end.

1997—Subsec. (b)(2)(E). Pub. L. 105-33, §4611(d), added subpar. (E).

Subsec. (b)(6). Pub. L. 105–33, §4512(c), inserted at end "For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services de-

Subsec. (b)(6)(C). Pub. L. 105–33, §4201(d)(3)(B), amend-subsec. (b)(6)(C). Pub. L. 105–33, §4205(d)(3)(B), amend-subsec. (b)(6)(C).

ed subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "in the case of services described in clauses (i), (ii), or (iv) of section 1395x(s)(2)(K) of this title payment shall be made to the employer of the physician assistant or nurse practitioner involved, and".

Subsec. (b)(6)(E). Pub. L. 105-33, §4432(b)(2), added subpar. (E).

Subsec. (b)(6)(F). Pub. L. 105-33, §4603(c)(2)(B)(i), added subpar. (F).

Subsec. (b)(8), (9). Pub. L. 105-33, §4316(a), amended pars. (8) and (9) generally. Prior to amendment, par. (8) related to determination of reasonable charges for physician services, including factors to be considered, provision for increase or decrease of charge, consideration of resource costs, accounting for regional differences in prevailing charges, and impact of changes in reasonable charges, and par. (9) related to notice of proposed reasonable charges to be published in Federal Register, provision for comments on proposed changes, and publication of final determinations with respect to change in reasonable charges.

Subsec. (b)(12). Pub. L. 105-33, §4512(b)(2), struck out par. (12) which read as follows:

"(12)(A) With respect to services described in clauses (i), (ii), or (iv) of section 1395x(s)(2)(K) of this title (relating to a physician assistants and nurse practi-

"(i) payment under this part may only be made on an assignment-related basis; and

"(ii) the prevailing charges determined under paragraph (3) shall not exceed—
'(I) in the case of services performed as an assist-

ant at surgery, 65 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, or

'(II) in other cases, the applicable percentage (as defined in subparagraph (B)) of the prevailing charge rate determined for such services (or, for services furnished on or after January 1. 1992. the fee schedule amount specified in section 1395w-4 of this title) performed by physicians who are not specialists.

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"(B) In subparagraph (A)(ii)(II), the term 'applicable percentage' means—

"(i) 75 percent in the case of services performed (other than as an assistant at surgery) in a hospital, and

"(ii) 85 percent in the case of other services."
Subsec. (b)(19). Pub. L. 105-33, §4531(a)(2), added par.

Subsec. (h)(8). Pub. L. 105–33, §4302(b), added par. (8). Subsec. (o). Pub. L. 105–33, §4556(a), added subsec. (o). Subsec. (p)(1), (2). Pub. L. 105–33, §4317(a), inserted "or practitioner specified in subsection (b)(18)(C)" after "by a physician".

Subsec. (p)(4). Pub. L. 105–33, §4317(b), added par. (4). Subsec. (s). Pub. L. 105–33, §4315(a), added subsec. (s). Subsec. (t). Pub. L. 105–33, §4432(b)(4), added subsec. (t).

1996—Subsec. (c)(6). Pub. L. 104–191, §202(b)(2), added par. (6).

Subsec. (r). Pub. L. 104–191, §221(b), inserted at end "Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers." 1994—Subsec. (b)(2)(A). Pub. L. 103–432, §126(g)(9),

1994—Subsec. (b)(2)(A). Pub. L. 103–432, \$126(g)(9), made technical amendment to directory language of Pub. L. 101–508, \$4118(j)(2). See 1990 Amendment note below.

Subsec. (b)(2)(D). Pub. L. 103-432, 151(b)(2)(B), added subpar. (D).

Subsec. (b)(3)(G). Pub. L. 103-432, \$151(b)(1)(B)(i), which directed striking out "and" at end of subpar. (G), could not be executed because "and" did not appear at end of subpar. (G) subsequent to amendment by Pub. L. 103-432, \$123(c)(2). See below.

Pub. L. 103-432, \$123(c)(2), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: "will provide to each nonparticipating physician, at the beginning of each year, a list of the physician's limiting charges established under section 1395w-4(g)(2) of this title for the year for the physicians' services mostly commonly furnished by that physician; and"

ly commonly furnished by that physician; and". Subsec. (b)(3)(H). Pub. L. 103-432, §151(b)(1)(B)(ii), which directed striking out "and" at end of subpar. (H), could not be executed because "and" does not appear at end

Subsec. (b)(3)(I). Pub. L. 103–432, \$151(b)(1)(B)(iii), added subpar. (I).

Subsec. (b)(6)(D). Pub. L. 103-432, §125(b)(1), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "payment may be made to a physician who arranges for visit services (including emergency visits and related services) to be provided to an individual by a second physician on an occasional, reciprocal basis if (i) the first physician is unavailable to provide the visit services, (ii) the individual has arranged or seeks to receive the visit services from the first physician, (iii) the claim form submitted to the carrier includes the second physician's unique identifier (provided under the system established under subsection (r) of this section) and indicates that the claim is for such a 'covered visit service (and related services)', and (iv) the visit services are not provided by the second physician over a continuous period of longer than 60 days.

Subsec. (b)(12)(C). Pub. L. 103-432, §123(b)(2)(B), struck out subpar. (C). Prior to amendment, subpar. (C) read "Except for deductible and coinsurance as follows: amounts applicable under section 1395l of this title, any person who knowingly and willfully presents, or causes to be presented, to an individual enrolled under this part a bill or request for payment for services described in clauses (i), (ii), or (iv) of section 1395x(s)(2)(K) of this title in violation of subparagraph (A)(i) is subject to a civil money penalty of not to exceed \$2,000 for each such bill or request. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

Subsec. (b)(16)(B)(iii). Pub. L. 103-432, \$126(a)(1), struck out ", simple and subcutaneous" after "Partial", substituted "injections and small joint" for "injections; small joint" and "femoral fracture and" for "femoral fracture treatments;", struck out "lobectomy;" after "thoracostomy;" and "enterectomy; colectomy; cholecystectomy;" after "aneurysm repair;", substituted "fulguration and resection" for "fulguration; transurerethral resection", and struck out "sacral laminectomy;" before "tympanoplasty".

Subsec. (b)(17). Pub. L. 103-432, \$126(e), redesignated

Subsec. (b)(17). Pub. L. 103–432, §126(e), redesignated par. (18), relating to payment for technical component of diagnostic tests, as (17) and inserted ", tests specified in paragraph (14)(C)(i)," after "diagnostic laboratory tests".

Subsec. (b)(18). Pub. L. 103–432, §126(e), redesignated par. (18), relating to payment for technical component of diagnostic tests, as (17).

Pub. L. 103-432, \$123(b)(1), added par. (18), relating to payment for service furnished by a practitioner described in subpar. (C).

Subsec. (c)(1). Pub. L. 103–432, §126(h)(2), struck out subpar. (A) designation before "Any contract entered" and struck out subpar. (B) which read as follows: "Of the amounts appropriated for administrative activities to carry out this part, the Secretary shall provide payments, totaling 1 percent of the total payments to carriers for claims processing in any fiscal year, to carriers under this section, to reward carriers for their success in increasing the proportion of physicians in the carrier's service area who are participating physicians or in increasing the proportion of total payments for physicians' services which are payments for such services rendered by participating physicians."

Subsec. (c)(4). Pub. L. 103-432, §125(a), added par. (4). Subsec. (c)(5). Pub. L. 103-432, §135(b)(2), added par. (5).

Subsec. (h)(7)(C). Pub. L. 103-432, \$123(c)(1)(B), struck out "shall include" before cl. (i).

Subsec. (h)(7)(D). Pub. L. 103-432, 123(c)(1)(A), (C), (D), added subpar. (D).

Subsec. (q)(1). Pub. L. 103-432, §126(c)(1), made technical amendment to Pub. L. 101-508, §4103(a). See 1990 Amendment note below.

Subsec. (q)(1)(B). Pub. L. 103–432, 126(c)(2)(A), substituted "shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:" for "shall be determined as follows:" in introductory provisions.

Subsec. (q)(1)(B)(iii). Pub. L. 103-432, 126(c)(2)(B), substituted "The adjusted prevailing charge conversion factor for" for "Subject to clause (iv), the prevailing charge conversion factor to be applied in".

1993—Subsec. (b)(4)(F). Pub. L. 103-66, §13515(a)(2), struck out subpar. (F) which related to prevailing charge or fee schedule amount in case of professional services of health care practitioner (other than primary care services and other than services furnished in rural area designated as health professional shortage area) furnished during practitioner's first through fourth years of practice.

Subsec. (b)(13)(A). Pub. L. 103-66, §13516(a)(2)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "In determining the reasonable charge under paragraph (3) of a physician for medical direction of two or more nurse anesthetists performing, on or after April 1, 1988, and before January 1, 1996, anesthesia services in whole or in part concurrently, the number of base units which may be recognized with respect to such medical direction for each concurrent procedure (other than cataract surgery or an iridectomy) shall be reduced by—

 $\lq\lq(i)$  10 percent, in the case of medical direction of 2 nurse anesthetists concurrently,

"(ii) 25 percent, in the case of medical direction of 3 nurse anesthetists concurrently, and

"(iii) 40 percent, in the case of medical direction of 4 nurse anesthetists concurrently."

Subsec. (b)(13)(B), (C). Pub. L. 103-66, §13516(a)(2), redesignated subpar. (C) as (B), substituted "subpara-

graph (A)" for "subparagraph (A) or (B)", and struck out former subpar. (B) which read as follows: "In determining the reasonable charge under paragraph (3) of a physician for medical direction of two or more nurse anesthetists performing, on or after January 1, 1989, and before January 1, 1996, anesthesia services in whole or in part concurrently, the number of base units which may be recognized with respect to such medical direction for each concurrent cataract surgery or iridectomy procedure shall be reduced by 10 percent.

Subsec. (c)(2)(B)(ii). Pub. L. 103-66, §13568(b), substituted "period ending on or before September 30, 1993" for "period" in subcl. (IV) and added subcl. (V).

Subsec. (c)(3)(B). Pub. L. 103-66, §13568(a), added cls. (i) and (ii) and struck out former cls. (i) and (ii) which read as follows:

"(i) with respect to claims received in the 3-month period beginning July 1, 1988, 10 days, and

'(ii) with respect to claims received in the 12-month

period beginning October 1, 1988, 14 days."
Subsec. (i)(2). Pub. L. 103-66, §13517(b), substituted "; the term" for ", and the term" and inserted before period at end "; and the term 'nonparticipating supplier or other person' means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1))'

1990—Subsec. (b)(2)(A). Pub. L. 101-508, §4118(j)(2), as amended by Pub. L. 103-432, §126(g)(9), substituted "section 1395w-1(e)(2)" for "section 1395w-1(f)(2)"

Subsec. (b)(3)(G). Pub. L. 101-508, §4118(f)(2)(B), substituted "section 1395w-4(g)(2) of this title" for "subsection (j)(1)(C) of this section'

Subsec. (b)(4)(A)(vi). Pub. L. 101–508, §4105(b)(1), substituted "60 percent" for "50 percent".

Subsec. (b)(4)(B)(iv). Pub. L. 101-508, §4105(a)(2), added cl. (iv).

Subsec. (b)(4)(E)(iv)(I). Pub. L. 101-508, §4118(a)(2). substituted "the list referred to in paragraph (14)(C)(i)" for "Table #2 in the Joint Explanatory Statement of the Committee of Conference submitted with the Conference Report to accompany H.R. 3299 (the 'Omnibus Budget Reconciliation Act of 1989'), 101st Congress'

Subsec. (b)(4)(E)(v). Pub. L. 101-508, §4105(a)(1), added cl. (v).

Subsec. (b)(4)(F). Pub. L. 101-508, §4106(a)(1), amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: "In determining the customary charges for physicians' services furnished during a calendar year (other than primary care services and other than services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is designated, under section 254e(a)(1)(A) of this title, as a health manpower shortage area) for which adequate actual charge data are not available because a physician has not yet been in practice for a sufficient period of time, the Secretary shall set a customary charge at a level no higher than 80 percent of the prevailing charge for a service. For the first calendar year during which the preceding sentence no longer applies, the Secretary shall set the customary charge at a level no higher than 85 percent of the prevailing charge for the service."

Subsec. (b)(4)(F)(i). Pub. L. 101-597 substituted

"health professional shortage area" for "health manpower shortage area?

Pub. L. 101-508, §4106(b)(2)(A), (B), substituted "professional services" for "physicians' services and professional services" and "practitioner's first" for "physician's or practitioner's first"

Subsec. (b)(4)(F)(ii)(II). Pub. L. 101-508, §4106(b)(2)(C), substituted "practitioner" for "physician or practitioner" in two places.

Subsec. (b)(6)(C). Pub. L. 101-508, §4155(c), substituted "clauses (i), (ii), or (iv) of section 1395x(s)(2)(K)" for "section 1395x(s)(2)(K)"

Subsec. (b)(6)(D). Pub. L. 101-508, §4110(a), added subpar. (D).

Subsec. (b)(12)(A). Pub. L. 101-508, §4155(c), substituted "clauses (i), (ii), or (iv) of section 1395x(s)(2)(K)" for "section 1395x(s)(2)(K)" in introductory provisions.

Subsec. (b)(12)(A)(ii)(II). Pub. L. 101-508, §4118(f)(2)(C), struck out ", as the case may be" after "section 1395w-4 of this title"

Pub. L. 101-508, §4118(f)(2)(A), made technical correction to Pub. L. 101-239, §6102(e)(4). See 1989 Amendment note below.

Subsec. (b)(12)(C). Pub. L. 101–508, \$4155(c), substituted "clauses (i), (ii), or (iv) of section stituted 1395x(s)(2)(K)" for "section 1395x(s)(2)(K)".

Subsec. (b)(13)(A), (B). Pub. L. 101–508, §4103(b), substituted "1996" for "1991".

Subsec. (b)(14)(A). Pub. L. 101-508, §4101(a), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (b)(14)(B)(iii)(I). Pub. L. 101-508, §4118(a)(1)(A), which directed amendment of subcl. (I) by substituting "practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101-M, 101st Congress, 1st Session) for the service" for "practice expense ratio for the service (specified in table #1 in the Joint Explanatory Statement referred to in subparagraph (C)(i))", was executed by making the substitution for "practice expense ratio for the service (specified in Table #1 in the Joint Explanatory Statement referred to in subparagraph (C)(i))" to reflect the probable intent of Congress.

(b)(14)(B)(iii)(II).Subsec. Pub. §4118(a)(1)(B), substituted "practice expense component (percent), divided by 100" for "practice expense ratio".

Subsec. (b)(14)(C)(i). Pub. L. 101-508, §4118(a)(1)(C), substituted "procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission" for "physicians' services specified in Table #2 in the Joint Explanatory Statement of the Committee of Conference submitted with the Conference Report to accompany H.R. 3299 (the 'Omnibus Budget Reconciliation Act of 1989'), 101st Congress,"

Subsec. (b)(14)(C)(iii). Pub. L. 101–508, §4118(a)(1)(D), which directed amendment of cl. (iii) by substituting "The 'percentage change' specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list" for "The percent change' specified in this clause, for a physicians' service specified in clause (i), is the percent change specified for the service in table #2 in the Joint Explanatory Statement", was executed by making the substitution for "The 'percent change' specified in this clause, for a physicians' service specified in clause (i), is the percent change specified for the service in Table #2 in the Joint Explanatory Statement" to reflect the probable intent of Congress.

Subsec. (b)(14)(C)(iv). Pub. L. 101-508, §4118(a)(1)(E), which directed amendment of cl. (iv) by substituting "the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research)" for "such value specified for the locality in table #3 in the Joint Explanatory Statement referred to in clause (i)", was executed by making the substitution for "such value specified for the locality in Table #3 in the Joint Explanatory Statement referred to in clause (i)" to reflect the probable intent of Congress.

Subsec. (b)(16). Pub. L.  $101-\bar{508}$ , §4101(b), added par. (16).

Subsec. (b)(18). Pub. L. 101-508, §4108(a), added par. (18).

Subsec. (q)(1). Pub. L. 101-508, §4103(a), as amended by Pub. L. 103-432, §126(c)(1), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (r). Pub. L. 101-508, §4118(i)(1), added subsec.

1989—Subsec. (b)(2)(A). Pub. L. 101-239, §6202(d)(2), inserted at end "The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1395hh of this title, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1395y(b) of this title may apply.

Pub. L. 101-234, \$201(a), repealed Pub. L. 100-360, \$202(e)(3)(C), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (b)(2)(C). Pub. L. 101-239, §6114(c)(2), added subpar. (C).

Subsec. (b)(3)(G). Pub. L. 101-239, §6102(e)(2), substituted "limiting charges established under subsection (j)(1)(C) of this section" for "maximum allowable actual charges (established under subsection (j)(1)(C) of this section)'

Subsec. (b)(3)(I) to (K). Pub. L. 101–234, §201(a), repealed Pub. L. 100-360, §§ 201(c), 202(e)(2), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below

Subsec. (b)(3)(L). Pub. L. 101-239, §6102(b), added subpar. (L).

Subsec. (b)(4)(A)(iv). Pub. L. 101-239, §6102(e)(3), inserted "and before January 1, 1992," after "January 1,

Subsec. (b)(4)(E)(iv). Pub. L. 101-239, §6107(b), added cl. (iv).

Subsec. (b)(4)(F). Pub. L. 101-239, §6108(a)(1), inserted "furnished during a calendar year" after "physicians' services" and inserted at end "For the first calendar year during which the preceding sentence no longer applies, the Secretary shall set the customary charge at a level no higher than 85 percent of the prevailing charge for the service.

Subsec. (b)(6)(A)(ii). Pub. L. 101-239, §6003(g)(3)(D)(ix), "rural primary care hospital," after "hos-

Subsec. (b)(6)(C). Pub. L. 101-239, §6114(c)(1), inserted

"or nurse practitioner" after "physician assistant". Subsec. (b)(12)(A). Pub. L. 101–239, §6114(b), substituted "physician assistants and nurse practitioners" for "physician assistant acting under the supervision of a physician" in introductory provisions.

Subsec. (b)(12)(A)(ii)(II). Pub. L. 101–239, §6102(e)(4), as amended by Pub. L. 101-508, §4118(f)(2)(A), inserted "(or, for services furnished on or after January 1, 1992, the fee schedule amount specified in section 1395w–4 of this title, as the case may be)" after "prevailing charge rate determined for such services'

Subsec. (b)(14). Pub. L. 101-239, §6104(a), added par. (14).

Subsec. (b)(15). Pub. L. 101-239, §6108(b)(1), added par.

Subsecs. (c)(1)(A), (2)(A), (3)(A), (4), (f)(3), (h)(1), (2), (4). Pub. L. 101-234, §201(a), repealed Pub. L. 100-360,  $\S202(c)(1)(A)$ , (B), (e)(1), (3)(A), (4)(A), (5), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment notes below.

Subsec. (j)(1)(B)(ii). Pub. L. 101–239, §6102(e)(9), substituted "December 31, 1990." for "the earlier of (I) December 31, 1990, or (II) one-year after the date the Secretary reports to Congress, under section 1395w-1(e)(3) of this title, on the development of the relative value scale under section 1395w-1 of this title.

Subsec. (j)(1)(C)(vii). Pub. L. 101–234, §301(b)(2), (c)(2), amended cl. (vii) identically, substituting "according" for "accordingly

Subsec. (j)(1)(D)(ii)(II). Pub. L. 101-239, §6104(b)(1), inserted "or (b)(14)(A)" after "(b)(10)(A)".

Subsec. (j)(1)(D)(ii)(IV). Pub. L. 101–239, §6108(b)(2)(A), inserted "or (b)(15)(A)" after "subsection (b)(11)(C)(i)". Subsec. (j)(1)(D)(iii)(II). Pub. L. 101-239, §6108(b)(2)(B),

substituted "(b)(14)(A), or (b)(15)(A)" for "or (b)(14)(A)". Pub. L. 101-239, \$6104(b)(2), substituted "(b)(11)(C)(i), or (b)(14)(A)" for "or (b)(11)(C)(i)".

Subsec. (j)(1)(D)(v). Pub. L. 101-239, §6102(e)(9), substituted "December 31, 1990." for "the earlier of (I) December 31, 1990, or (II) one-year after the date the Secretary reports to Congress, under section 1395w-1(e)(3) of this title, on the development of the relative value scale under section 1395w-1 of this title.

Subsec. (j)(2). Pub. L. 101-234, §301(b)(6), (d)(3), which directed identical amendments to subsec. (j)(2) by substituting "subsections" for "paragraphs" in subpar. (B) as amended by section 8(c)(2)(A) of the Medicare and Medicaid Fraud and Abuse Patient Protection Act of 1987 [probably meaning section 8(c)(2)(A) of Pub. L. 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, which amended subpar. (A) of subsec. (j)(2), generally] could not be executed because the word "paragraphs" did not appear.

Subsec. (o). Pub. L. 101–234, §201(a), repealed Pub. L. 100-360, §202(c)(1)(C), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (q). Pub. L. 101-239, §6106(a), added subsec. (q). 1988—Subsec. (b)(2). Pub. L. 100–360, §411(i)(2), amended Pub. L. 100-203, §4082(c), see 1987 Amendment note below.

Subsec. (b)(2)(A). Pub. L. 100-485, §608(d)(5)(G), inserted ", including claims processing functions" after 'and related functions" in last sentence.

Pub. L. 100-360, §411(f)(1)(B), inserted reference to section 1395w-1(f)(2) of this title in third sentence.

Pub. L. 100-360, §202(e)(3)(C), as amended by Pub. L. 100-485, §608(d)(5)(F), inserted at end "With respect to activities relating to implementation and operation (and related functions) of the electronic system established under subsection (o)(4) of this section, the Secretary may enter into contracts with carriers under this section to perform such activities on a regional basis.

Subsec. (b)(3). Pub. L. 100-360, §411(i)(4)(C)(vi), added Pub. L. 100-203, §4085(i)(24), see 1987 Amendment note below.

Pub. L. 100-360, §411(f)(4)(B)(ii), added Pub. L. 100-203, §4045(c)(2)(D), see 1987 Amendment note below.

Pub. L. 100-360, §411(f)(11)(A), (14), renumbered and amended Pub. L. 100-203, §4053(a), see 1987 Amendment note below.

Subsec. (b)(3)(B)(ii). Pub. L. 100-360, §411(j)(4)(A), made technical correction to directory language of Pub. L. 100-203, § 4096(a)(1)(A), see 1987 Amendment note

Subsec. (b)(3)(I). Pub. L. 100-360, §201(c), added subpar. (I) requiring notice that an individual has reached the part B catastrophic limit on out-of-pocket cost sharing for the year.

Subsec. (b)(3)(J). Pub. L. 100-360, §202(e)(2), added subpar. (J) relating to requirements for determinations or payments with respect to covered outpatient drugs, to receive information and respond to requests by participating pharmacies.

Subsec. (b)(3)(K). Pub. L. 100-485, §608(d)(5)(C), inserted ", including claims processing functions," after 'and for related functions'

Pub. L. 100-360, §202(e)(2), added subpar. (K) requiring contracts with organizations described in subsection (f)(3) of this section to implement and operate the electronic system established under subsection (o)(4) of this section for covered outpatient drugs.

Subsec. (b)(4)(A)(iv). Pub. L. 100-360, \$411(f)(2)(F)(i), as amended by Pub. L. 100-485, \$608(d)(21)(B), redesignated and amended Pub. L. 100-203, §4042(c)(1), see 1987 Amendment note below

Subsec. (b)(4)(A)(iv)(II). Pub. L. 100-360, §411(f)(2)(E), substituted "before January 1, 1989" for "before January 1, 1988'

Subsec. (b)(4)(A)(vi). Pub. L. 100–360, §411(f)(3)(A), made technical amendment to directory language of Pub. L. 100-203, §4044(a), see 1987 Amendment note below.

Pub. L. 100-360, §411(f)(3)(B), substituted "subsection (i)(4)" for "subparagraph (E)(iii)" and "the estimated

average prevailing charge levels based on the best available data" for "the average of the prevailing charge levels" and struck out "for participating physicians" before "under the third".

Subsec. (b)(4)(A)(vii). Pub. L. 100-360, §411(f)(2)(D), added Pub. L. 100-203, §4042(b)(2)(A), see 1987 Amendment note below.

Pub. L. 100–360,  $\S411(f)(3)(A)$ , made technical amendment to directory language of Pub. L. 100-203, §4044(a), see 1987 Amendment note below.

Subsec. (b)(4)(E). Pub. L. 100–360,  $\S411(f)(2)(C)$ , added Pub. L. 100-203, §4042(b)(1)(C), (D), see 1987 Amendment notes below.

Subsec. (b)(4)(F). Pub. L. 100–360, §411(f)(2)(C), added Pub. L. 100-203, §4042(b)(1)(D), see 1987 Amendment note

Subsec. (b)(4)(F)(ii)(I). Pub. L. 100-360, \$411(f)(2)(B), abstituted "subsection (i)(4)" for "subparagraph substituted (E)(iii)".

Subsec. (b)(4)(F)(iii). Pub. L. 100–360, §411(f)(2)(A), substituted "services," for "services;" in subcl. (I) and "physicians" for "physician's" in subcl. (II).

Subsec. (b)(4)(G). Pub. L. 100-360, §411(f)(2)(C), added Pub. L. 100-203, § 4042(b)(1)(D), see 1987 Amendment note

Pub. L. 100-360, §411(f)(6)(B), substituted "other than primary care services" for "other primary care services" and struck out "(as determined under the third and fourth sentences of paragraph (3) and under paragraph (4))" after "the prevailing charge"

Subsec. (b)(7)(B)(iii). Pub. L. 100-360, §411(i)(4)(C)(vi), added Pub. L. 100-203, §4085(i)(22)(C), see 1987 Amendment note below.

Subsec. (b)(10)(A)(i). Pub. L. 100-360,  $\S411(f)(4)(A)(i)$ , struck out "under paragraph (3)" after "reasonable charge", substituted "subparagraph (B)" for "subparagraph (C)", and struck out "for participating and nonparticipating physicians" after "charge for such proce-

Subsec. (b)(10)(A)(iii). Pub. L. 100-360, §411(f)(4)(A)(ii),

substituted ''clause (i)(I)'' for ''clause (i)(II)''. Subsec. (b)(10)(B). Pub. L. 100-360,  $\S411(f)(4)(A)(iii)$ , inserted "(including subsequent insertion of an intraocular lens)" after "cataract surgery"

Subsec. (b)(10)(D). Pub. L. 100–360, \$411(f)(4)(A)(iv), substituted "under section 1395ff" for "section 1395ff". Subsec. (b)(11)(B)(i). Pub. L. 100–360, \$411(f)(4)(B)(i), amended Pub. L. 100-203, §4045(c)(2)(B), see 1987 Amendment note below.

Subsec. (b)(11)(C)(i). Pub. L. 100-360, §411(f)(5)(A), substituted "insertion" for "implantation".

Subsec. (b)(11)(C)(ii). Pub. L. 100–360, §411(g)(2)(A),

substituted "inserted during or subsequent to" for "implanted during"

Subsec. (b)(12)(C). Pub. L. 100–360, §411(i)(4)(C)(vi), added Pub. L. 100-203, §4085(i)(25), see 1987 Amendment note below.

Subsec. (b)(13), (14). Pub. L. 100-360, §411(f)(7)(A), redesignated par. (14) as (13).

Subsec. (c)(1)(A). Pub. L. 100-360, §202(e)(3)(A), designated existing provisions as cl. (i), inserted ", except as provided in clause (ii)," after "under this part, and" and added cl. (ii) relating to payment for implementation and operation of the electronic system for covered outpatient drugs.

Subsec. (c)(1)(A)(ii). Pub. L. 100-485, §608(d)(5)(D), inserted ", including claims processing functions" after "and related functions"

Subsec. (c)(2)(A), (3)(A). Pub. L. 100–360,  $\S 202(e)(5)(A)$ , as amended by Pub. L. 100-485, §608(d)(5)(H), substituted "Except as provided in paragraph (4), each" for "Each".

Subsec. (c)(4). Pub. L. 100-360,  $\S 202(e)(5)(B)$ , added par. (4) requiring contracts for the disbursement of funds with respect to claims for payment for covered outpatient drugs to provide for a payment cycle, and requiring interest if such requirements are not met.

Subsec. (f)(3). Pub. L. 100–485, 608(d)(5)(B), inserted ", including claims processing functions" after "and related functions'

Pub. L. 100-360, §202(e)(1), added par. (3) which read as follows: "with respect to implementation and operation (and related functions) of the electronic system established under subsection (o)(4) of this section, a voluntary association, corporation, partnership, or other nongovernmental organization, which the Secretary determines to be qualified to conduct such activities.

Subsec. (h)(1). Pub. L. 100-360, §202(c)(1)(A), inserted ", except that, with respect to a supplier of covered outpatient drugs, the term 'participating supplier' means a participating pharmacy (as defined in subsection (o)(1) of this section)" after "part during such

Subsec. (h)(2). Pub. L. 100–360, §202(e)(4)(A), inserted "(other than a carrier described in subsection (f)(3) of this section)" after "Each carrier".

Subsec. (h)(3)(B). Pub. L. 100-360, §411(i)(1)(A), substituted "payment determination" for "claims determination", "shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order" for "including such information as the Secretary determines is generally provided", "enter into agreements" for "enter into arrangements", and "under this subparagraph by a carrier" for "under this subparagraph" and inserted ", and such user fees shall be collected and retained by

Subsec. (h)(4). Pub. L. 100-360, §202(c)(1)(B), inserted at end "In publishing directories under this paragraph, the Secretary shall provide for separate directories (wherever appropriate) for participating pharmacies.

Subsec. (h)(5). Pub. L. 100-360, §223(b), designated existing provisions as subpar. (A), inserted "through an annual mailing", struck out at end "The Secretary shall include such notice in the mailing of appropriate benefit checks provided under subchapter II of this chapter.", and added subpar. (B).

Subsec. (h)(7). Pub. L. 100–360, §411(f)(2)(C), added Pub. L. 100-203, §4042(b)(1)(A), see 1987 Amendment note below.

Pub. L. 100-360, §223(c), in subpar. (A) inserted "prominent" before "reminder" and substituted "and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),"

"7E), and" and added subpar. (C).
Subsec. (h)(8). Pub. L. 100–360, §411(f)(2)(C), added Pub. L. 100-203, §4042(b)(1)(B), see 1987 Amendment note below.

Subsec. (i). Pub. L. 100-360, §411(f)(2)(C), added Pub. L. 100-203, §4042(b)(1)(B), see 1987 Amendment note below. Subsec. (i)(2), (3). Pub. L. 100-360, §411(f)(2)(C), added Pub. L. 100-203, §4042(b)(1)(C), see 1987 Amendment note

Subsec. (i)(3). Pub. L. 100–485, §608(d)(21)(A), substituted "subsection (b)(3)" for "paragraph (3)". Subsec. (i)(4). Pub. L. 100–360, §411(f)(2)(C), added Pub.

L. 100–203,  $\S4042(b)(1)(E)$ , see 1987 Amendment note below.

Subsec. (j)(1)(C)(i). Pub. L. 100-360, §411(f)(2)(F)(ii), added Pub. L. 100-203, §4042(c)(2), see 1987 Amendment note below.

Subsec. (j)(1)(C)(viii). Pub. L. 100–360, §411(f)(1)(A), amended Pub. L. 100-203, §4041(a)(1)(B), see 1987 Amendment note below.

Subsec. (j)(1)(C)(ix). Pub. L. 100-360, §411(f)(7)(B), added Pub. L. 100-203, §4048(e), see 1987 Amendment note below.

Subsec. (j)(1)(D)(ii)(IV). Pub. L. 100–360, §411(f)(5)(B), struck out "is" after "limit"

Subsec. (j)(1)(D)(ii)(V). Pub. L. 100–360, §411(g)(2)(B), redesignated subcl. (IV) as (V) and struck out "is" after 'limit''.

Subsec. (j)(1)(D)(iii). Pub. L. 100-360, §411(g)(2)(C), amended Pub. L. 100-203, §4063(a)(2)(B), see 1987 Amendment note below.

Subsec. (j)(1)(D)(iv). Pub. L. 100-360, §411(f)(4)(C), sub-

stituted "bills" for "imposes a charge". Subsec. (j)(2). Pub. L. 100-360, §411(i)(4)(C)(vi), as amended by Pub. L. 100–485,  $\S608(d)(24)(B)$ , added Pub. L. 100–203, \$4085(i)(26), see 1987 Amendment note below. Subsec. (l)(1)(C)(i). Pub. L. 100–360, \$411(i)(4)(C)(vi), added Pub. L. 100-203, §4085(i)(27), see 1987 Amendment note below.

Subsec. (n)(1). Pub. L. 100–360, §411(f)(9)(A), in introductory provisions, struck out "to a patient" after "includes a charge", inserted "the bill or request for" after "for which", and substituted "shares a practice" for "shares his practice" and "supervised the performance of the test, the" for "supervised the test, the".

Subsec. (n)(1)(A). Pub. L. 100-485, \$608(d)(17), substituted "the supplier's" for "the the supplier's".

Pub. L. 100–360, §411(f)(9)(B), as amended by Pub. L. 100–485, §608(d)(21)(D), substituted "(or other applicable limit)" for "to individuals enrolled under this part".

Pub. L. 100–360,  $\S411(a)(3)(A)$ , (C)(i), clarified that illegible matter after "or, if lower, the" was "the supplier's reasonable charge to individuals enrolled under this part for the test".

Subsec. (n)(2)(A). Pub. L. 100-360,  $\S411(f)(9)(C)$ , inserted "the payment amount specified in paragraph (1)(A) and" after "other than".

Subsec. (n)(3). Pub. L. 100-360, §411(f)(9)(D), struck out "or supplier" after "such physician".

Subsec. (0). Pub. L. 100–360, \$202(c)(1)(C), added subsec. (0) relating to "participating pharmacies" as entities authorized under State law to dispense covered outpatient drugs which had entered into agreements with Secretary to participate in catastrophic coverage program.

Subset. (o)(1)(A)(i). Pub. L. 100-485, \$608(d)(5)(A)(i), substituted "paragraph (4)" for "subparagraph (D)(i)".

Subsec. (0)(1)(B)(ii). Pub. L. 100–485, \$608(d)(5)(A)(ii), substituted "an eligible organization" for "eligible organization"

Subsec. (p). Pub. L. 100–360, §202(g), added subsec. (p). 1987—Subsec. (b)(2). Pub. L. 100–203, §4082(c), as amended by Pub. L. 100–360, §411(i)(2), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 100–203, §4041(a)(3)(A)(i), inserted at end "In establishing such standards and criteria, the Secretary shall provide a system to measure a carrier's performance of responsibilities described in paragraph (3)(H) and subsection (h) of this section."

Subsec. (b)(3). Pub. L. 100-203, \$4085(i)(24), as added by Pub. L. 100-360, \$411(i)(4)(C)(vi), substituted "In the case of physicians' services" for "In the case of physician services" and "(with respect to physicians' services" for "(with respect to physicians services" in fourth sentence.

Pub. L. 100–203, §4045(c)(2)(D), as added by Pub. L. 100–360, §411(f)(4)(B)(ii), inserted "(or under any other provision of law affecting the prevailing charge level)" in fourth sentence.

Pub. L. 100–203, §4053(a), formerly §4052(a), as renumbered and amended by Pub. L. 100–360, §411(f)(11)(A), (14), inserted ", and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level" before period at end of penultimate sentence.

Subsec. (b)(3)(B)(ii). Pub. L. 100–203, \$4096(a)(1)(A), as amended by Pub. L. 100–360, \$411(j)(4)(A), added subcl. (II), redesignated former subcl. (II) as (III), and inserted "(and to refund amounts already collected)".

Subsec. (b)(3)(C). Pub. L. 100-203, §4085(i)(5), substituted "less than \$500" for "not more than \$500".

Subsec. (b)(4)(A)(iv). Pub. L. 100–203, §4042(c)(1), formerly §4042(c), as redesignated and amended by Pub. L. 100–360, §411(f)(2)(F)(i), and by Pub. L. 100–485, §608(d)(21)(B), amended cl. (iv) generally. Prior to amendment, cl. (iv) read as follows: "In determining the prevailing charge level under the third and fourth sentences of paragraph (3) for a physicians' service furnished on or after January 1, 1987, by a nonparticipating physician, the Secretary shall set the level at 96 percent of the prevailing charge levels established under such sentences with respect to such service furnished by participating physicians."

Subsec. (b)(4)(A)(v). Pub. L. 100–203, \$4041(a)(1)(A)(i), added cl. (v). Former cl. (v) redesignated (vi).

Subsec. (b)(4)(A)(vi). Pub. L. 100-203, \$4044(a), as amended by Pub. L. 100-360, \$411(f)(3)(A), added cl. (vi). Former cl. (vi) redesignated (vii).

Pub. L. 100-203, \$4041(a)(1)(A)(i), redesignated former cl. (v) as (vi).

Subsec. (b)(4)(A)(vii). Pub. L. 100-203, \$4042(b)(2)(A), as added by Pub. L. 100-360, \$411(f)(2)(D), substituted "subsection (i)(3)" for "subparagraph (E)(ii)".

Pub. L. 100-203, \$4044(a), as amended by Pub. L. 100-360, \$411(f)(3)(A), redesignated former cl. (vi) as (vii).

Subsec. (b)(4)(B)(iii). Pub. L. 100-203, §4041(a)(1)(A)(ii), added cl. (iii).

Subsec. (b)(4)(E). Pub. L. 100-203, \$4042(b)(1)(D), as added by Pub. L. 100-360, \$411(f)(2)(C), redesignated subpar. (F) as (E). Former subpar. (E) transferred to subsec. (i).

Pub. L. 100-203, §4042(b)(1)(C), as added by Pub. L. 100-360, §411(f)(2)(C), struck out "(E) In this section:" before cl. (i), redesignated cls. (i) and (ii) as pars. (2) and (3), respectively, and transferred those pars. to subsec. (i).

Subsec. (b)(4)(F). Pub. L. 100-203, \$4042(b)(1)(D), as added by Pub. L. 100-360, \$411(f)(2)(C), redesignated subpar. (G) as (F). Former subpar. (F) redesignated (E).

Pub. L. 100-203, §4042(a), added subpar. (F).

Subsec. (b)(4)(G). Pub. L.  $100-20\overline{3}$ , \$4042(b)(1)(D), as added by Pub. L. 100-360, \$411(f)(2)(C), redesignated subpar. (G) as (F).

Pub. L. 100-203, §4047(a), added subpar. (G).

Subsec. (b)(7)(B)(iii). Pub. L. 100–203, §4085(i)(22)(C), as added by Pub. L. 100–360, §411(i)(4)(C)(vi), substituted "an assignment-related basis" for "the basis of an assignment described in paragraph (3)(B)(ii) or under the procedure described in section 1395gg(f)(1) of this title".

Subsec. (b)(10). Pub. L. 100-203, \$4045(a), amended par. (10) generally, revising and restating as subpars. (A) to (D) provisions of former subpars. (A) to (C).

Subsec. (b)(11)(B)(i). Pub. L. 100–203, §4045(c)(2)(B), as amended by Pub. L. 100–360, §411(f)(4)(B)(i), struck out "and shall be further reduced by 2 percent with respect to procedures performed in 1988" after "in 1987" and struck out second sentence which read as follows: "A reduced prevailing charge under this subparagraph shall become the prevailing charge level for subsequent years for purposes of applying the economic index under the fourth sentence of paragraph (3)."

Subsec. (b)(11)(C). Pub. L. 100-203,  $\S4063(a)(1)(A)$ , designated existing provisions as cl. (i) and added cl. (ii). Pub. L. 100-203,  $\S4046(a)(1)(B)$ , (C), added subpar. (C) and redesignated former subpar. (C) as (D).

Pub. L. 100–203, §4045(c)(1)(Å), struck out former cl. (i) designation before "In the case of" and substituted ", the physician's actual charge is subject to a limit under subsection (j)(1)(D)." for "(subject to clause (iv)), the physician may not charge the individual more than the limiting charge (as defined in clause (ii)) plus (for services furnished during the 12-month period beginning on the effective date of the reduction) ½ of the amount by which the physician's actual charges for the service for the previous 12-month period exceeds the limiting charge.", and struck out former cls. (ii) to (iv) which read as follows:

"(ii) In clause (i), the term 'limiting charge' means, with respect to a service, 125 percent of the prevailing charge for the service after the reduction referred to in clause (i).

"(iii) If a physician knowingly and willfully imposes charges in violation of clause (i), the Secretary may apply sanctions against such physician in accordance with subsection (i)(2) of this section.

"(iv) This subparagraph shall not apply to services furnished after the earlier of (I) December 31, 1990, or (II) one-year after the date the Secretary reports to Congress, under section 1395w-1(e)(3) of this title, on the development of the relative value scale under section 1395w-1 of this title."

Subsec. (b)(11)(D). Pub. L. 100-203, §4063(a)(1)(B), which directed that subpar. (D) be amended by inserting "or item" after "service" or "services" each place either appears, was executed by inserting "or item" after "service" wherever appearing. The word "services" does not appear because of a prior amendment by

section 4045(c)(1)(A) of Pub. L. 100-203 to subpar. (D), formerly (C), see above.

Pub. L. 100-203, \$4046(a)(1)(A), (B), redesignated former subpar. (C) as (D) and substituted "subparagraph (B) or (C)" for "subparagraph (B)". Subsec. (b)(12)(C). Pub. L. 100-203,  $\S4085(i)(25)$ , as

added by Pub. L. 100–360, §411(i)(4)(C)(vi), substituted "money penalty" for "monetary penalty" and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a penalty shall be imposed in the same manner as civil monetary penalties are imposed under section 1320a-7a of this title with respect to actions described in subsection (a) of that section.

Subsec. (b)(14). Pub. L. 100-203, §4048(a), added par.

Subsec. (c)(1). Pub. L. 100-203, §4041(a)(3)(A)(ii), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 100-203, §4035(a)(2), inserted at end "The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for carriers under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.

Subsec. (c)(3). Pub. L. 100-203, §4031(a)(2), added par.

Subsec. (h)(3). Pub. L. 100-203, §4081(a), designated existing provisions as subpar. (A) and added subpar. (B). Subsec. (h)(5). Pub. L. 100-203,  $\S4085(i)(6)$ , substituted "the participation program" for "the the participation program".

Subsec. (h)(7). Pub. L. 100-203. §4042(b)(1)(A), as added by Pub. L. 100-360, \$411(f)(2)(C), struck out ", described in paragraph (8)" after "assignment-related basis" in

introductory provisions.
Subsec. (h)(8). Pub. L. 100–203, §4042(b)(1)(B), as added by Pub. L. 100-360, §411(f)(2)(C), substituted "(1) A" for "(8) For purposes of this subchapter, a", indented such par. 2 ems, and inserted subsec. (i) designation and "For purposes of this subchapter:", effectively transferring former subsec. (h)(8) to subsec. (i).

Subsec. (i). Pub. L. 100-203, § 4042(b)(1)(B), as added by Pub. L. 100-360, §411(f)(2)(C), transferred introductory

provisions and par. (1) from former subsec. (h)(8). Subsec. (i)(2), (3). Pub. L. 100-203, \$4042(b)(1)(C), as added by Pub. L. 100-360, \$411(f)(2)(C), transferred pars. (2) and (3) from subsec. (b)(4)(E). Subsec. (i)(4). Pub. L. 100-203,  $\S4042$ (b)(1)(E), as added

by Pub. L. 100-360, §411(f)(2)(C), added par. (4).

Subsec. (j)(1)(B)(i). Pub. L. 100-203, §4054(a)(1), (2), formerly §4053(a)(1), (2), as renumbered by Pub. L. 100-360, §411(f)(14), substituted "the actual charges of each such physician" for "each such physician's actual charges" and "on a repeated basis for such a service an actual charge" for "for such a service a physician's actual charge (as defined in subparagraph (C)(vi)"

Subsec. (j)(1)(C)(i). Pub. L. 100-203, § 4085(i)(7)(A), inserted "maximum allowable" after "If the physi-

Pub. L. 100-203, §4042(c)(2), as added by Pub. L. 100-360, §411(f)(2)(F)(ii), substituted "applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved" for "prevailing charge for the year involved for such service furnished by nonparticipating physicians" in subcls. (I) and (II).

Subsec. (j)(1)(C)(v). Pub. L. 100-203, §4085(i)(7)(B), substituted "1986" for "1987"

Subsec. (j)(1)(C)(vi). Pub. L. 100-203, §4054(a)(3), formerly §4053(a)(3), as renumbered by Pub. L. 100-360, §411(f)(14), struck out "and subparagraph (B)" after 'purposes of this subparagraph''.

Subsec. (j)(1)(C)(vii). Pub. L. 100-203, §4085(i)(7)(C), added cl. (vii).

Subsec. (j)(1)(C)(viii). Pub. L. 100–203, §4041(a)(1)(B), as amended by Pub. L. 100-360,  $\S411(f)(1)(A)$ , added cl. (viii).

Subsec. (j)(1)(C)(ix). Pub. L. 100–203, § 4048(e), as added by Pub. L. 100-360, §411(f)(7)(B), added cl. (ix).

Subsec. (j)(1)(D). Pub. L. 100-203, §4045(c)(1)(B), added subpar. (D).

Subsec. (j)(1)(D)(ii)(IV). Pub. L. 100-203, §4063(a)(2)(A), added subcl. (IV) relating to establishment of reasonable charge limit under subsec. (b)(11)(C)(ii) of this sec-

Pub. L. 100-203, §4046(a)(2)(A), added subcl. (IV) relating to establishment of prevailing charge limit under subsec. (b)(11)(C)(i) of this section. Former subcl. (IV) redesignated (V).

(j)(1)(D)(ii)(V), (VI). Pub. L. 100-203. Subsec. § 4063(a)(2)(A), redesignated former subcl. (V) as (VI).

Pub. L. 100-203, §4046(a)(2)(A), redesignated former subcl. (IV) as (V).

Subsec. (j)(1)(D)(iii). Pub. L. 100-203, §4063(a)(2)(B), as amended by Pub. L. 100-360, §411(g)(2)(C), struck out 'or" at end of subcl. (I), substituted "; or" for period

at end of subcl. (II), and added subcl. (III). Pub. L. 100-203, \$4046(a)(2)(B), substituted ", (b)(11)(B), or (b)(11)(C)(i)" for "or (b)(11)(B)" in subcl.

Subsec. (j)(2). Pub. L. 100-203, §4085(i)(26), as added by Pub. L. 100-360, §411(i)(4)(C)(vi), and amended by Pub. L. 100–485, 608(d)(24)(B), substituted "chapter" for "subchapter" in subpar. (A), struck out "the imposition of" before "civil monetary penalties" and inserted "and assessments" in subpar. (B), substituted "chapter" for "subchapter" in two places in last sentence, and amended last sentence generally. Prior to amendment, last sentence read as follows: "No payment may be made under this chapter with respect to any item or service furnished by a physician during the period when he is excluded from participation in the programs under this chapter pursuant to this subsection.

Pub. L. 100-93,  $\S8(c)(2)(A)$ , amended subpar. (A) generally and substituted "excluded from participation in the programs" for "barred from participation in the program" in last sentence. Prior to amendment, subpar. (A) read as follows: "barring a physician from participation under the program under this subchapter for a period not to exceed 5 years, in accordance with the procedures of paragraphs (2) and (3) of section 1395y(d) of this title, or

Subsec. (j)(3)(A). Pub. L. 100–93, §8(c)(2)(B), sub-

stituted "exclude" for "bar". Subsec. (k)(1), (2). Pub. L. 100-203, 4085(g)(1), substituted "subsection (j)(2) in the case of surgery performed on or after March 1, 1987" for "subsection

Subsec. (l)(1)(A)(iii). Pub. L. 100-203, §4096(a)(1)(B), designated existing provisions as subcl. (I) and added subcl. (II).

Subsec. (l)(1)(C). Pub. L. 100-203, §4096(a)(1)(C), inserted "in the case described in subparagraph (A)(iii)(I)" after "to an individual" in introductory provisions.

Subsec. (l)(1)(C)(i). Pub. L. 100-203, §4085(i)(27), as added by Pub. L. 100-360, \$411(i)(4)(C)(vi), inserted "the physician establishes that" after "(i)".

Subsec. (n). Pub. L. 100-203, §4051(a), added subsec.

1986—Subsec. (b)(3). Pub. L. 99–509, §9331(c)(3)(A), inserted "or (with respect to physicians services furnished in a year after 1987) the level determined under this sentence for the previous year" after "ending June 1973," and "year-to-year" before "economic changes" in fourth sentence.

Pub. L. 99-272, §9301(d)(1)(B), (C), substituted "June 30 last preceding the start of the calendar year" for "March 31 last preceding the start of the twelve-month period (beginning October 1 of each year)" in third sentence, and struck out "the twelve-month period beginning on October 1 in" before "any calendar year after 1974" in eighth sentence.

Subsec. (b)(3)(C). Pub. L. 99–509,  $\S 9341(a)(2)$ , substituted "at least \$100, but not more than \$500" for "\$100 or more"

Subsec. (b)(3)(F). Pub. L. 99-272, §9301(d)(1)(A), struck out "(ending on September 30)" after "before the year".

Subsec. (b)(3)(G). Pub. L. 99-509, §9331(b)(2), added

(b)(3)(H). Pub. L. 99-509, §9332(a)(1), added subpar. (H).

Subsec. (b)(4)(A)(i), (ii). Pub. L. 99-272, §9301(b)(1)(A), designated existing provisions as cl. (i) and added cl.

Subsec. (b)(4)(A)(iii). Pub. L. 99–509, §9331(a)(1), added cl. (iii) and struck out former cl. (iii) which read as follows: "In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during a 12-month period beginning on or after January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for services furnished during the previous calendar year (without regard to clause (ii)(II)) for physicians who were participating physicians during that year.

Pub. L. 99-272, §9301(b)(1)(A)(ii), added cl. (iii). Subsec. (b)(4)(A)(iv), (v). Pub. L. 99-509, §9331(a)(1), added cls. (iv) and (v).

Subsec. (b)(4)(B). Pub. L. 99-272, §9301(b)(1)(B), designated existing provisions as cl. (i) and added cl. (ii). Subsec. (b)(4)(C). Pub. L. 99-509, 9331(a)(2), directed

amendment of subpar. (C) by striking out "(i)" after "(C)" and striking out cl. (ii), applicable to services furnished on or after Jan. 1, 1987, which is identical to amendment by Pub. L. 99-514, §1895(b)(14)(A), as amended, effective as if included in enactment of Pub. L.

Pub. L. 99–514, §1895(b)(14)(A), as amended by Pub. L. 99–509,  $\S 9307(c)(2)(A)$ , struck out cl. (i) designation, and struck out cl. (ii) which read as follows: "In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the periods beginning after December 31, 1986, by a physician who was not a participating physician on that date, the Secretary shall treat the level as set under subparagraph (A)(ii) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(ii)."

Pub. L. 99-272, §9301(b)(1)(C), designated existing provisions as cl. (i), substituted "subparagraph (A)(i)" for "subparagraph (A)" wherever appearing, and added cl.

Subsec. (b)(4)(D)(i) to (iii). Pub. L. 99–272, §9301(b)(1)(D), designated existing provisions as cl. (i), substituted "In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985" for "In determining the customary charges for physicians' services furnished during the 12-month period beginning October 1, 1985, or October 1, 1986, by a physician who at no time for any services furnished during the 12-month period beginning October 1, 1984, was a participating physician (as defined in subsection (h)(1))", and added cls. (ii) and

Subsec. (b)(4)(D)(iv). Pub. L. 99-509, §9331(b)(3), added cl. (iv).

Subsec. (b)(4)(E). Pub. L. 99-509, §9331(a)(3), added sub-

Subsec. (b)(6). Pub. L. 99-509, §9338(c), substituted "except that (A) payment may be made (i)" for "except that payment may be made (A)(i)", substituted "(B) payment may be made" for "or (B)", and inserted before the period at end ", and (C) in the case of services described in section 1395x(s)(2)(K) of this title payment shall be made to the employer of the physician assistant involved"

Subsec. (b)(7)(B)(ii)(III). Pub. L. 99-272, §9219(b)(1)(A), realigned margin of subcl. (III).

Subsec. (b)(7)(B)(iii). Pub. L. 99-272, §9219(b)(2)(A), realigned margin of cl. (iii).

Subsec. (b)(8). Pub. L. 99-509, §9333(a), designated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, and added subpars. (B) and (C).

Pub. L. 99–272, §9304(a), added par. (8). Subsec. (b)(9). Pub. L. 99–509, §9333(b), added par. (9). Former par. (9) redesignated (11).

Pub. L. 99-272, §9306(a), added par. (9).

Subsec. (b)(10). Pub. L. 99–509, 9333(b), added par. (10). Subsec. (b)(11). Pub. L. 99-509, §9334(a), designated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, and added subpars. (B) and (C).

Pub. L. 99-509, §9333(b), redesignated former par. (9) as (11).

Subsec. (b)(12). Pub. L. 99-509, §9338(b), added par. (12). Subsec. (c). Pub. L. 99-509, §9311(c), designated existing provisions as par. (1) and added par. (2).

Subsec. (h)(1). Pub. L. 99–272,  $\S 9301(d)(2)$ , substituted 'before the beginning of any year beginning with 1984' for "before October 1 of any year beginning with 1984", "on an assignment-related basis" for "on the basis of an assignment described in subsection (b)(3)(B)(ii) of this section, in accordance with subsection (b)(6)(B) of this section, or under the procedure described in section 1395gg(f)(1) of this title", "during such year" "during the 12-month period beginning on October 1 of such year", "after the beginning of a year" for "after October 1 of a year", and "during the remainder of the year" for "during the remainder of the 12-month period beginning on such October 1".

Subsec. (h)(2). Pub. L. 99-509, §9332(b)(1)(A), struck out period at end and substituted "and may request a copy of an appropriate directory published under paragraph (4). Each such carrier shall, without charge, mail a copy of such directory upon such a request.'

Subsec. (h)(4). Pub. L. 99-509, §9332(b)(2), inserted at end "Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians."

Pub. L. 99-272, §9301(c)(3)(D), redesignated par. (2) of subsec. (i) as par. (4) of this subsection.

Subsec. (h)(5). Pub. L. 99-509, §9332(b)(1)(B), substituted "the participation program under this subsection and the publication and availability of the directories" for "publication of the directories" and inserted at end "The Secretary shall include such notice in the mailing of appropriate benefit checks provided under subchapter II of this chapter.'

Pub. L. 99-514, §1895(b)(15)(A), struck out "such" before "the directories" and before "the appropriate area directory

Pub. L. 99-272, §9301(c)(3)(D), redesignated par. (3) of subsec. (i) as par. (5) of this subsection.

Subsec. (h)(6). Pub. L. 99-509, §9332(b)(1)(C), inserted before period at end of second sentence "and that an appropriate number of copies of each such directory is sent to hospitals located in the area" and inserted at end "Such copies shall be sent free of charge.

Pub. L. 99-514, §1895(b)(15)(B), substituted "the" for 'the the'' before "directories"

Pub. L. 99-272, §9301(c)(3)(D), redesignated par. (4) of subsec. (i) as par. (6) of this subsection.

Subsec. (h)(7), (8). Pub. L. 99-272, §9301(c)(4), added pars. (7) and (8).

Subsec. (i)(1). Pub. L. 99-272, §9301(c)(3)(A), struck out par. (1) which required the Secretary to publish a list containing the name, address, specialty, and percent of claims submitted with respect to each physician and supplier during preceding year that were paid on the basis of an assignment described in subsec. (b)(3)(B)(ii) of this section, in accordance with subsec. (b)(6)(B) of this section, or under procedure described in section 1395gg(f)(1) of this title.

Subsec. (i)(2). Pub. L. 99–272, 9301(c)(3)(D), redesignated par. (2) of this subsection as par. (4) of subsec. (h).

Pub. L. 99-272, §9301(d)(3), substituted "year" for "fiscal year", wherever appearing.

Pub. L. 99-272, §9301(c)(2)(A), (B), (3)(B), substituted "shall publish directories (for appropriate local geographic areas)" for "shall publish a directory", inserted "for that area" before "for that fiscal year", substituted "Each directory shall" for "The directory shall", and substituted "paragraph (1)" for "subsection (h)(1) of this section".

Subsec. (i)(3). Pub. L. 99–272, §9301(c)(3)(D), redesignation.

Subsec. (i)(3). Pub. L. 99-272, §9301(c)(3)(D), redesignated par. (3) of this subsection as par. (5) of subsec.

Pub. L. 99–272, §9301(c)(2)(C), (3)(C), struck out "directory" first place it appeared and inserted in lieu "the directories", struck out "directory" second place it appeared and inserted in lieu "the appropriate area directory or directories", and struck out "list and" wherever appearing.

Subsec. (i)(4). Pub. L. 99-272, §9301(c)(3)(D), redesignated par. (4) of this subsection as par. (6) of subsec.

Pub. L. 99–272, §9301(c)(2)(D), (3)(C), struck out "list and" after "The Secretary shall provide that the" in first sentence, substituted "the directories shall" for "directory shall", and inserted provision requiring the Secretary to provide that each appropriate area directory be sent to each participating physician located in that area.

Subsec. (j)(1). Pub. L. 99-509, §9331(b)(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C). Pub. L. 99-272, §9301(b)(2), amended first sentence gen-

Pub. L. 99–272, §9301(b)(2), amended first sentence generally. Prior to amendment, first sentence read as follows: "In the case of a physician who is not a participating physician, the Secretary shall monitor each such physician's actual charges to individuals enrolled under this part for physicians' services furnished during the 15-month period beginning July 1, 1984."

Subsec. (j)(2). Pub. L. 99–509, § 9320(e)(3), substituted "this paragraph" for "paragraph (1) or subsection (k) of this section" in introductory text.

Pub. L. 99-272, §9307(c)(1), inserted reference to subsec. (k) of this section in introductory text.

Subsec. (k). Pub. L. 99-514, §1895(b)(16)(A), inserted "presents or causes to be presented a claim or" in pars. (1) and (2).

Pub. L. 99-272, § 9307(c)(2), added subsec. (k).

Subsec. (l). Pub. L. 99–509, §9332(c)(1), added subsec.

Subsec. (m). Pub. L. 99–509, §9332(d)(1), added subsec.

1984—Subsec. (b)(2). Pub. L. 98–369, \$2326(c)(2), inserted at end provision that the Secretary publish in the Federal Register standards and criteria for efficient and effective performance of contract obligations under this section and provide an opportunity for public comment prior to implementation.

ment prior to implementation.

Subsec. (b)(3). Pub. L. 98-369, §2306(b)(1)(B), (C), substituted "during the 12-month period ending on the March 31 last preceding" for "during the last preceding calendar year elapsing prior to" in third sentence and substituted "October 1" for "July 1" wherever appearing in third and eighth sentences.

Pub. L. 98-369, §2354(b)(14), substituted "(I)" and "(II)" for "(i)" and "(ii)", respectively in concluding provisions.

Pub. L. 98-369, \$2663(j)(2)(F)(iv), substituted "Health and Human Services" for "Health, Education, and Welfare" in concluding provisions.

Subsec. (b)(3)(B)(ii)(II). Pub. L. 98–369, §2354(b)(13), struck out the period after "subchapter".

Subsec. (b)(3)(F). Pub. L. 98–369, §2306(b)(1)(A), substituted "September 30" for "June 30".

Subsec. (b)(4), (5). Pub. L. 98-369, \$2306(a), added par. (4) and redesignated former pars. (4) and (5) as (5) and (6), respectively.

Subsec. (b)(6). Pub. L. 98-369, §2339, redesignated cl. (A) as cl. (A)(i) and former cl. (B) as cl. (A)(ii), added a new cl. (B), and in the provisions after cl. (B), substituted "clause (A) of such sentence" for "clause (A) or (B) of such sentence".

Pub. L. 98-369, \$2306(a), redesignated par. (5) as (6). Former par. (6) redesignated (7).

Subsec. (b)(7). Pub. L. 98–369, §2306(a), redesignated par. (6) as (7).

Subsec. (b)(7)(A). Pub. L. 98–617,  $\S 3$ (b)(5)(B), struck out at end "If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished patients in the hospital on the basis of an assignment described in paragraph (3)(B)(ii) or under the procedure described in section 1395gg(f)(1) of this title, notwithstanding clause (ii) of this subparagraph, the carrier shall provide for payment in an amount equal to 90 percent of the prevailing charges paid for similar services in the same locality." Pub. L. 98–369,  $\S 2307(a)(1)$ , as amended by Pub. L.

Pub. L. 98-369, §2307(a)(1), as amended by Pub. L. 98-617, §3(a)(1), inserted "If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished patients in the hospital on the basis of an assignment described in paragraph (3)(B)(ii) or under the procedure described in section 1395gg(f)(1) of this title, notwithstanding clause (ii) of this subparagraph, the carrier shall provide for payment in an amount equal to 90 percent of the prevailing charges paid for similar services in the same locality." at the end.

Subsec. (b)(7)(A)(ii). Pub. L. 98-617, §3(b)(5)(A), substituted "the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B)" for "the amount of the payment exceeds the reasonable charge for the services (with the customary charge determined consistent with subparagraph (B)".

Subsec. (b)(7)(B)(i). Pub. L. 98–369, §2307(a)(2)(A), (B), substituted "physician who is not a teaching physician (as defined by the Secretary)" for "physician who has a substantial practice outside the teaching setting" and "practice outside the teaching setting" for "outside practice".

Subsec. (b)(7)(B)(ii). Pub. L. 98–369, §2307(a)(2)(C), (D), substituted "In the case of a teaching physician" for "In the case of a physician who does not have a practice described in clause (i)" and "greatest" for "greater".

Subsec. (b)(7)(B)(ii)(III). Pub. L. 98–369.

Subsec. (b)(7)(B)(ii)(III). Pub. L. 98–369 \$2307(a)(2)(E)-(G), added subcl. (III).

Subsec. (b)(7)(B)(iii). Pub. L. 98–617,  $\S 3$ (b)(6), added cl. (iii).

Subsec. (c). Pub. L. 98–369, §2326(d)(2), inserted provision that the Secretary, in determining a carrier's necessary and proper cost of administration with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract.

Subsec. (h). Pub. L. 98–369, §2306(c), added subsec. (h). Pub. L. 98–369, §2303(e), struck out subsec. (h) providing for payment for laboratory tests.

viding for payment for laboratory tests.
Subsecs. (i), (j). Pub. L. 98–369, §2306(c), added subsecs.
(i) and (j).

1982—Subsec. (b)(3)(B)(ii)(II). Pub. L. 97–248, \$128(d)(1), substituted "section 1395y(a)" for "section 1395y". Subsec. (b)(3). Pub. L. 97–248, \$104(a), in provisions

Subsec. (b)(3). Pub. L. 97–248, \$104(a), in provisions following subpar. (F), inserted provisions that in determining the reasonable charge for outpatient services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

Subsec. (b)(6)(D). Pub. L. 97–248, §113(a), added subpar.

1981—Subsec. (b)(3). Pub. L. 97-35 inserted provision that the amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1395x(v)(1)(K) of this

1980—Subsec. (b)(3). Pub. L. 96-499, §946(a), in provisions following subpar. (F), substituted "service is rendered" for "bill is submitted or the request for payment is made".

Subsec. (b)(3)(F). Pub. L. 96–499, 946(b), added subpar. (F).

Subsec. (b)(6). Pub. L. 96-499, §948(b), added par. (6). Subsec. (h). Pub. L. 96-499, §918(a)(1), added subsec. (h)

1977—Subsec. (b)(3). Pub. L. 95–216 provided that, with respect to power-operated wheelchairs for which payment may be made in accordance with section 1395x(s)(6) of this title, charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality

Subsec. (b)(5). Pub. L. 95–142 inserted provisions relating to payments under a reassignment or power of attorney in cases other than direct payments to physicians or service providers.

1976—Subsec. (b)(3). Pub. L. 94–368 substituted "for the twelve-month period beginning on July 1 in any calendar year after 1974" for "for the fiscal year beginning July 1, 1975,", "prior to the start of the twelve-month period (beginning July 1, of each year) in which the bill is submitted or the request for payment is made" for "prior to the start of the fiscal year in which the bill is submitted or the request for payment is made", and "for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence" for "for any fiscal year beginning after June 30, 1973).

1975—Subsec. (b)(3). Pub. L. 94–182 inserted provisions relating to raising for fiscal year beginning July 1, 1975 inadequate prevailing charge levels for services of physicians in certain localities.

1974—Subsec. (g). Pub. L. 93-445 substituted "section 231f(d) of title 45" for "section 228s-2(b) of title 45".

1972—Subsec. (a). Pub. L. 92–603, §227(e)(3), substituted "which involve payments for physicians' services on a reasonable charge basis" for "which involve payments for physicians' services".

Subsec. (b)(3). Pub. L. 92-603, §§ 244(a), 258(a), inserted provisions relating to determination of reasonableness of physician charges, medical services, supplies, and equipment and for the extension of time for filing claims for supplementary medical insurance benefits where the delay is due to administrative error, at end thereof.

Subsec. (b)(3)(B)(ii). Pub. L. 92–603, §§211(c)(3), 281(d), designated existing provisions as subcl. (I), added subcl. II, inserted exception in the case of services furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title.

Subsec. (b)(3)(C). Pub. L. 92-603, \$262(a), inserted provisions setting a \$100 minimum amount on claims to establish entitlement to a hearing.

Subsec. (b)(5). Pub. L. 92–603, §236(a), added par. (5). Subsec. (g). Pub. L. 92–603, §263(d)(5), added subsec.

1968—Subsec. (b)(3)(B). Pub. L. 90–248 provided that payment be made on the basis of an itemized bill instead of a receipted bill as formerly required, and established a time limit within which payment may be requested, and inserted "(except as otherwise provided in section 1395gg(f) of this title)" after "payment will".

#### Statutory Notes and Related Subsidiaries

#### CHANGE OF NAME

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

#### EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by section 5012(c)(2) of Pub. L. 114–255 applicable to items and services furnished on or after Jan.

1, 2019, see section 5012(d) of Pub. L. 114-255, set out as a note under section 1395l of this title.

Pub. L. 114-255, div. C, title XVI, §16006(b), Dec. 13, 2016, 130 Stat. 1328, provided that:

"(1) EFFECTIVE DATE.—The amendments made by subsection (a) [amending this section] shall apply to services furnished beginning not later than six months after the date of the enactment of this Act [Dec. 13, 2016].

"(2) IMPLEMENTATION.—The Secretary of Health and Human Services may implement subparagraph (J) of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as added by subsection (a)(2), by program instruction or otherwise."

#### EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–40 applicable to contracts entered into or renewed on or after Jan. 1, 2012, see section 261(e) of Pub. L. 112–40, set out as a note under section 1320c of this title.

#### EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 6404(a)(2)(A) of Pub. L. 111–148 applicable to services furnished on or after Jan. 1, 2010, and in case of services furnished before Jan. 1, 2010, a bill or request for payment under 42 U.S.C. 1395u(b)(3)(B) to be filed not later than Dec. 31, 2010, see section 6404(b) of Pub. L. 111–148, set out as a note under section 1395f of this title.

Amendment by section 6406(a) of Pub. L. 111-148 applicable to orders, certifications, and referrals made on or after Jan. 1, 2010, see section 6406(d) of Pub. L. 111-148, set out as a note under section 1320a-7 of this title.

#### EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 154(a)(2)(B) of Pub. L. 110–275 effective June 30, 2008, see section 154(e) of Pub. L. 110–275, set out as a note under section 1395m of this title.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110-54, §1(b), Aug. 3, 2007, 121 Stat. 551, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after the date of the enactment of this section [Aug. 3, 2007]."

#### EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §110(b), Dec. 20, 2006, 120 Stat. 2985, provided that: "The amendment made by subsection (a) [amending this section] shall apply to drugs furnished on or after January 1, 2008. The Secretary of Health and Human Services shall address the implementation of such amendment in the rulemaking process under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for payment for physicians' services for 2008, consistent with the previous sentence."

Pub. L. 109–432, div. B, title II, §205(c), Dec. 20, 2006, 120 Stat. 2990, provided that: "The amendments made by this section [amending this section, section 1395ww of this title, and provisions set out as a note under section 1395eee of this title] shall take effect as if included in the enactment of the Deficit Reduction Act of 2005 (Public Law 109–171)."

Pub. L. 109–432, div. B, title IV, §405(c)(2)(A), Dec. 20, 2006, 120 Stat. 2999, provided that the amendment made by section 405(c)(2)(A) is effective as if included in the enactment of the Deficit Reduction Act of 2005 (Public Law 109–171).

Pub. L. 109–171, title V, §5114(c), Feb. 8, 2006, 120 Stat. 45, provided that: "The amendments made by this section [amending this section and section 1395x of this title] shall apply to services furnished on or after January 1, 2006."

Amendment by section 5202(a)(2) of Pub. L. 109–171 applicable to claims submitted on or after Jan. 1, 2006, see section 5202(b) of Pub. L. 109–171, set out as a note under section 1395h of this title.

#### EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 627(b)(2) of Pub. L. 108–173 applicable to items furnished on or after Jan. 1, 2005, see section 627(c) of Pub. L. 108–173, set out as a note under section 1395/ of this title.

Amendment by section 911(c) of Pub. L. 108–173 effective Oct. 1, 2005, except as otherwise provided, with transition rules authorizing Secretary of Health and Human Services to continue to enter into contracts under this section prior to such date, and provisions authorizing continuation of Medicare Integrity Program functions during the period that begins on Dec. 8, 2003, and ends on Oct. 1, 2011, see section 911(d) of Pub. L. 108–173, set out as an Effective Date; Transition Rule note under section 1395kk–1 of this title.

Pub. L. 108–173, title IX, §952(c), Dec. 8, 2003, 117 Stat. 2427, provided that: "The amendments made by this section [amending this section] shall apply to payments made on or after the date of the enactment of this Act [Dec. 8, 2003]."

#### EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title I,  $\S105(d)$ ] of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I,  $\S105(e)$ ] of Pub. L. 106-554, set out as a note under section 1395l of this title.

Pub. L. 106-554, \$1(a)(6) [title I, \$114(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-474, provided that: "The amendment made by subsection (a) [amending this section] shall apply to items furnished on or after January 1, 2001"

Pub. L. 106-554, §1(a)(6) [title II, §222(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-487, provided that: "The amendments made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 21, 2000]."

Pub. L. 106-554, \$1(a)(6) [title III, \$313(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A-499, provided that: "The amendments made by subsections (a) and (b) [amending this section and sections 1395y and 1395cc of this title] shall apply to services furnished on or after January 1, 2001."

Pub. L. 106-554, \$1(a)(6) [title IV, \$432(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A-526, provided that: "The amendments made by this section [amending this section and sections 1395y and 1395qq of this title] shall apply to services furnished on or after July 1, 2001."

#### EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, \$1000(a)(6) [title III, \$305(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–362, provided that: "The amendments made by this section [amending this section and section 1395y of this title] shall apply to payments for services provided on or after the date of enactment of this Act [Nov. 29, 1999]."

Amendment by section 1000(a)(6) [title III, §321(k)(4)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

#### EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4201(c)(1) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4205(d)(3)(B) of Pub. L. 105-33 effective Aug. 5, 1997, see section 4205(d)(4) of Pub. L. 105-33, set out as a note under section 1395x of this title.

Pub. L. 105-33, title IV, §4302(c), Aug. 5, 1997, 111 Stat. 382, provided that: "The amendments made by this section [amending this section and section 1395cc of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and apply to the entry and renewal of contracts on or after such date."

Amendment by section 4315(a) of Pub. L. 105-33, to the extent such amendment substitutes fee schedules for

reasonable charges, applicable to particular services as of date specified by the Secretary of Health and Human Services, see section 4315(c) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4316(a) of Pub. L. 105–33 effective Aug. 5, 1997, see section 4316(c) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Pub. L. 105-33, title IV, §4317(c), Aug. 5, 1997, 111 Stat. 392, provided that: "The amendments made by this section [amending this section] shall apply to items and services furnished on or after January 1, 1998."

Amendment by section 4432(b)(2), (4) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 of this title.

Amendment by section 4512(b)(2), (c) of Pub. L. 105–33 applicable with respect to services furnished and supplies provided on and after Jan. 1, 1998, see section 4512(d) of Pub. L. 105–33, set out as a note under section 13957 of this title.

Amendment by section 4556(a) of Pub. L. 105–33 applicable to drugs and biologicals furnished on or after Jan. 1, 1998, see section 4556(d) of Pub. L. 105–33, set out as a note under section 1395/ of this title.

Amendment by section 4603(c)(2)(B)(i) of Pub. L. 105–33 applicable to cost reporting periods beginning on or after Oct. 1, 1999, except as otherwise provided, see section 4603(d) of Pub. L. 105–33, set out as an Effective Date note under section 1395fff of this title.

Amendment by section 4611(d) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, and for purposes of applying such amendment, any home health spell of illness that began, but did not end, before such date, to be considered to have begun as of such date, see section 4611(f) of Pub. L. 105–33, set out as a note under section 1395d of this title.

#### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 123(b)(1), (2)(B) of Pub. L. 103-432 applicable to services furnished on or after Jan. 1, 1995, see section 123(f)(2) of Pub. L. 103-432, set out as a note under section 1395l of this title.

Pub. L. 103-432, title I, §123(f)(3), (4), Oct. 31, 1994, 108 Stat. 4413, provided that:

"(3) EOMBs.—The amendments made by subsection (c)(1) [amending this section] shall apply to explanations of benefits provided on or after July 1, 1995.

"(4) CARRIER DETERMINATIONS.—The amendments made by subsection (c)(2) [amending this section] shall apply to contracts as of January 1, 1995."

Pub. L. 103-432, title I, \$125(b)(2), Oct. 31, 1994, 108 Stat. 4414, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after the first day of the first month beginning more than 60 days after the date of the enactment of this Act [Oct. 31, 1994]."

Amendment by section 126(a)(1), (c), (e), (g)(9) of Pub. L. 103-432 effective as if included in the enactment of Pub. L. 101-508, see section 126(i) of Pub. L. 103-432, set out as a note under section 1395m of this title.

Pub. L. 103-432, title I, \$126(h)(2), Oct. 31, 1994, 108 Stat. 4416, provided that the amendment made by that section is effective for payments for fiscal years beginning with fiscal year 1994.

Pub. L. 103-432, title I, §135(b)(2), Oct. 31, 1994, 108 Stat. 4423, provided that the amendment made by that section is effective for standards applied for contract years beginning after Oct. 31, 1994.

Amendment by section 151(b)(1)(B), (2)(B) of Pub. L. 103-432 applicable to contracts with fiscal intermediaries and carriers under this subchapter for contract years beginning with 1995, see section 151(b)(4) of Pub. L. 103-432, set out as a note under section 1395h of this title.

#### EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103-66, title XIII, §13515(d), Aug. 10, 1993, 107 Stat. 583, provided that: "The amendments made by subsection (a) [amending this section and section 1395w-4 of this title] shall apply to services furnished on or after January 1, 1994."

Amendment by section 13568(a), (b) of Pub. L. 103–66 applicable to claims received on or after Oct. 1, 1993, see section 13568(c) of Pub. L. 103–66, set out as a note under section 1395h of this title.

#### EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV,  $\S4105(b)(3)$ , Nov. 5, 1990, 104 Stat. 1388–60, as amended by Pub. L. 103–432, title I,  $\S126(g)(2)(A)(ii)$ , Oct. 31, 1994, 108 Stat. 4415, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after January 1, 1991."

Pub. L. 101-508, title IV, \$4106(d), Nov. 5, 1990, 104 Stat. 1388-62, provided that:

"(1) The amendments made by subsection (a) [amending this section and provisions set out below] apply to services furnished after 1990, except that—

"(A) the provisions concerning the third and fourth years of practice apply only to physicians' services furnished after 1990 and 1991, respectively, and

"(B) the provisions concerning the second, third, and fourth years of practice apply only to services of a health care practitioner furnished after 1991, 1992, and 1993, respectively.

"(2) The amendments made by subsection (b) [amending this section and section 1395w-4 of this title] shall apply to services furnished after 1991."

Pub. L. 101-508, title IV, §4108(b), Nov. 5, 1990, 104 Stat. 1388-63, provided that: "The amendment made by subsection (a) [amending this section] shall apply to tests and services furnished on or after January 1, 1991."

Pub. L. 101–508, title IV, §4110(b), Nov. 5, 1990, 104 Stat. 1388–64, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after the first day of the first month beginning more than 60 days after the date of the enactment of this Act [Nov. 5, 1990]."

Pub. L. 101-508, title IV, §4118(a)(3), Nov. 5, 1990, 104 Stat. 1388-67, provided that: "The amendments made by paragraphs (1) and (2) [amending this section] apply to services furnished after March 1990."

Pub. L. 101–508, title IV,  $\S4118(f)(2)(A)$ , Nov. 5, 1990, 104 Stat. 1388–69, provided that the amendment by that section is effective as if included in the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239.

Pub. L. 101–508, title IV, §4118(f)(2)(B), Nov. 5, 1990, 104 Stat. 1388–69, provided that the amendment by that section is effective Jan. 1, 1991.

Amendment by section 4155(c) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4155(e) of Pub. L. 101–508, set out as a note under section 1395k of this title.

#### EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6102(e)(3), Dec. 19, 1989, 103 Stat. 2187, provided that the amendment made by that section is effective for physicians' services furnished on or after Jan. 1, 1992.

Pub. L. 101-239, title VI, §6106(b), Dec. 19, 1989, 103 Stat. 2210, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1990."

Pub. L. 101–239, title VI, §6108(a)(2), Dec. 19, 1989, 103 Stat. 2212, as amended by Pub. L. 101–508, title IV, §4106(a)(2), Nov. 5, 1990, 104 Stat. 1388–61, provided that:

"(A) Subject to subparagraph (B), the amendments made by paragraph (1) [amending this section] apply to services furnished in 1990 or 1991 which were subject to the first sentence of section 1842(b)(4)(F) of the Social Security Act [42 U.S.C. 1395u(b)(4)(F)] in 1989 or 1990.

"(B) The amendments made by paragraph (1) shall not apply to services furnished in 1990 before April 1, 1990. With respect to physicians' services furnished during 1990 on and after April 1, such amendments shall be applied as though any reference, in the matter inserted by such amendments, to the 'first calendar year during

which the preceding sentence no longer applies' were deemed a reference to the remainder of 1990."

Pub. L. 101–239, title VI, §6108(b)(3), Dec. 19, 1989, 103 Stat. 2213, provided that: "The amendments made by this subsection [amending this section] apply to procedures performed after March 31, 1990."

Pub. L. 101-239, title VI, §6114(f), Dec. 19, 1989, 103 Stat. 2218, provided that: "The amendments made by this section [amending this section and section 1395x of this title] shall apply to services furnished on or after April 1, 1990."

Amendment by section 6202(d)(2) of Pub. L. 101–239 applicable to agreements and contracts entered into or renewed on or after Dec. 19, 1989, see section 6202(d)(3) of Pub. L. 101–239, set out as a note under section 1395h of this title.

Amendment by section 201(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a-7a of this title.

Pub. L. 101–234, title III, §301(e), Dec. 13, 1989, 103 Stat. 1986, provided that: "The provisions of this section [amending this section and sections 1395m, 1395cc, 1395ll, and 1395wv of this title, enacting provisions set out as notes under section 1395m of this title, and repealing provisions set out as notes under sections 1395b, 1395b–1, 1395b–2, and 1395h of this title and section 8902 of Title 5, Government Organization and Employees] (other than subsections (c) and (d) [amending this section and sections 1395m, 1395cc, 1395ll, and 1395wv of this title and enacting provisions set out as a note under section 1395m of this title]) shall take effect January 1, 1990, except that—

"(1) the repeal of certical 451 and 1305m, 1

"(1) the repeal of section 421 of MCCA [Pub. L. 100-360, set out as a note under section 1395b of this title] shall not apply to duplicative part A benefits for periods before January 1, 1990, and

"(2) the amendments made by subsection (b) [amending this section and sections 1395m, 1395cc, 1395ll, and 1395ww of this title] shall take effect on the date of the enactment of this Act [Dec. 13, 1989]."

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Pub. L. 100–360, title II, §202(m), July 1, 1988, 102 Stat. 721, as amended by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981, provided that:

"(1) [Repealed. Prior to repeal by Pub. L. 101–234, par. (1) read as follows: 'IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section [enacting section 1395w–3 of this title and amending this section and sections 1320a–7a, 1395l, 1395m, 1395x, 1395y, 1395cc, 1395mm, and 1396b of this title] shall apply to items dispensed on or after January 1, 1990.']

"(2) [Repealed. Prior to repeal by Pub. L. 101–234, par. (2) read as follows: 'Carriers.—The amendments made by subsection (e) [amending this section] shall take effect on the date of the enactment of this Act [July 1, 1988]; except that the amendments made by subsection (e)(5) [amending this section] shall take effect on January 1, 1991, but shall not be construed as requiring payment before February 1, 1991.']

"(3) [Repealed. Prior to repeal by Pub. L. 101–234, par. (3) read as follows: 'HMO/CMP ENROLLMENTS.—The amendment made by subsection (f) [amending section 1395mm of this title] shall apply to enrollments effected on or after January 1, 1990.']

"(4) DIAGNOSTIC CODING.—The amendment made by subsection (g) [amending this section] shall apply to services furnished after March 31, 1989.

"(5) [Repealed. Prior to repeal by Pub. L. 101–234, par. (5) read as follows: 'TRANSITION.—With respect to administrative expenses (and costs of the Prescription Drug Payment Review Commission) for periods before January 1, 1990, amounts otherwise payable from the Federal Catastrophic Drug Insurance Trust Fund shall

be payable from the Federal Supplementary Medical Insurance Trust Fund and shall also be treated as a debit to the Medicare Catastrophic Coverage Account.'l."

[Amendment of section 202(m) of Pub. L. 100–360, set out above, effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as an Effective Date of 1989 Amendment note under section 1320a–7a of this title.]

Pub. L. 100–360, title II, 223(d)(2), (3), July 1, 1988, 102 Stat. 748, provided that:

"(2) The amendments made by subsection (b) [amending this section] shall apply to annual notices beginning with 1989.

"(3) The amendments made by subsection (c) [amending this section] shall first apply to explanations of benefits provided for items and services furnished on or after January 1, 1989."

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(a)(3)(A), (C)(i), (f)(1)(A), (B), (2)–(4)(C), (5), (6)(B), (7), (9), (11)(A), (14), (g)(2)(A)–(C), (i)(1)(A), (2), (4)(C)(vi), and (j)(4)(A) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

#### EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by section 4031(a)(2) of Pub. L. 100-203 applicable to claims received on or after July 1, 1988, see section 4031(a)(3)(A) of Pub. L. 100-203, set out as a note under section 1395h of this title.

Amendment by section 4035(a)(2) of Pub. L. 100–203 effective Dec. 22, 1987, and applicable to budgets for fiscal years beginning with fiscal year 1989, see section 4035(a)(3) of Pub. L. 100–203, set out as a note under section 1395h of this title.

Pub. L. 100-203, title IV, §4044(b), Dec. 22, 1987, 101 Stat. 1330-86, provided that: "The amendments made by subsection (a) [amending this section] shall apply to payment for physicians' services furnished on or after January 1, 1989."

Pub. L. 100–203, title IV, §4045(d), Dec. 22, 1987, 101 Stat. 1330–88, provided that: "The amendments made by this section [amending this section and sections 1395\( \) and 1395\( \)—1 of this title and amending provisions set out below] shall apply to items and services furnished on or after April 1, 1988, except the amendment made by subsection (c)(2)(B) [amending this section] shall apply to services furnished on or after January 1, 1988."

apply to services furnished on or after January 1, 1988." Pub. L. 100-203, title IV, §4046(b), Dec. 22, 1987, 101 Stat. 1330-89, provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988."

services furnished on or after April 1, 1988."

Pub. L. 100–203, title IV, §4047(b), Dec. 22, 1987, 101

Stat. 1330–89, as amended by Pub. L. 100–360, title IV, §411(f)(6)(C), July 1, 1988, 102 Stat. 779, provided that: "The amendment made by subsection (a) [amending this section] shall apply to physicians who first furnish services to medicare beneficiaries on or after April 1, 1988."

Pub. L. 100-203, title IV, §4051(c), Dec. 22, 1987, 101 Stat. 1330-94, provided that:

"(1) The amendment made by subsection (a) [amending this section] shall apply to diagnostic tests performed on or after April 1, 1988.

"(2) The Secretary of Health and Human Services shall complete the review and make an appropriate adjustment of prevailing charge levels under subsection (b) [set out below] for items and services furnished no later than January 1, 1989."

Pub. L. 100-203, title IV, §4053(b), formerly §4052(b), Dec. 22, 1987, 101 Stat. 1330-97, as renumbered and amended by Pub. L. 100-360, title IV, §411(f)(11)(B), (14), July 1, 1988, 102 Stat. 781, provided that: "The amendment made by subsection (a) [amending this section] shall apply to payment for services furnished on or after April 1, 1988."

Pub. L. 100-203, title IV, §4054(c), formerly §4053(c), Dec. 22, 1987, 101 Stat. 1330-97, as renumbered by Pub. L.

100-360, title IV, §411(f)(14), July 1, 1988, 102 Stat. 781, provided that: "The amendment made by subsection (a) [amending this section] shall apply to charges imposed for services furnished on or after April 1, 1988."

Amendment by section 4063(a) of Pub. L. 100-203 applicable to items furnished on or after July 1, 1988, see section 4063(c) of Pub. L. 100-203, set out as a note under section 1395(f) of this title

section 1395(*l*) of this title.

Pub. L. 100–203, title IV, §4081(c)(1), Dec. 22, 1987, 101

Stat. 1330–127, provided that: "The amendment made by subsection (a) [amending this section] shall apply to contracts with carriers for claims for items and services furnished by participating physicians and suppliers on or after January 1, 1989."

on or after January 1, 1989." Pub. L. 100–203, title IV, §4082(e)(3), Dec. 22, 1987, 101 Stat. 1330–129, provided that: "The amendments made by subsection (c) [amending this section] shall apply to evaluation of performance of carriers under contracts entered into or renewed on or after October 1, 1988."

Pub. L. 100–203, title IV, §4085(g)(2), Dec. 22, 1987, 101 Stat. 1330–131, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective as if included in section 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985 [Pub. L. 99–272]."

Pub. L. 100-203, title IV, §4085(i)(7), Dec. 22, 1987, 101 Stat. 1330-132, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 99-509.

Amendment by section 4096(a)(1) of Pub. L. 100–203 applicable to services furnished on or after Jan. 1, 1988, see section 4096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

Amendment by Pub. L. 100-93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100-93, set out as a note under section 1320a-7 of this title.

#### EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-514, title XVIII, §1895(b)(16)(B), Oct. 22, 1986, 100 Stat. 2934, provided that: "The amendment made by subparagraph (A) [amending this section] shall apply to claims presented after the date of the enactment of this Act [Oct. 22, 1986]."

Amendment by section 1895(b)(14)(A), (15) of Pub. L.

Amendment by section 1895(b)(14)(A), (15) of Pub. L. 99-514 effective, except as otherwise provided, as if included in enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99-272, see section 1895(e) of Pub. L. 99-514, set out as a note under section 162 of Title 26, Internal Revenue Code.

section 162 of Title 26, Internal Revenue Code. Pub. L. 99–509, title IX, \$9307(c)(2), Oct. 21, 1986, 100 Stat. 1995, provided that the amendment made by section 9307(c)(2)(A) of Pub. L. 99–509 [amending directory language of section 1895(b)(14)(A)(ii) of Pub. L. 99–514 which amended this section] is effective as if included in the enactment of the Tax Reform Act of 1986, Pub. L. 99–514.

Amendment by section 9311(c) of Pub. L. 99–509 applicable to claims received on or after Nov. 1, 1986, with subsec. (c)(2)(C) of this section applicable to claims received on or after Apr. 1, 1987, see section 9311(d) of Pub. L. 99–509, set out as a note under section 1395h of this title.

Amendment by section 9320(e)(3) of Pub. L. 99–509 applicable to services furnished on or after Jan. 1, 1989, with exceptions for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9320(i), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395k of this title.

Pub. L. 99-509, title IX, \$9331(a)(4), Oct. 21, 1986, 100 Stat. 2019, provided that: "The amendments made by this subsection [amending this section] shall apply to services furnished on or after January 1, 1987."

Pub. L. 99–509, title IX, §9331(b)(4), Oct. 21, 1986, 100 Stat. 2020, provided that: "The amendments made by this subsection [amending this section] shall apply to services furnished on or after January 1, 1987."

Pub. L. 99–509, title IX, \$9331(0)(3)(B), Oct. 21, 1986, 100 Stat. 2021, provided that: "The amendments made by

subparagraph (A) [amending this section] shall apply to physicians' services furnished on or after January 1, 1988."

Pub. L. 99-509, title IX, §9332(a)(4)(A), Oct. 21, 1986, 100 Stat. 2023, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective for contracts under section 1842 of the Social Security Act [42 U.S.C. 1395u] as of October 1, 1987."

Pub. L. 99-509, title IX, §9332(b)(3), Oct. 21, 1986, 100 Stat. 2023, provided that: "The amendments made by this paragraph [probably means 'this subsection' which amended this section] shall first apply to directories for 1987."

Pub. L. 99-509, title IX, §9332(c)(2), Oct. 21, 1986, 100 Stat. 2024, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after October 1, 1987."

Pub. L. 99–509, title IX, §9332(d)(2), Oct. 21, 1986, 100 Stat. 2025, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to surgical procedures performed on or after October 1, 1987."

Pub. L. 99-509, title IX, §9333(d), Oct. 21, 1986, 100 Stat. 2028, provided that: "The amendments made by this section [amending this section] shall take effect on the date of the enactment of this Act [Oct. 21, 1986]."

Pub. L. 99-509, title IX, §9334(c), Oct. 21, 1986, 100 Stat. 2029, provided that: "The amendments made by this section [amending this section] shall apply to services furnished on or after January 1, 1987."

Amendment by section 9338(b), (c) of Pub. L. 99-509

Amendment by section 9338(b), (c) of Pub. L. 99-509 applicable to services furnished on or after Jan. 1, 1987, see section 9338(f) of Pub. L. 99-509 set out as a note under section 1395x of this title.

Amendment by section 9341(a)(2) of Pub. L. 99–509 applicable to items and services furnished on or after Jan. 1, 1987, see section 9341(b) of Pub. L. 99–509, set out as a note under section 1395ff of this title.

Pub. L. 99–272, title IX, \$9219(b)(1)(D), Apr. 7, 1986, 100 Stat. 183, provided that: "The amendments made by this paragraph [amending this section and sections 1395x and 1395yy of this title] shall be effective as if they had been originally included in the Deficit Reduction Act of 1984 [Pub. L. 98–369]."

rion Act of 1984 [Pub. L. 98-369]."
Pub. L. 99-272, title IX, §9219(b)(2)(B), Apr. 7, 1986, 100
Stat. 183, provided that: "The amendment made by subparagraph (A) [amending this section] shall be effective as if it had been originally included in Public Law

Pub. L. 99–272, title IX, \$9301(b)(4), Apr. 7, 1986, 100 Stat. 186, provided that: "The amendments made by this subsection [amending this section and enacting provisions set out as a note under this section] shall apply to services furnished on or after May 1, 1986."

Pub. L. 99–272, title IX, §9301(c)(5), Apr. 7, 1986, 100 Stat. 187, as amended by Pub. L. 99–514, title XVIII, §1895(b)(14)(B), Oct. 22, 1986, 100 Stat. 2934, provided that: "Section 1842(h)(7) of the Social Security Act [42 U.S.C. 1395u(h)(7)], as added by paragraph (4) of this subsection, shall apply to explanations of benefits provided on or after such date (not later than October 1, 1986) as the Secretary of Health and Human Services shall specify."

Pub. L. 99–272, title IX, §9301(d)(4), Apr. 7, 1986, 100 Stat. 188, provided that: "The amendments made by this subsection [amending this section and enacting provisions set out as a note under this section] shall apply to items and services furnished on or after October 1, 1986."

Pub. L. 99–272, title IX, §9306(b), Apr. 7, 1986, 100 Stat. 193, provided that: "The amendments made by this section [amending this section] shall apply to items and services furnished on or after April 1, 1986."

services furnished on or after April 1, 1986." Amendment by section 9307(c) of Pub. L. 99–272 applicable to services performed on or after April 1, 1986, see section 9307(e) of Pub. L. 99–272, set out as a note under section 1320c–3 of this title.

#### EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L.

98--369, see section 3(c) of Pub. L. 98-617, set out as a note under section 1395f of this title.

Amendment by section 2303(e) of Pub. L. 98–369 applicable to clinical diagnostic laboratory tests furnished on or after July 1, 1984, but not applicable to clinical diagnostic laboratory tests furnished to inpatients of a provider operating under a waiver granted pursuant to section 602(k) of Pub. L. 98–21, set out as a note under section 1395y of this title, see section 2303(j)(1), (3) of Pub. L. 98–369, set out as a note under section 1395l of this title.

Pub. L. 98-369, div. B, title III, §2306(b)(2), July 18, 1984, 98 Stat. 1071, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to items and services furnished on or after October 1, 1985."

Pub. L. 98–369, div. B, title III, §2307(a)(3), July 18, 1984, 98 Stat. 1073, provided that: "The amendments made by this subsection [amending this section] shall apply to services furnished on or after July 1, 1984."

Amendment by section 2326(d)(2) of Pub. L. 98-369 applicable to agreements and contracts entered into or renewed after Sept. 30, 1984, see section 2326(d)(3) of Pub. L. 98-369, set out as a note under section 1395h of this title.

Amendment by section 2354(b)(13), (14) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

Amendment by section 2663(j)(2)(F)(iv) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2664(b) of Pub. L. 98–369, set out as a note under section 401 of this title.

#### Effective Date of 1982 Amendment

Pub. L. 97–248, title I, §104(b), Sept. 3, 1982, 96 Stat. 337, as amended by Pub. L. 97–448, title III, §309(a)(2), Jan. 12, 1983, 96 Stat. 2408, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to services furnished on or after October 1, 1982."

Pub. L. 97–248, title I, §113(b)(1), Sept. 3, 1982, 96 Stat. 341, provided that: "The amendment made by subsection (a) [amending this section] is effective with respect to services performed on or after October 1, 1982."

Amendment by section 128(d)(1) of Pub. L. 97–248 effective Sept. 3, 1982, see section 128(e)(3) of Pub. L. 97–248, set out as a note under section 1395x of this title.

#### EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96–499, title IX, §918(a)(2), Dec. 5, 1980, 94 Stat. 2626, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to bills submitted and requests for payment made on or after such date (not later than April 1, 1981) as the Secretary of Health and Human Services prescribes by a notice published in the Federal Register."

Pub. L. 96-499, title IX, §946(c), Dec. 5, 1980, 94 Stat. 2643, provided that: "The amendments made by subsections (a) and (b) [amending this section] shall become effective with respect to bills submitted or requests for payment made on or after July 1, 1981."

Pub. L. 96-499, title IX, §948(c)(2), Dec. 5, 1980, 94 Stat. 2645, provided that: "The amendment made by subsection (b) [amending this section] shall apply with respect to cost accounting periods beginning on or after January 1, 1981."

#### EFFECTIVE DATE OF 1977 AMENDMENT

Amendment by Pub. L. 95–216 effective in the case of items and services furnished after Dec. 20, 1977, see section 501(c) of Pub. L. 95–216, set out as a note under section 1395x of this title.

Amendment by Pub. L. 95-142 applicable with respect to care and services furnished on or after Oct. 25, 1977,

see section 2(a)(4) of Pub. L. 95–142, set out as a note under section 1395g of this title.

#### EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94-368, §4, July 16, 1976, 90 Stat. 997, provided that: "The amendments made by sections 2 and 3 of this Act [amending this section and provisions set out as a note under section 390e of Title 7, Agriculture] shall be effective with respect to periods beginning after June 30, 1976; except that, for the twelve-month period beginning July 1, 1976, the amendments made by section 3 [amending this section and provisions set out as a note under section 390e of Title 7, Agriculture] shall be applicable with respect to claims filed under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] (after June 30, 1976, and before July 1, 1977) with a carrier designated pursuant to section 1842 of such Act [42 U.S.C. 1395u], and processed by such carrier after the appropriate changes were made pursuant to such section 3 in the prevailing charge levels for such twelve-month period under the third and fourth sentences of section 1842(b)(3) of the Social Security Act [42 U.S.C. 1395u(b)(3)].

#### EFFECTIVE DATE OF 1974 AMENDMENT

Amendment by Pub. L. 93-445 effective Jan. 1, 1975, see section 603 of Pub. L. 93-445, set out as a note under section 402 of this title.

#### EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 211(c)(3) of Pub. L. 92–603 applicable to services furnished with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 92–603, set out as a note under section 1395f of this title

Amendment by section 227(e)(3) of Pub. L. 92–603 applicable with respect to accounting periods beginning after June 30, 1973, see section 227(g) of Pub. L. 92–603, set out as a note under section 1395x of this title.

Pub. L. 92-603, title II, §236(c), Oct. 30, 1972, 86 Stat. 1415, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to bills submitted and requests for payments made after the date of the enactment of this Act [Oct. 30, 1972]. The amendments made by subsection (b) [amending section 1396a of this title] shall be effective January 1, 1973 (or earlier if the State plan so provides)."

Pub. L. 92–603, title II, §258(b), Oct. 30, 1972, 86 Stat. 1447, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to bills submitted and requests for payment made after March 1968."

Pub. L. 92-603, title II, §262(b), Oct. 30, 1972, 86 Stat. 1448, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to hearings requested (under the procedures established under section 1842(b)(3)(C) of the Social Security Act [42 U.S.C. 1395u(b)(3)(C)]) after the date of the enactment of this Act [Oct. 30, 1972]."

Amendment by section 263(d)(5) of Pub. L. 92–603 with respect to collection of premiums applicable to premiums becoming due and payable after the fourth month following the month of enactment of Pub. L. 92–603 which was approved on Oct. 30, 1972, see section 263(f) of Pub. L. 92–603, set out as a note under section 1395s of this title.

Amendment by section 281(d) of Pub. L. 92-603 to apply in the case of notices sent to individuals after 1968, see section 281(g) of Pub. L. 92-603, set out as a note under section 1395gg of this title.

#### EFFECTIVE DATE OF 1968 AMENDMENT

Pub. L. 90–248, title I, §125(b), Jan. 2, 1968, 81 Stat. 846, provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to claims on which a final determination has not been made on or before the date of enactment of this Act [Jan. 2, 1968]."

#### TRANSFER OF FUNCTIONS

Physician Payment Review Commission (PPRC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 4022(c)(2), (3) of Pub. L. 105–33, set out as a note under section 1395b–6 of this title. Section 4022(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by PPRC, and that, for that purpose, any reference in law to PPRC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

#### PART B ADVANCE PAYMENTS

Pub. L. 116–159, div. C, title V,  $\S2501(a)(2),$  Oct. 1, 2020, 134 Stat. 735, provided that:

"(A) IN GENERAL.—In the case of a payment made under the terms of the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation) on or after the date of the enactment of the CARES Act (Public Law 116–136) [Mar. 27, 2020] and so made during the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)), the Secretary of Health and Human Services shall, upon request of the provider of services or supplier receiving such payment—

"(i) provide 1 year before payments for items and services furnished by such provider or supplier are offset to recoup payments under such program;

"(ii) provide that any such offset be an amount equal to—

"(I) during the first 11 months in which any such offsets are made with respect to payment for items and services furnished by such provider or supplier, 25 percent of the amount of such payment for such items and services: and

"(II) during the succeeding 6 months, 50 percent of the amount of such payment for such items and services; and

"(iii) allow 29 months from the date of the first payment under such program to such provider or supplier before requiring that the outstanding balance be paid in full. "(B) LIMITATION ON FURTHER PART B ADVANCE PAY-

"(B) LIMITATION ON FURTHER PART B ADVANCE PAY-MENTS.—With respect to the period of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b-5(g)(1)(B)) beginning on the date of the enactment of this Act [Oct. 1, 2020], the total amount of payments made under the terms of the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation)—

"(i) for the portion of 2020 occurring during such period of the emergency period and for each year, shall not exceed \$10.000.000:

"(ii) for each year beginning and ending during such period of the emergency period, shall not exceed \$10,000,000; and

"(iii) for the last year beginning during such period of the emergency period, the portion of such last year occurring during such period of the emergency period, shall not exceed \$10,000,000."

LINKAGE OF REVISED DRUG PAYMENTS AND INCREASES FOR DRUG ADMINISTRATION

Pub. L. 108–173, title III, §303(f), Dec. 8, 2003, 117 Stat. 2253, provided that: "The Secretary [of Health and Human Services] shall not implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments made by subsection (b) [amending this section] with respect to 2004 unless the Secretary concurrently makes adjustments to the practice expense payment adjustment under the amendments made by subsection (a) [amending section 1395w–4 of this title]."

### CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS

Pub. L. 108–173, title III, \$303(h), Dec. 8, 2003, 117 Stat. 2253, provided that: "Nothing in the amendments made by this section [enacting sections 1395w–3a and 1395w–3b

of this title, amending this section and sections 1395*l*, 1395w-4, 1395x, 1395y, and 1396r-8 of this title, and repealing provisions set out as a note under this section] shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for radiopharmaceuticals, including the use by carriers of invoice pricing methodology."

#### IMPLEMENTATION OF 2003 AMENDMENT

Pub. L. 108–173, title III, §303(i)(5), Dec. 8, 2003, 117 Stat. 2255, provided that: "The provisions of chapter 8 of title 5, United States Code, shall not apply with respect to regulations implementing the amendments made by subsections (a), (b), and (e)(3) [sic] [amending this section and section 1395w-4 of this title], to regulations implementing section 304 [set out as a note under this section], and to regulations implementing the amendment made by section 305(a) [amending this section], insofar as such regulations apply in 2004."

### APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Pub. L. 108–173, title III, §303(j), Dec. 8, 2003, 117 Stat. 2255, provided that: "Insofar as the amendments made by this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395l–1395w–4, 1395x, 1395y, and 1396r–8 of this title, and repealing provisions set out as a note under this section] apply to payments for drugs or biologicals and drug administration services furnished by physicians, such amendments shall only apply to physicians in the specialties of hematology, hematology/oncology, and medical oncology under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]."

Pub. L. 108-173, title III, §304, Dec. 8, 2003, 117 Stat. 2255, provided that: "Notwithstanding section 303(j) [set out above], the amendments made by section 303 [enacting sections 1395w-3a and 1395w-3b of this title, amending this section and sections 1395l, 1395w-4, 1395x, 1395y, and 1396r-8 of this title, and repealing provisions set out as a note under this section] shall also apply to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology."

#### ISSUANCE OF TEMPORARY NATIONAL CODES

Pub. L. 108–173, title VII, §731(c), Dec. 8, 2003, 117 Stat. 2351, provided that: "Not later than July 1, 2004, the Secretary [of Health and Human Services] shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.]."

### REVISED PART B PAYMENT FOR DRUGS AND BIOLOGICALS AND RELATED SERVICES

Pub. L. 106-554, \$1(a)(6) [title IV, \$429], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that:

"(a) RECOMMENDATIONS FOR REVISED PAYMENT METH-ODOLOGY FOR DRUGS AND BIOLOGICALS.—

"(1) STUDY.-

"(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the reimbursement for drugs and biologicals under the current medicare payment methodology (provided under section 1842(0) of the Social Security Act (42 U.S.C. 1395u(0))) and for related services under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.]. In the study, the Comptroller General shall—

"(i) identify the average prices at which such drugs and biologicals are acquired by physicians and other suppliers:

"(ii) quantify the difference between such average prices and the reimbursement amount under such section; and

"(iii) determine the extent to which (if any) payment under such part is adequate to compensate physicians, providers of services, or other

suppliers of such drugs and biologicals for costs incurred in the administration, handling, or storage of such drugs or biologicals.

"(B) CONSULTATION.—In conducting the study under subparagraph (A), the Comptroller General shall consult with physicians, providers of services, and suppliers of drugs and biologicals under the medicare program under title XVIII of such Act [42 U.S.C. 1395 et seq.], as well as other organizations involved in the distribution of such drugs and biologicals to such physicians, providers of services, and suppliers.

"(2) REPORT.—Not later than 9 months after the date of the enactment of this Act [Dec. 21, 2000], the Comptroller General shall submit to Congress and to the Secretary of Health and Human Services a report on the study conducted under this subsection, and shall include in such report recommendations for revised payment methodologies described in paragraph

"(A) IN GENERAL.—The Comptroller General shall provide specific recommendations for revised payment methodologies for reimbursement for drugs and biologicals and for related services under the medicare program. The Comptroller General may include in the recommendations—

"(i) proposals to make adjustments under subsection (c) of section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for the practice expense component of the physician fee schedule under such section for the costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals, if appropriate: and

"(ii) proposals for new payments to providers of services or suppliers for such costs, if appropriate. "(B) ENSURING PATIENT ACCESS TO CARE.—In making recommendations under this paragraph, the Comptroller General shall ensure that any proposed revised payment methodology is designed to ensure that medicare beneficiaries continue to have appropriate access to health care services under the medicare program.

"(C) MATTERS CONSIDERED.—In making recommendations under this paragraph, the Comptroller General shall consider—

"(i) the method and amount of reimbursement for similar drugs and biologicals made by large group health plans;

"(ii) as a result of any revised payment methodology, the potential for patients to receive inpatient or outpatient hospital services in lieu of services in a physician's office; and

"(iii) the effect of any revised payment methodology on the delivery of drug therapies by hospital outpatient departments.

"(D) COORDINATION WITH BBRA STUDY.—In making recommendations under this paragraph, the Comptroller General shall conclude and take into account the results of the study provided for under section 213(a) of BBRA [Pub. L. 106–113, §1000(a)(6) [title II, §213(a)], set out as a note under section 1395l of this title] (113 Stat. 1501A–350).

"(b) IMPLEMENTATION OF NEW PAYMENT METHOD-OLOGY.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, based on the recommendations contained in the report under subsection (a), the Secretary of Health and Human Services, subject to paragraph (2), shall revise the payment methodology under section 1842(o) of the Social Security Act (42 U.S.C. 13950(o)) for drugs and biologicals furnished under part B of the medicare program [42 U.S.C. 1395j et seq.]. To the extent the Secretary determines appropriate, the Secretary may provide for the adjustments to payments amounts referred to in subsection (a)(3)(A)(i) or additional payments referred to in subsection (a)(2)(A)(ii).

"(2) LIMITATION.—In revising the payment methodology under paragraph (1), in no case may the estimated aggregate payments for drugs and biologicals under the revised system (including additional payments referred to in subsection (a)(3)(A)(ii)) exceed the aggregate amount of payment for such drugs and biologicals, as projected by the Secretary, that would have been made under the payment methodology in effect under such section 1842(o).

"(c) MORATORIUM ON DECREASES IN PAYMENT RATES.—Notwithstanding any other provision of law, effective for drugs and biologicals furnished on or after January 1, 2001, the Secretary may not directly or indirectly decrease the rates of reimbursement (in effect as of such date) for drugs and biologicals under the current medicare payment methodology (provided under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o))) until such time as the Secretary has reviewed the report submitted under subsection (a)(2)."

### IMPLEMENTATION OF INHERENT REASONABLENESS (IR) AUTHORITY

Pub. L. 106–113, div. B, \$1000(a)(6) [title II, \$223(a), (b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, 1501A–353, provided that:

"(a) LIMITATION ON USE.—The Secretary of Health and Human Services may not use, or permit fiscal intermediaries or carriers to use, the inherent reasonableness authority provided under section 1842(b)(8) of the Social Security Act (42 U.S.C. 1395u(b)(8)) until after—

"(1) the Comptroller General of the United States releases a report pursuant to the request for such a report made on March 1, 1999, regarding the impact of the Secretary's, fiscal intermediaries', and carriers' use of such authority; and

"(2) the Secretary has published a notice of final rulemaking in the Federal Register that relates to such authority and that responds to such report and to comments received in response to the Secretary's interim final regulation relating to such authority that was published in the Federal Register on January 7, 1998.

''(b) REEVALUATION OF IR CRITERIA.—In promulgating the final regulation under subsection (a)(2), the Secretary shall—

"(1) reevaluate the appropriateness of the criteria included in such interim final regulation for identifying payments which are excessive or deficient; and "(2) take appropriate steps to ensure the use of

valid and reliable data when exercising such authority."

#### INITIAL BUDGET NEUTRALITY

Pub. L. 105–33, title IV, §4315(d), Aug. 5, 1997, 111 Stat. 390, provided that: "The Secretary, in developing a fee schedule for particular services (under the amendments made by this section [amending this section and section 1395 of this title]), shall set amounts for the first year period to which the fee schedule applies at a level so that the total payments under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for those services for that year period shall be approximately equal to the estimated total payments if such fee schedule had not been implemented."

### IMPROVEMENTS IN ADMINISTRATION OF LABORATORY TESTS BENEFIT

Pub. L. 105–33, title IV,  $\$4554,\ {\rm Aug.}\ 5,\ 1997,\ 111\ {\rm Stat.}\ 460,\ {\rm provided\ that:}$ 

"(a) SELECTION OF REGIONAL CARRIERS.—

"(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall—

``(A) divide the United States into no more than 5 regions, and

"(B) designate a single carrier for each such region, for the purpose of payment of claims under part B of title XVIII of the Social Security Act [42]

U.S.C. 1395j et seq.] with respect to clinical diagnostic laboratory tests furnished on or after such date (not later than July 1, 1999) as the Secretary specifies.

''(2) DESIGNATION.—In designating such carriers, the Secretary shall consider, among other criteria—

"(A) a carrier's timeliness, quality, and experience in claims processing, and

"(B) a carrier's capacity to conduct electronic data interchange with laboratories and data matches with other carriers.

"(3) SINGLE DATA RESOURCE.—The Secretary shall select one of the designated carriers to serve as a central statistical resource for all claims information relating to such clinical diagnostic laboratory tests handled by all the designated carriers under such part.

"(4) ALLOCATION OF CLAIMS.—The allocation of claims for clinical diagnostic laboratory tests to particular designated carriers shall be based on whether a carrier serves the geographic area where the laboratory specimen was collected or other method specified by the Secretary.

"(5) SECRETARIAL EXCLUSION.—Paragraph (1) shall not apply with respect to clinical diagnostic laboratory tests furnished by physician office laboratories if the Secretary determines that such offices would be unduly burdened by the application of billing responsibilities with respect to more than one carrier. "(b) ADOPTION OF NATIONAL POLICIES FOR CLINICAL LABORATORY TESTS BENEFIT.—

"(1) IN GENERAL.—Not later than January 1, 1999, the Secretary shall first adopt, consistent with paragraph (2), national coverage and administrative policies for clinical diagnostic laboratory tests under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.

"(2) Considerations in design of national policies.—The policies under paragraph (1) shall be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory tests payable under such part in connection with the following:

lowing:

"(A) Beneficiary information required to be submitted with each claim or order for laboratory tests.

"(B) The medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act [42 U.S.C. 1395y(a)(1)(A)]).

"(C) The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.

"(D) The medical documentation that is required by a medicare contractor at the time a claim is submitted for a laboratory test in accordance with section 1833(e) of the Social Security Act [42 U.S.C. 1395/(e)]

"(E) Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements.

"(F) Procedures for filing claims and for providing remittances by electronic media.

"(G) Limitation on frequency of coverage for the same tests performed on the same individual.

"(3) CHANGES IN LABORATORY POLICIES PENDING ADOPTION OF NATIONAL POLICY.—During the period that begins on the date of the enactment of this Act [Aug. 5, 1997] and ends on the date the Secretary first implements national policies pursuant to regulations promulgated under this subsection, a carrier under such part may implement changes relating to requirements for the submission of a claim for clinical diagnostic laboratory tests.

"(4) USE OF INTERIM POLICIES.—After the date the Secretary first implements such national policies,

the Secretary shall permit any carrier to develop and implement interim policies of the type described in paragraph (1), in accordance with guidelines established by the Secretary, in cases in which a uniform national policy has not been established under this subsection and there is a demonstrated need for a policy to respond to aberrant utilization or provision of unnecessary tests. Except as the Secretary specifically permits, no policy shall be implemented under this paragraph for a period of longer than 2 years.

"(5) INTERIM NATIONAL POLICIES.—After the date the Secretary first designates regional carriers under subsection (a), the Secretary shall establish a process under which designated carriers can collectively develop and implement interim national policies of the type described in paragraph (1). No such policy shall be implemented under this paragraph for a period of longer than 2 years.

"(6) BIENNIAL REVIEW PROCESS.—Not less often than once every 2 years, the Secretary shall solicit and review comments regarding changes in the national policies established under this subsection. As part of such biennial review process, the Secretary shall specifically review and consider whether to incorporate or supersede interim policies developed under paragraph (4) or (5). Based upon such review, the Secretary may provide for appropriate changes in the national policies previously adopted under this subsection.

"(7) REQUIREMENT AND NOTICE.—The Secretary shall ensure that any policies adopted under paragraph (3), (4), or (5) shall apply to all laboratory claims payable under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.], and shall provide for advance notice to interested parties and a 45-day period in which such parties may submit comments on the proposed change.

"(c) INCLUSION OF LABORATORY REPRESENTATIVE ON CARRIER ADVISORY COMMITTEES.—The Secretary shall direct that any advisory committee established by a carrier to advise such carrier with respect to coverage and administrative policies under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] shall include an individual to represent the independent clinical laboratories and such other laboratories as the Secretary deems appropriate. The Secretary shall consider recommendations from national and local organizations that represent independent clinical laboratories in such selection"

### WHOLESALE PRICE STUDY AND REPORT

Pub. L. 105–33, title IV, §4556(e), Aug. 5, 1997, 111 Stat. 463, which directed the Secretary of Health and Human Services to study the effect on the average wholesale price of drugs and biologicals of the amendments to this section by section 4556(a) of Pub. L. 105–33, and to report to Congress the result of such study not later than July 1, 1999, was repealed by Pub. L. 108–173, title III, §303(i)(6), Dec. 8, 2003, 117 Stat. 2255.

#### BUDGET NEUTRALITY ADJUSTMENT

Pub. L. 103-66, title XIII, §13515(b), Aug. 10, 1993, 107 Stat. 583, provided that: "Notwithstanding any other provision of law, the Secretary of Health and Human Services shall reduce the following values and amounts for 1994 (to be applied for that year and subsequent years) by such uniform percentage as the Secretary determines to be required to assure that the amendments made by subsection (a) [amending this section and section 1395w-4 of this title] will not result in expenditures under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in 1994 that exceed the amount of such expenditures that would have been made if such amendments had not been made:

"(1) The relative values established under section 1848(c) of such Act [42 U.S.C. 1395w-4(c)] for services (other than anesthesia services) and, in the case of anesthesia services, the conversion factor established under section 1848 of such Act for such services.

''(2) The amounts determined under section 1848(a)(2)(B)(ii)(I) of such Act.

"(3) The prevailing charges or fee schedule amounts to be applied under such part for services of a health care practitioner (as defined in section 1842(b)(4)(F)(ii)(I) of such Act [42 U.S.C. 1395u(b)(4)(F)(ii)(I)], as in effect before the date of the enactment of this Act [Aug. 10, 1993])."

#### PROCEDURE CODES

Pub. L. 101–508, title IV, \$4101(b)(2), Nov. 5, 1990, 104 Stat. 1388–55, as amended by Pub. L. 103–432, title I, \$126(a)(2), Oct. 31, 1994, 108 Stat. 4414, provided that: "In applying section 1842(b)(16)(B) of the Social Security Act [42 U.S.C. 1395u(b)(16)(B)]:

"(A) The codes for the procedures specified in clause (ii) are as follows: Hospital inpatient medical services (HCPCS codes 90200 through 90292), consultations (HCPCS codes 90600 through 90654), other visits (HCPCS code 90699), preventive medicine visits (HCPCS codes 90750 through 90764), psychiatric services (HCPCS codes 90801 through 90862), emergency care facility services (HCPCS codes 99062 through 99065), and critical care services (HCPCS codes 99160 through 99174).

"(B) The codes for the procedures specified in clause (iii) are as follows: Partial mastectomy (HCPCS code 19160); tendon sheath injections and small joint arthrocentesis (HCPCS codes 20550, 20600, 20605, and 20610); femoral fracture and trochanteric fracture treatments (HCPCS codes 27230, 27232, 27234, 27238, 27240, 27242, 27246, and 27248); endotracheal intubation (HCPCS code 31500); thoracentesis (HCPCS code 32000); thoracostomy (HCPCS codes 32020, 32035, and 32036); aneurysm repair (HCPCS codes 35111); cystourethroscopy (HCPCS code 52340); transurethral fulguration and resection (HCPCS codes 52606 and 52620); tympanoplasty with mastoidectomy (HCPCS code 69645); and ophthalmoscopy (HCPCS codes 92250 and 92260)."

### STUDY OF RELEASE OF PREPAYMENT MEDICAL REVIEW SCREEN PARAMETERS

Pub. L. 101–508, title IV, §4111, Nov. 5, 1990, 104 Stat. 1388–64, directed Secretary of Health and Human Services to conduct a study of effect of release of medicare prepayment medical review screen parameters on physician billings for services to which the parameters apply, such study to be based upon the release of the screen parameters at a minimum of six carriers, with Secretary to report results of study to Congress not later than Oct. 1, 1992.

### FREEZE IN CHARGES FOR PARENTERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND EQUIPMENT

Pub. L. 103-66, title XIII, §13541, Aug. 10, 1993, 107 Stat. 587, provided that: "In determining the amount of payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] with respect to parenteral and enteral nutrients, supplies, and equipment during 1994 and 1995, the charges determined to be reasonable with respect to such nutrients, supplies, and equipment may not exceed the charges determined to be reasonable with respect to such nutrients, supplies, and equipment during 1993."

Pub. L. 101–508, title IV, §4152(d), Nov. 5, 1990, 104 Stat. 1388–79, provided that: "In determining the amount of payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] for enteral and parenteral nutrients, supplies, and equipment furnished during 1991, the charges determined to be reasonable with respect to such nutrients, supplies, and equipment may not exceed the charges determined to be reasonable with respect to such items for 1990."

### PROHIBITION ON REGULATIONS CHANGING COVERAGE OF CONVENTIONAL EYEWEAR

Pub. L. 101-508, title IV, §4153(b)(1), Nov. 5, 1990, 104 Stat. 1388-84, provided that:

"(A) Notwithstanding any other provision of law (except as provided in subparagraph (B)) the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') may not issue any regulation that changes the coverage of conventional eyewear furnished to individuals (enrolled under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.]) following cataract surgery with insertion of an intraocular lens.

"(B) Paragraph (1) shall not apply to any regulation issued for the sole purpose of implementing the amendments made by paragraph (2)."

DIRECTORY OF UNIQUE PHYSICIAN IDENTIFIER NUMBERS

Pub. L. 101–508, title IV, §4164(c), Nov. 5, 1990, 104 Stat. 1388–102, as amended by Pub. L. 103–432, title I, §147(f)(7)(B), Oct. 31, 1994, 108 Stat. 4432, provided that: "Not later than March 31, 1991, the Secretary of Health and Human Services shall publish, and shall periodically update, a directory of the unique physician identification numbers of all physicians providing services for which payment may be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.], and shall include in such directory the names, provider numbers, and billing addressess [sic] of all listed physicians."

### TREATMENT OF CERTAIN EYE EXAMINATION VISITS AS PRIMARY CARE SERVICES

Pub. L. 101–239, title VI, §6102(e)(10), Dec. 19, 1989, 103 Stat. 2188, provided that: "In applying section 1842(i)(4) of the Social Security Act [42 U.S.C. 1395u(i)(4)] for services furnished on or after January 1, 1990, intermediate and comprehensive office visits for eye examinations and treatments (codes 92002 and 92004) shall be considered to be primary care services."

DELAY IN UPDATE UNTIL APRIL 1, 1990, AND REDUCTION IN PERCENTAGE INCREASE IN MEDICARE ECONOMIC INDEX

Pub. L. 101-239, title VI, §6107(a), Dec. 19, 1989, 103 Stat. 2211, provided that:

'(1) IN GENERAL.—Subject to the amendments made by this section [amending this section], any increase or adjustment in customary, prevailing, or reasonable charges, fee schedule amounts, maximum allowable actual charges, and other limits on actual charges with respect to physicians' services and other items and services described in paragraph (2) under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] which would otherwise occur as of January 1, 1990, shall be delayed so as to occur as of April 1, 1990, and, notwithstanding any other provision of law, the amount of payment under such part for such items and services which are furnished during the period beginning on January 1, 1990, and ending on March 31, 1990, shall be determined on the same basis as the amount of payment for such services furnished on December 31, 1989.

"(2) ITEMS AND SERVICES COVERED.—The items and services described in this paragraph are items and services (other than ambulance services and clinical diagnostic laboratory services) for which payment is made under part B of title XVIII of the Social Security Act on the basis of a reasonable charge or a fee schedule.

 $\lq\lq(3)$  Extension of participation agreements and related provisions.—Notwithstanding any other provision of law—

"(A) subject to the last sentence of this paragraph, each participation agreement in effect on December 31, 1989, under section 1842(h)(1) of the Social Security Act [42 U.S.C. 1395u(h)(1)] shall remain in effect for the 3-month period beginning on January 1, 1990;

"(B) the effective period for such agreements under such section entered into for 1990 shall be the 9month period beginning on April 1, 1990, and the Secretary of Health and Human Services shall provide an opportunity for physicians and suppliers to enroll as participating physicians and suppliers before April 1, 1990. "(C) instead of publishing, under section 1842(h)(4) of the Social Security Act [42 U.S.C. 1395u(h)(4)], at the beginning of 1990, directories of participating physicians and suppliers for 1990, the Secretary shall provide for such publication, at the beginning of the 9-month period beginning on April 1, 1990, of such directories of participating physicians and suppliers for such period; and

"(D) instead of providing to nonparticipating physicians under section 1842(b)(3)(G) of the Social Security Act [42 U.S.C. 1395u(b)(3)(G)] at the beginning of 1990, a list of maximum allowable actual charges for 1990, the Secretary shall provide, at the beginning of the 9-month period beginning on April 1, 1990, such physicians such a list for such 9-month period.

An agreement with a participating physician or supplier described in subparagraph (A) in effect on December 31, 1989, under section 1842(h)(1) of the Social Security Act shall not remain in effect for the period described in subparagraph (A) if the participating physician or supplier requests on or before December 31, 1989, that the agreement be terminated."

STATE DEMONSTRATION PROJECTS ON APPLICATION OF LIMITATION ON VISITS PER MONTH PER RESIDENT ON AGGREGATE BASIS FOR A TEAM

Pub. L. 101–239, title VI, §6114(e), Dec. 19, 1989, 103 Stat. 2218, provided that: "The Secretary of Health and Human Services shall provide for at least 1 demonstration project under which, in the application of section 1842(b)(2)(C) of the Social Security Act [42 U.S.C. 1395u(b)(2)(C)] (as added by subsection (c)(2) of this section) in one or more States, the limitation on the number of visits per month per resident would be applied on an average basis over the aggregate total of residents receiving services from members of the team."

APPLICATION OF DIFFERENT PERFORMANCE STANDARDS FOR ELECTRONIC SYSTEM FOR COVERED OUTPATIENT DRIGS

Pub. L. 100–360, title II, §202(e)(3)(B), July 1, 1988, 102 Stat. 717, as amended by Pub. L. 100–485, title VI, §608(d)(5)(E), Oct. 13, 1988, 102 Stat. 2414, which required Secretary of Health and Human Services, before entering into contracts under section 1395u of this title with respect to implementation and operation of electronic system for covered outpatient drugs, to establish standards with respect to performance with respect to such activities, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

DELAY IN APPLICATION OF COORDINATION OF BENEFITS WITH PRIVATE HEALTH INSURANCE

Pub. L. 100–360, title II, §202(e)(4)(B), July 1, 1988, 102 Stat. 717, which provided that the provisions of section 1395u(h)(3) of this title not apply to covered outpatient drugs (other than drugs described in section 1395x(s)(2)(J) of this title as of July 1, 1988) dispensed before January 1, 1993, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

EXTENSION OF PHYSICIAN PARTICIPATION AGREEMENTS AND RELATED PROVISIONS

Pub. L. 100–203, title IV, \$4041(a)(2), Dec. 22, 1987, 101 Stat. 1330–83, provided that: "Notwithstanding any other provision of law—

"(A) subject to the last sentence of this paragraph, each agreement with a participating physician in effect on December 31, 1987, under section 1842(h)(1) of the Social Security Act [42 U.S.C. 1395u(h)(1)] shall remain in effect for the 3-month period beginning on January 1, 1988:

"(B) the effective period for agreements under such section entered into for 1988 shall be the nine-month period beginning on April 1, 1988, and the Secretary shall provide an opportunity for physicians to enroll as participating physicians prior to April 1, 1988;

"(C) instead of publishing, under section 1842(h)(4) of the Social Security Act [42 U.S.C. 1395u(h)(4)] at

the beginning of 1988, directories of participating physicians for 1988, the Secretary shall provide for such publication, at the beginning of the 9-month period beginning on April 1, 1988, of such directories of participating physicians for such period; and

"(D) instead of providing to nonparticipating physicians, under section 1842(b)(3)(G) of the Social Security Act [42 U.S.C. 1395u(b)(3)(G)] at the beginning of 1988, a list of maximum allowable actual charges for 1988, the Secretary shall provide, at the beginning of the 9-month period beginning on April 1, 1988, to such physicians such a list for such 9-month period.

An agreement with a participating physician in effect on December 31, 1987, under section 1842(h)(1) of the Social Security Act shall not remain in effect for the perriod described in subparagraph (A) if the participating physician requests on or before December 31, 1987, that the agreement be terminated."

#### DEVELOPMENT OF UNIFORM RELATIVE VALUE GUIDE

Pub. L. 100–203, title IV, §4048(b), Dec. 22, 1987, 101 Stat. 1330–90, as amended by Pub. L. 101–508, title IV, §4118(h)(1), Nov. 5, 1990, 104 Stat. 1388–70, provided that: "The Secretary of Health and Human Services, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all carrier localities in making payment for physician anesthesia services furnished under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] on and after March 1, 1989. Such guide shall be designed so as to result in expenditures under such title [42 U.S.C. 1395 et seq.] for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur."

[Pub. L. 101–508, title IV, §4118(h), Nov. 5, 1990, 104 Stat. 1388–70, provided that the amendment by that section to section 4048(b) of Pub. L. 100–203, set out above, is effective as if included in enactment of Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.]

#### STUDY OF PREVAILING CHARGES FOR ANESTHESIA SERVICES

Pub. L. 100–203, title IV, §4048(c), Dec. 22, 1987, 101 Stat. 1330–90, which required Secretary of Health and Human Services to study variations in conversion factors used by carriers under section 1395u(b) of this title to determine prevailing charge for anesthesia services and to report results of study and make recommendations for appropriate adjustments in such factors not later than Jan. 1, 1989, was repealed by Pub. L. 101–508, title IV, §4118(g)(2), Nov. 5, 1990, 104 Stat. 1388–70.

#### GAO STUDIES

Pub. L. 100-203, title IV, \$4048(d), Dec. 22, 1987, 101 Stat. 1330-90, provided that:

"(1) The Comptroller General shall conduct a study—
"(A) to determine the average anesthesia times reported for medicare reimbursement purposes,

"(B) to verify those times from patient medical records.

"(C) to compare anesthesia times to average surgical times, and

"(D) to determine whether the current payments for physician supervision of nurse anesthetists are excessive

The Comptroller General shall report to Congress, by not later than January 1, 1989, on such study and in the report include recommendations regarding the appropriateness of the anesthesia times recognized by medicare for reimbursement purposes and recommendations regarding adjustments of payments for physician supervision of nurse anesthetists.

"(2) The Comptroller General shall conduct a study on the impact of the amendment made by subsection (a) [amending this section], and shall report to Congress on the results of such study by April 1, 1990."

#### ADJUSTMENT IN MEDICARE PREVAILING CHARGES

Pub. L. 100–203, title IV, \$4051(b), Dec. 22, 1987, 101 Stat. 1330–94, provided that:

"(1) REVIEW.—The Secretary of Health and Human Services shall review payment levels under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for diagnostic tests (described in section 1861(s)(3) of such Act [42 U.S.C. 1935x(s)(3)], but excluding clinical diagnostic laboratory tests) which are commonly performed by independent suppliers, sold as a service to physicians, and billed by such physicians, in order to determine the reasonableness of payment amounts for such tests (and for associated professional services component of such tests). The Secretary may require physicians and suppliers to provide such information on the purchase or sale price (net of any discounts) for such tests as is necessary to complete the review and make the adjustments under this subsection. The Secretary shall also review the reasonableness of payment levels for comparable in-office diagnostic tests.

'(2) ESTABLISHMENT OF REVISED PAYMENT SCREENS.— If, as a result of such review, the Secretary determines, after notice and opportunity of at least 60 days for public comment, that the current prevailing charge levels (under the third and fourth sentences of section 1842(b) of the Social Security Act [42 U.S.C. 1395u(b)]) for any such tests or associated professional services are excessive, the Secretary shall establish such charge levels at levels which, consistent with assuring that the test is widely and consistently available to medicare beneficiaries, reflect a reasonable price for the test without any markup. Alternatively, the Secretary, pursuant to guidelines published after notice and opportunity of at least 60 days for public comment, may delegate to carriers with contracts under section 1842 of the Social Security Act the establishment of new prevailing charge levels under this paragraph. When such charge levels are established, the provisions of section 1842(j)(1)(D) of such Act shall apply in the same manner as they apply to a reduction under section 1842(b)(8)(A) of such Act.

### ADJUSTMENT FOR MAXIMUM ALLOWABLE ACTUAL CHARGE

Pub. L. 100–203, title IV, §4054(b), formerly §4053(b), Dec. 22, 1987, 101 Stat. 1330–97, as renumbered by Pub. L. 100–360, title IV, §411(f)(14), July 1, 1988, 102 Stat. 781, provided that: "In the case of a physician who did not have actual charges under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for a procedure in the calendar quarter beginning on April 1, 1984, but who establishes to the satisfaction of a carrier that he or she had actual charges (whether under such title or otherwise) for the procedure performed prior to June 30, 1984, the carrier shall compute the maximum allowable actual charge under section 1842(j) of the Social Security Act [42 U.S.C. 1395u(j)] for such procedure performed by such physician in 1988 based on such physician's actual charges for the procedure."

### PHYSICIAN PAYMENT STUDIES; DEFINITIONS OF MEDICAL AND SURGICAL PROCEDURES

Pub. L. 100–203, title IV, \$4056(a), formerly \$4055(a), Dec. 22, 1987, 101 Stat. 1330–98, as renumbered and amended by Pub. L. 100–360, title IV, \$411(f)(13)(A), (14), July 1, 1988, 102 Stat. 781; Pub. L. 101–508, title IV, \$4118(g)(4), Nov. 5, 1990, 104 Stat. 1388–70, provided that:

"(1) REPORT ON VARIATIONS IN CARRIER PAYMENT PRACTICE.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a study of variations in payment practices for physicians' services among the different carriers under section 1842 of the Social Security Act [42 U.S.C. 1395u]. Such study shall examine carrier variations in the services included in global fees and pre- and post-operative services included in payment for the operation.

"(2) UNIFORM DEFINITIONS OF PROCEDURES FOR PAY-MENT PURPOSES.—The Secretary shall develop, in consultation with appropriate national medical specialty societies and by not later than July 1, 1989, uniform definitions of physicians' services (including appropriate classification scheme for procedures) which could serve as the basis for making payments for such services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.]. In developing such definitions, to the extent practicable—

"(A) ancillary services commonly performed in conjunction with a major procedure would be included with the major procedure;

"(B) pre- and post-procedure services would be included in the procedure; and

"(C) similar procedures would be listed together if the procedures are similar in resource requirements."

PAYMENTS FOR DURABLE MEDICAL EQUIPMENT, PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS; 1-YEAR FREEZE ON CHARGE LIMITATIONS

Pub. L. 100-203, title IV, \$4062(a), Dec. 22, 1987, 101 Stat. 1330-100, provided that:

"(1) IN GENERAL.—In imposing limitations on allowable charges for items and services (other than physicians' services) furnished in 1988 under part B of title XVIII of such Act [42 U.S.C. 1395] et seq.] and for which payment is made on the basis of the reasonable charge for the item or service, the Secretary of Health and Human Services shall not impose any limitation at a level higher than the same level as was in effect in December 1987.

"(2) Transition.—The provisions of section 4041(a)(2) (other than subparagraph (D) thereof) of this subtitle [set out as a note above] shall apply to suppliers of items and services described in paragraph (1), and directories of participating suppliers of such items and services, in the same manner as such section applies to physicians furnishing physicians' services, and directories of participating physicians."

### SPECIAL RULE WITH RESPECT TO PAYMENT FOR INTRAOCULAR LENSES

Pub. L. 100–203, title IV, \$4063(d), Dec. 22, 1987, 101 Stat. 1330–110, provided that: "With respect to the establishment of a reasonable charge limit under section 1842(b)(11)(C)(ii) of the Social Security Act [42 U.S.C. 1395u(b)(11)(C)(ii)], in applying section 1842(j)(1)(D)(i) of such Act, the matter beginning with 'plus' shall be considered to have been deleted."

STUDY ON COST EFFECTIVENESS OF HEARING PRIOR TO HEARING BY ADMINISTRATIVE LAW JUDGE ON CARRIER DETERMINATIONS; REPORT TO CONGRESS

Pub. L. 100–203, title IV, §4082(d), Dec. 22, 1987, 101 Stat. 1330–128, provided that: "The Comptroller General shall conduct a study concerning the cost effectiveness of requiring hearings with a carrier under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] before having a hearing before an administrative law judge respecting carrier determinations under that part. The Comptroller General shall report to the Congress on the results of such study by not later than June 30, 1989."

#### CAPACITY TO SET GEOGRAPHIC PAYMENT LIMITS

Pub. L. 100–203, title IV, §4085(e), Dec. 22, 1987, 101 Stat. 1330–131, provided that: "The Secretary of Health and Human Services shall develop the capability to implement (for services furnished on or after January 1, 1989) geographic limits on charges and payments under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] for physicians' services based on statewide, regional, or national average (or percentile in a distribution) of prevailing charges or payment amounts (weighted by frequency of services). Any such limits shall take into account adjustments for geographic differences in cost of practice and cost of living."

UTILIZATION SCREENS FOR PHYSICIAN SERVICES PROVIDED TO PATIENTS IN REHABILITATION HOSPITALS

Pub. L. 101-508, title IV, §4114, Nov. 5, 1990, 104 Stat. 1388-65, as amended by Pub. L. 103-432, title I, §126(g)(4), Oct. 31, 1994, 108 Stat. 4416, provided that: "Not later than 180 days after the date of the enactment of this

Act [Nov. 5, 1990], the Secretary of Health and Human Services shall issue guidelines to assure a uniform level of review of physician visits to patients of a rehabilitation hospital or unit after the medical review screen parameter established under section 4085(h) of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203, set out below] has been exceeded."

Pub. L. 100-203, title IV, §4085(h), Dec. 22, 1987, 101 Stat. 1330-131, provided that:

"(1) The Secretary of Health and Human Services shall establish (in consultation with appropriate physician groups, including those representing rehabilitative medicine) a separate utilization screen for physician visits to patients in rehabilitation hospitals and rehabilitative units (and patients in long-term care hospitals receiving rehabilitation services) to be used by carriers under section 1842 of the Social Security Act [42 U.S.C. 1395u] in performing functions under subsection (a) of such section related to the utilization practices of physicians in such hospitals and units.

"(2) Not later than 12 months after the date of enactment of this Act [Dec. 22, 1987], the Secretary of Health and Human Services shall take appropriate steps to implement the utilization screen established under paragraph (1)."

#### PLAN AMENDMENTS NOT REQUIRED UNTIL JANUARY 1, 1989

For provisions directing that if any amendments made by subtitle A or subtitle C of title XI [§§1101–1147 and 1171–1177] or title XVIII [§§1800–1899A] of Pub. L. 99–514 require an amendment to any plan, such plan amendment shall not be required to be made before the first plan year beginning on or after Jan. 1, 1989, see section 1140 of Pub. L. 99–514, as amended, set out as a note under section 401 of Title 26, Internal Revenue Code.

#### AMENDMENTS IN CONTRACTS AND REGULATIONS

The Secretary of Health and Human Services to provide for such timely amendments to contracts under this section, and regulations, to such extent as may be necessary to implement Pub. L. 99–509 on a timely basis, see section 9311(d)(3) of Pub. L. 99–509, set out as an Effective Date of 1986 Amendment note under section 1395h of this title.

#### MEDICARE ECONOMIC INDEX

Pub. L. 99–509, title IX, 9331(c)(1), (2), (4)–(6), Oct. 21, 1986, 100 Stat. 2020, 2021, provided that:

"(1) FOR 1987.—Notwithstanding any other provision of law, for purposes of part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for physicians' services furnished in 1987, the percentage increase in the MEI (as defined in section 1842(b)(4)(E)(ii) of the Social Security Act [42 U.S.C. 1395u(b)(4)(E)(ii)]) shall be 3.2 percent.

"(2) PROHIBITING RETROACTIVE ADJUSTMENT OF MEDICARE ECONOMIC INDEX.—The Secretary of Health and Human Services is not authorized to revise the MEI in a manner that provides, for any period before January 1, 1985, for the substitution of a rental equivalence or rental substitution factor for the housing component of the consumer price index."

"(4) STUDY.—The Secretary shall conduct a study of the extent to which the MEI appropriately and equitably reflects economic changes in the provision of the physicians' services to medicare beneficiaries. In conducting such study the Secretary shall consult with appropriate experts.

"(5) LIMITATION ON CHANGES IN MEI METHODOLOGY.— The Secretary shall not change the methodology (including the basis and elements) used in the MEI from that in effect as of October 1, 1985, until completion of the study under paragraph (4). After the completion of the study, the Secretary may not change such methodology except after providing notice in the Federal Register and opportunity for public comment.

"(6) MEI DEFINED.—In this subsection, the term 'MEI' means the economic index referred to in the fourth sen-

tence of section 1842(b)(3) of the Social Security Act [42 U.S.C. 1395u(b)(3)]."

DEVELOPMENT AND USE OF HCFA COMMON PROCEDURE CODING SYSTEM

Pub. L. 99-509, title IX, §9331(d), Oct. 21, 1986, 100 Stat. 2021, provided that:

"(1) Not later than July 1, 1989, the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary'), after public notice and opportunity for public comment and after consulation [consultation] with appropriate medical and other experts, shall group the procedure codes contained in any HCFA Common Procedure Coding System for payment purposes to minimize inappropriate increases in the intensity or volume of services provided as a result of coding distinctions which do not reflect substantial differences in the services rendered.

"(2) Not later than January 1, 1990, each carrier with which the Secretary has entered into a contract under section 1842 of the Social Security Act [42 U.S.C. 1395u] shall make payments under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] based on the grouping of procedure codes effected under paragraph (1)."

### MEASURING CARRIER PERFORMANCE; CARRIER BONUSES FOR GOOD PERFORMANCE

Pub. L. 99–509, title IX, 9332(a)(2), (3), Oct. 21, 1986, 100 Stat. 2022, as amended by Pub. L. 100-203, title IV, §4085(i)(21)(B), Dec. 22, 1987, 101 Stat. 1330-133, which provided that the Secretary of Health and Human Services was to provide, in the standards and criteria established under section 1842(b)(2) of the Social Security Act [42 U.S.C. 1395u(b)(2)] for contracts under that section, a system to measure a carrier's performance of the responsibilities described in sections 1842(b)(3)(H)and 1842(h) of such Act and that, of the amounts appropriated for administrative activities to carry out part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], the Secretary of Health and Human Services was to provide payments, totaling 1 percent of the total payments to carriers for claims processing in any fiscal year, to carriers under section 1842 of such Act, to reward such carriers for their success in increasing the proportion of physicians in the carrier's service area who were participating physicians or in increasing the proportion of total payments for physicians' services which were payments for such services rendered by participating physicians, was repealed by Pub. L. 100-203, title IV, § 4041(a)(3)(B)(i), Dec. 22, 1987, 101 Stat.

Pub. L. 99–509, title IX, \$9332(a)(4)(B), (C), Oct. 21, 1986, 100 Stat. 2023, as amended by Pub. L. 100–203, title IV, \$4041(a)(3)(B)(ii), (iii), Dec. 22, 1987, 101 Stat. 1330–84; Pub. L. 100–360, title IV, \$411(f)(1)(C), July 1, 1988, 102 Stat. 776, provided that:

"(B) PERFORMANCE MEASURES.—The Secretary of Health and Human Services shall provide for the establishment of the standards and criteria required under the last sentence of section 1842(b)(2) of the Social Security Act [42 U.S.C. 1395u(b)(2)] by not later than October 1, 1987, which shall apply to contracts as of October 1, 1987.

"(C) Carrier Bonuses.—From the amounts appropriated for each fiscal year (beginning with fiscal year 1988), the Secretary of Health and Human Services shall first provide for payments of bonuses to carriers under section 1842(c)(1)(B) of the Social Security Act [42 U.S.C. 1395u(c)(1)(B)] not later than September 30, 1988, to reflect performance of carriers during the enrollment period before April 1, 1988."

#### REVIEW OF PROCEDURES

Pub. L. 99–509, title IX, §9333(c), Oct. 21, 1986, 100 Stat. 2028, provided that: "Not later than October 1, 1987, the Secretary of Health and Human Services shall review the inherent reasonableness of the reasonable charges for at least 10 of the most costly procedures with respect to which payment is made under part B of title

XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] (determined on the basis of the aggregate annual payments under such part with respect to each such procedure)."

#### RATIFICATION OF REGULATIONS

Pub. L. 99–509, title IX, 9334(b), Oct. 21, 1986, 100 Stat. 2028, as amended by Pub. L. 100–203, title IV, 4045(c)(2)(C), Dec. 22, 1987, 101 Stat. 1330–88, provided that:

"(1) IN GENERAL.—The Congress hereby ratifies the final regulation of the Secretary of Health and Human Services published on page 35693 of volume 51 of the Federal Register on October 7, 1986, relating to reasonable charge payment limits for anesthesia services under the medicare program.

"(2) PATIENT PROTECTIONS.—In the case of any reduction in the reasonable charge for physicians' services effected under the regulation described in paragraph (1), the provisions of section 1842(j)(1)(D) of the Social Security Act [42 U.S.C. 1395u(j)(1)(D)] (added by the amendment made by subsection (a)(3)) shall apply in the same manner and to the same extent as they apply to a reduction in the reasonable charge for a physicians' service effected under section 1842(b)(8) of such Act."

### PAYMENT FOR PARENTERAL AND ENTERAL NUTRITION SUPPLIES AND EQUIPMENT

Pub. L. 99-509, title IX, §9340, Oct. 21, 1986, 100 Stat. 2037, provided that: "The Secretary of Health and Human Services shall apply the sixth sentence of section 1842(b)(3) of the Social Security Act [42 U.S.C. 1395u(b)(3)] to payment—

"(1) for enteral nutrition nutrients, supplies, and equipment and parenteral nutrition supplies and equipment furnished on or after January 1, 1987, and "(2) for parenteral nutrition nutrients furnished on or after October 1, 1987."

#### REPORTING OF OPD SERVICES USING HCPCS

Pub. L. 99–509, title IX, §9343(g), Oct. 21, 1986, 100 Stat. 2041, provided that: "Not later than July 1, 1987, each fiscal intermediary which processes claims under part B of title XVIII of the Social Security Act [42 U.S.C. 1395] et seq.] shall require hospitals, as a condition of payment for outpatient hospital services under that part, to report claims for payment for such services under such part using a HCFA Common Procedure Coding System."

### PERIOD FOR ENTERING INTO PARTICIPATION AGREEMENTS

Pub. L. 99–272, title IX, 9301(b)(3), Apr. 7, 1986, 100 Stat. 186, provided that: "The Secretary of Health and Human Services shall provide, during the month of April 1986, that physicians and suppliers may enter into an agreement under section 1842(h)(1) of the Social Security Act [42 U.S.C. 1395u(h)(1)] for the 8-month period beginning May 1, 1986, or terminate such an agreement previously entered into for fiscal year 1986. In the case of a physician or supplier who entered into such an agreement for fiscal year 1986, the physician or supplier shall be deemed to have entered into such agreement for such 8-month period and for each succeeding year unless the physician or supplier terminates such agreement before the beginning of the respective period. At the beginning of such 8-month period, the Secretary shall publish a new directory (described in section 1842(h)(4) of that Act [42 U.S.C. 1395u(h)(4)], as redesignated by subsection (c)(3)(D) of this section) of participating physicians and suppliers."

### TRANSITIONAL PROVISIONS FOR MEDICARE PART B PAYMENTS

Pub. L. 99-272, title IX, §9301(d)(5), Apr. 7, 1986, 100 Stat. 188, provided that: "Notwithstanding any other provision of law, for purposes of making payment under part B of title XVIII of the Social Security Act [42]

U.S.C. 1395j et seq.], customary and prevailing charges (and the lowest charges determined under the sixth sentence of section 1842(b)(3) of such Act [42 U.S.C. 1395u(b)(3)]) for items and services furnished during the period beginning on October 1, 1986, and ending on December 31, 1986, shall be determined on the same basis as for items and services furnished on September 30, 1986;

### COMPUTATION OF CUSTOMARY CHARGES FOR CERTAIN FORMER HOSPITAL-COMPENSATED PHYSICIANS

Pub. L. 99-272, title IX, §9304(b), Apr. 7, 1986, 100 Stat. 190, provided that:

"(1) In applying section 1842(b) of the Social Security Act [42 U.S.C. 1395u(b)] to payment for physicians' services performed during the 8-month period beginning May 1, 1986, in the case of a physician who at anytime during the period beginning on October 31, 1982, and ending on January 31, 1985, was a hospital-compensated physician (as defined in paragraph (3)) but who, as of February 1, 1985, was no longer a hospital-compensated physician, the physician's customary charges shall—

"(A) be based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985, and

"(B) in the case of a physician who was not a participating physician (as defined in section 1842(h)(1) of the Social Security Act [42 U.S.C. 1395u(h)(1)]) on September 30, 1985, and who is not such a physician on May 1, 1986, be deflated (to take into account the legislative freeze on actual charges for nonparticipating physicians' services) by multiplying the physician's customary charges by .85.

"(2) In applying section 1842(b) of the Social Security Act [42 U.S.C. 1395u(b)] to payment for physicians' services performed during the 8-month period beginning May 1, 1986, in the case of a physician who during the period beginning on February 1, 1985, and ending on December 31, 1986, changes from being a hospital-compensated physician to not being a hospital-compensated physician, the physician's customary charges shall be determined in the same manner as if the physician were considered to be a new physician.

"(3) In this subsection, the term 'hospital-compensated physician' means, with respect to services furnished to patients of a hospital, a physician who is compensated by the hospital for the furnishing of physicians' services for which payment may be made under this part."

### EXTENSION OF MEDICARE PHYSICIAN PAYMENT PROVISIONS

Period of 15 months referred to in subsec. (j)(1) of this section for monitoring the charges of nonparticipating physicians to be deemed to include the period Oct. 1, 1985, to Mar. 14, 1986, see section 5(b) of Pub. L. 99–107, set out as a note under section 1395ww of this title.

SIMPLIFICATION OF PROCEDURES WITH RESPECT TO CLAIMS AND PAYMENTS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Pub. L. 98–369, div. B, title III, §2303(h), July 18, 1984, 98 Stat. 1066, provided that: "The Secretary of Health and Human Services shall simplify the procedures under section 1842 of the Social Security Act [42 U.S.C. 1395u] with respect to claims and payments for clinical diagnostic laboratory tests so as to reduce unnecessary paperwork while assuring that sufficient information is supplied to identify instances of fraud and abuse."

STUDY OF AMOUNTS BILLED FOR PHYSICIAN SERVICES AND PAID BY CARRIERS UNDER SUBSECTION (b)(7) OF THIS SECTION; REPORT TO CONGRESS

Pub. L. 98-369, div. B, title III, §2307(c), July 18, 1984, 98 Stat. 1074, directed Comptroller General to conduct a study of the amounts billed for physician services and paid by carriers under subsec. (b)(7) of this section to determine whether such payments were made only where the physician satisfied the requirements of sub-

sec. (b)(7)(A)(i) of this section, and to submit to Congress a report on results of such study not later than 18 months after July 18, 1984.

REPLACEMENT OF AGENCY, ORGANIZATION, OR CARRIER PROCESSING MEDICARE CLAIMS; NUMBER OF AGREEMENTS AND CONTRACTS AUTHORIZED FOR FISCAL YEARS 1985 THROUGH 1993

For provision authorizing two agreements under section 1395h of this title and two contracts under this section for replacement of an agency, organization, or carrier in the lowest 20th percentile, see section 2326(a) of Pub. L. 98-369, as amended, set out as a note under 1395h of this title.

#### RULES AND REGULATIONS

Pub. L. 97–248, title I, §113(b)(2), Sept. 3, 1982, 96 Stat. 341, provided that: "The Secretary of Health and Human Services shall first issue such final regulations (whether on an interim or other basis) before October 1, 1982, as may be necessary to implement the amendment made by subsection (a) [amending this section] on a timely basis. If such regulations are promulgated on an interim final basis, the Secretary shall take such steps as may be necessary to provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than January 31, 1983."

### REPORT ON REIMBURSEMENT OF CLINICAL LABORATORIES

Pub. L. 96-499, title IX, §918(a)(3), Dec. 5, 1980, 94 Stat. 2626, provided that not later than 24 months after an effective date (not later than Apr. 1, 1981) which was to have been prescribed by the Secretary of Health and Human Services, the Secretary was to report to the Congress (A) the proportion of bills and requests for payment submitted (during the 18-month period beginning on such effective date) under this subchapter for laboratory tests which did not identify who performed the tests, (B) the proportion of bills and requests for payment submitted during such period for laboratory tests with respect to which the amount paid under this subchapter was less than the amount that would otherwise have been payable in the absence of subsec. (h) of this section, (C) with respect to requests for payment described in subparagraph (B) which were submitted by patients, the average additional cost per laboratory test to patients resulting from reductions in payment that would otherwise have been made for such tests in the absence of such subsec. (h), and (D) with respect to bills described in subparagraph (B) which were submitted by physicians, the average reduction in payment per laboratory test to physicians resulting from the application of such subsec. (h).

### PREVAILING CHARGE LEVELS FOR FISCAL YEAR BEGINNING JULY 1, 1975

Pub. L. 94–182, title I, \$101(b), Dec. 31, 1975, 89 Stat. 1051, provided that: "The amendment made by subsection (a) [amending subsec. (b)(3) of this section] shall be applicable with respect to claims filed under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with a carrier designated pursuant to section 1842 of such Act [42 U.S.C. 1395u] and processed by such carrier after the appropriate changes were made in the prevailing charge levels for the fiscal year beginning July 1, 1975, on the basis of economic index data under the third and fourth sentences of section 1842(b)(3) of such Act [42 U.S.C. 1395u(b)(3)]; except that (1) if less than the correct amount was paid (after the application of subsection (a) of this section) on any claim processed prior to the enactment of this section [Dec. 31, 1975], the correct amount shall be paid by such carrier at such time (not exceeding 6 months after the date of the enactment of this section) [Dec. 31, 1975] as is administratively feasible, and (2) no such payment shall be made on any claim where the difference between the amount paid and the correct amount due is less than \$1."

REPORT BY HEALTH INSURANCE BENEFITS ADVISORY COUNCIL ON METHODS OF REIMBURSEMENT OF PHYSI-CIANS FOR THEIR SERVICES

Pub. L. 92-603, title II, §224(b), Oct. 30, 1972, 86 Stat. 1395, directed Health Insurance Benefits Advisory Council to conduct a study of methods of reimbursement for physicians' services under Medicare with respect to fees, extent of assignments accepted by physicians, and share of physician-fee costs which Medicare program does not pay and submit such study to Congress by Jan. 1, 1973.

#### **Executive Documents**

#### EXECUTIVE ORDER No. 13947

Ex. Ord. No. 13947, July 24, 2020, 85 F.R. 59171, which related to a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price, was revoked by Ex. Ord. No. 13948, §5, Sept. 13, 2020, 85 F.R. 59650, set out below.

Ex. Ord. No. 13948. Lowering Drug Prices by Putting America First

Ex. Ord. No. 13948, Sept. 13, 2020, 85 F.R. 59649, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. Purpose. Americans pay more per capita for prescription drugs than residents of any other developed country in the world. It is unacceptable that Americans pay more for the exact same drugs, often made in the exact same places. Other countries' governments regulate drug prices by negotiating with drug manufacturers to secure bargain prices, leaving Americans to make up the difference—effectively subsidizing innovation and) [sic] lower-cost drugs for the rest of the world. The Council of Economic Advisers has found that Americans finance much of the biopharmaceutical innovation that the world depends on, allowing foreign governments, many of which are the sole healthcare payers in their respective countries, to enjoy bargain prices for such innovations. Americans should not bear extra burdens to compensate for the shortfalls that result from the nationalized public healthcare systems of wealthy countries abroad.

In addition to being unfair, high drug prices in the United States also have serious economic and health consequences for patients in need of treatment. High prices cause Americans to divert too much of their scarce resources to pharmaceutical treatments and away from other productive uses. High prices are also a reason many patients skip doses of their medications, take less than the recommended doses, or abandon treatment altogether. The consequences of these behaviors can be severe. For example, patients may develop acute conditions that result in poor clinical outcomes or that require drastic and expensive medical interventions.

In most markets, the largest buyers pay the lowest prices, but this has not been true for prescription drugs. The Federal Government is the largest payer for prescription drugs in the world, but it pays more than many smaller buyers, including other developed nations. When the Federal Government purchases a drug covered by Medicare—the cost of which is shared by American seniors who take the drug and American taxpayers—it should insist on, at a minimum, the lowest price at which the manufacturer sells that drug to any other developed nation.

SEC. 2. *Policy*. (a) It is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price.

(b) The "most-favored-nation price" shall mean the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Cooperation and Development (OECD) that has a comparable per-capita gross domestic product.

SEC. 3. Payment Model on the Most-Favored-Nation

SEC. 3. Payment Model on the Most-Favored-Nation Price in Medicare Part B. To the extent consistent with law, the Secretary of Health and Human Services shall immediately take appropriate steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price. The model would test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with high drug costs.

SEC. 4. Payment Model on the Most-Favored-Nation Price in Medicare Part D. To the extent consistent with law, the Secretary shall take appropriate steps to develop and implement a rulemaking plan, selecting for testing, consistent with section 1315a(b)(2)(A) of title 42, United States Code, a payment model pursuant to which Medicare would pay, for Part D prescription drugs or biological products where insufficient competition exists and seniors are faced with prices above those in OECD member countries that have a comparable per-capita gross domestic product to the United States, after adjusting for volume and differences in national gross domestic product, no more than the most-favored-nation price, to the extent feasible. The model should test whether, for patients who require pharmaceutical treatment, paying no more than the most-favored-nation price would mitigate poor clinical outcomes and increased expenditures associated with

high drug costs. SEC. 5. Revocation of Executive Order. The Executive Order of July 24, 2020 (Lowering Drug Prices by Putting America First) [Ex. Ord. No. 13947, formerly set out above], is revoked.

SEC. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

tive, or legislative proposals.
(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

#### § 1395v. Agreements with States

### (a) Duty of Secretary; enrollment of eligible individuals

The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into an agreement with such State pursuant to which all eligible individuals in either of the coverage groups described in subsection (b) (as specified in the agreement) will be enrolled under the program established by this part.

#### (b) Coverage of groups to which applicable

An agreement entered into with any State pursuant to subsection (a) may be applicable to either of the following coverage groups:

(1) individuals receiving money payments under the plan of such State approved under subchapter I or subchapter XVI; or