111 Stat. 428; amended Pub. L. 108–173, title VII, § 706(a), Dec. 8, 2003, 117 Stat. 2339.)

AMENDMENTS

2003—Subsec. (a). Pub. L. 108–173, § 706(a)(1), inserted ''and for home health services furnished an individual by a religious nonmedical health care institution'' after ''religious nonmedical health care institution'' in introductory provisions.

Subsec. (a)(2). Pub. L. 108–173, § 706(a)(2), substituted '', extended care services, or home health services'' for ''or extended care services'' and inserted '', or receiving services from a home health agency,'' after ''skilled nursing facility''.

EFFECTIVE DATE

Pub. L. 105–33, title IV, § 4454(d), Aug. 5, 1997, 111 Stat. 431, provided that: ''The amendments made by this section [enacting this section and amending sections 1320a–1, 1320c–11, 1395x, 1396a, and 1396g of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and shall apply to items and services furnished on or after such date. By not later than July 1, 1998, the Secretary of Health and Human Services shall first issue regulations to carry out such amendments. Such regulations may be issued so they are effective on an interim basis pending notice and opportunity for public comment. For periods before the effective date of such regulations, such regulations shall recognize elections entered into in good faith in order to comply with the requirements of section 1821(b) of the Social Security Act [42 U.S.C. 1395i–5(b)].''

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR AGED AND DISABLED

§ 1395j. Establishment of supplementary medical insurance program for aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

(Aug. 14, 1935, ch. 531, title XVIII, § 1831, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 301; amended Pub. L. 92–603, title II, § 201(a)(3), Oct. 30, 1972, 86 Stat. 1371.)

AMENDMENTS

1972—Pub. L. 92–603 substituted ''aged and disabled individuals'' for ''individuals 65 years of age or over''.

STUDY REGARDING COVERAGE UNDER PART B OF MEDICARE FOR NONREIMBURSABLE SERVICES PROVIDED BY OPTOMETRISTS FOR PROSTHETIC LENSES FOR PATIENTS WITH APHAKIA

Pub. L. 94–182, title I, § 109, Dec. 31, 1975, 89 Stat. 1053, provided that the Secretary of Health, Education, and Welfare conduct a study on the appropriateness of reimbursement under the insurance program established by this part for services performed by optometrists with respect to the provision of prosthetic lenses for patients with aphakia and submit such study to Congress not later than 4 months after Dec. 31, 1975.

STUDY TO DETERMINE FEASIBILITY OF INCLUSION OF CERTAIN ADDITIONAL SERVICES UNDER PART B

Pub. L. 90–248, title I, § 141, Jan. 2, 1968, 81 Stat. 855, directed Secretary to conduct a study relating to inclusion under the supplementary medical insurance program under this part of services of additional types of licensed practitioners performing health services in independent practice and submit such study to Congress prior to Jan. 1, 1969.

§ 1395k. Scope of benefits; definitions

(a) Scope of benefits

The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1395u(b)(6) of this title; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding—

(i) physician services except where furnished by—

(I) a resident or intern of a hospital, or

(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1395x(b) of this title (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital) where the conditions specified in paragraph (7) of such section are met,

(ii) services for which payment may be made pursuant to section 1395n(b)(2) of this title,

(iii) services described by section 1395x(s)(2)(K)(i) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;[1]

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; and[2]

(C) outpatient physical therapy services (other than services to which the second sentence of section 1395x(p) of this title applies), outpatient occupational therapy services (other than services to which such sentence applies through the operation of section 1395x(g) of this title), and outpatient speech-language pathology services (other than services to which the second sentence of section 1395x(p) of this title applies through the application of section 1395x(*ll*)(2) of this title);

(D)(i) rural health clinic services and (ii) Federally qualified health center services;

(E) comprehensive outpatient rehabilitation facility services;

[1] So in original. The semicolon probably should be a comma.

[2] So in original. The word ''and'' probably should not appear.

(F) facility services furnished in connection with surgical procedures specified by the Secretary—

(i) pursuant to section 1395*l*(i)(1)(A) of this title and performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the Secretary in regulations) if the center has an agreement in effect with the Secretary by which the center agrees to accept the standard overhead amount determined under section 1395*l*(i)(2)(A) of this title as full payment for such services (including intraocular lens in cases described in section 1395*l*(i)(2)(A)(iii) of this title) and to accept an assignment described in section 1395u(b)(3)(B)(ii) of this title with respect to payment for all such services (including intraocular lens in cases described in section 1395*l*(i)(2)(A)(iii) of this title) furnished by the center to individuals enrolled under this part, or

(ii) pursuant to section 1395*l*(i)(1)(B) of this title and performed by a physician, described in paragraph (1), (2), or (3) of section 1395x(r) of this title, in his office, if the Secretary has determined that—

(I) a quality improvement organization (having a contract with the Secretary under part B of subchapter XI of this chapter) is willing, able, and has agreed to carry out a review (on a sample or other reasonable basis) of the physician's performing such procedures in the physician's office,

(II) the particular physician involved has agreed to make available to such organization such records as the Secretary determines to be necessary to carry out the review, and

(III) the physician is authorized to perform the procedure in a hospital located in the area in which the office is located,

and if the physician agrees to accept the standard overhead amount determined under section 1395*l*(i)(2)(B) of this title as full payment for such services and to accept payment on an assignment-related basis with respect to payment for all services (including all pre- and post-operative services) described in paragraphs (1) and (2)(A) of section 1395x(s) of this title and furnished in connection with such surgical procedure to individuals enrolled under this part;

(G) covered items (described in section 1395m(a)(13) of this title) furnished by a provider of services or by others under arrangements with them made by a provider of services;

(H) outpatient critical access hospital services (as defined in section 1395x(mm)(3) of this title);

(I) prosthetic devices and orthotics and prosthetics (described in section 1395m(h)(4) of this title) furnished by a provider of services or by others under arrangements with them made by a provider of services; and

(J) partial hospitalization services provided by a community mental health center (as described in section 1395x(ff)(2)(B) of this title).

(b) Definitions

For definitions of ''spell of illness'', ''medical and other health services'', and other terms used in this part, see section 1395x of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1832, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 302; amended Pub. L. 90–248, title I, §§129(c)(6)(B), 133(d), Jan. 2, 1968, 81 Stat. 848, 851; Pub. L. 92–603, title II, §§227(e)(1), 251(a)(4), Oct. 30, 1972, 86 Stat. 1406, 1445; Pub. L. 95–210, §1(a), Dec. 13, 1977, 91 Stat. 1485; Pub. L. 96–499, title IX, §§930(g), 933(a), 934(a), 948(a)(2), Dec. 5, 1980, 94 Stat. 2631, 2635, 2637, 2643; Pub. L. 97–248, title I, §148(c), Sept. 3, 1982, 96 Stat. 394; Pub. L. 98–369, div. B, title III, §§2341(b), 2354(b)(6), July 18, 1984, 98 Stat. 1094, 1100; Pub. L. 99–509, title IX, §§9320(d), 9337(a), 9343(e)(1), Oct. 21, 1986, 100 Stat. 2013, 2033, 2041; Pub. L. 100–203, title IV, §§4062(d)(2), 4063(e)(2), 4073(b)(1), 4077(b)(2), 4085(i)(22)(A), Dec. 22, 1987, 101 Stat. 1330–108, 1330–118, 1330–120, as amended Pub. L. 100–360, title IV, §411(g)(2)(E), (h)(4)(A), (7)(B), (i)(4)(C)(vi), July 1, 1988, 102 Stat. 783, 786, 787, 789; Pub. L. 100–360, title I, §104(d)(3), title II, §§203(a), 205(a), July 1, 1988, 102 Stat. 689, 721, 729, 783; Pub. L. 101–234, title I, §101(a), title II, §201(a), Dec. 13, 1989, 103 Stat. 1979, 1981; Pub. L. 101–239, title VI, §6116(a)(2), Dec. 19, 1989, 103 Stat. 2219; Pub. L. 101–508, title IV, §§4153(a)(2)(A), 4155(b)(1), 4157(b), 4161(a)(3)(A), 4162(b)(1), Nov. 5, 1990, 104 Stat. 1388–83, 1388–86, 1388–89, 1388–93, 1388–96; Pub. L. 105–33, title IV, §§4201(c)(1), 4432(b)(5)(B), 4511(c), 4603(c)(2)(B)(ii), Aug. 5, 1997, 111 Stat. 373, 421, 443, 471; Pub. L. 106–113, div. B, §1000(a)(6) [title II, §227(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–354; Pub. L. 106–554, §1(a)(6) [title I, §113(b)(1)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473; Pub. L. 110–275, title I, §143(b)(1), July 15, 2008, 122 Stat. 2542; Pub. L. 112–40, title II, §261(a)(3)(B), Oct. 21, 2011, 125 Stat. 423.)

AMENDMENTS

2011—Subsec. (a)(2)(F)(ii)(I). Pub. L. 112–40 substituted ''quality improvement'' for ''quality control and peer review''.

2008—Subsec. (a)(2)(C). Pub. L. 110–275 substituted '', outpatient'' for ''and outpatient'' and inserted '', and outpatient speech-language pathology services (other than services to which the second sentence of section 1395x(p) of this title applies through the application of section 1395x(*ll*)(2) of this title)'' before semicolon at end.

2000—Subsecs. (b), (c). Pub. L. 106–554 redesignated subsec. (c) as (b) and struck out former subsec. (b), which related to extension of coverage of immunosuppressive drugs for individuals who would exhaust benefits under section 1395x(s)(2)(J)(v) of this title in a year during the 5-year period beginning with 2000, and set forth provisions relating to extension periods for each year.

1999—Subsecs. (b), (c). Pub. L. 106–113 added subsec. (b) and redesignated former subsec. (b) as (c).

1997—Subsec. (a)(1). Pub. L. 105–33, §4603(c)(2)(B)(ii), substituted ''subparagraphs (E) and (F) of section 1395u(b)(6) of this title;'' for ''section 1395u(b)(6)(E) of this title;''.

Pub. L. 105–33, §4432(b)(5)(B), substituted ''(2) and section 1395u(b)(6)(E) of this title;'' for ''(2);''.

Subsec. (a)(2)(B)(iv). Pub. L. 105–33, §4511(c), substituted ''but only if no facility or other provider charges or is paid any amounts with respect to the fur-

nishing of such services'' for ''provided in a rural area (as defined in section 1395ww(d)(2)(D) of this title)''.

Subsec. (a)(2)(H). Pub. L. 105–33, § 4201(c)(1), substituted ''critical access'' for ''rural primary care''.

1990—Subsec. (a)(2)(A), (B). Pub. L. 101–508, § 4153(a)(2)(A)(i), substituted ''subparagraph (G) or subparagraph (I)'' for ''subparagraph (G)''.

Subsec. (a)(2)(B)(iii). Pub. L. 101–508, § 4157(b), amended cl. (iii) generally. Prior to amendment, cl. (iii) related to services of a certified registered nurse anesthetist.

Subsec. (a)(2)(B)(iv). Pub. L. 101–508, § 4155(b)(1), added cl. (iv).

Subsec. (a)(2)(D). Pub. L. 101–508, § 4161(a)(3)(A), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (a)(2)(I). Pub. L. 101–508, § 4153(a)(2)(A)(ii)–(iv), added subpar. (I).

Subsec. (a)(2)(J). Pub. L. 101–508, § 4162(b)(1), added subpar. (J).

1989—Subsec. (a). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, §§ 203(a), 205(a), 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. (a)(2)(H). Pub. L. 101–239 added subpar. (H).

Subsec. (b). Pub. L. 101–234, § 101(a), repealed Pub. L. 100–360, § 104(d)(3), 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.

1988—Subsec. (a). Pub. L. 100–360, § 205(a)(2), inserted sentence at end relating to in-home care provided to a chronically dependent individual on any day.

Subsec. (a)(2)(A). Pub. L. 100–360, § 205(a)(1), designated existing provisions as cl. (i) and added cl. (ii) relating to in-home care for a chronically dependent individual.

Pub. L. 100–360, § 203(a), inserted ''and home intravenous drug therapy services'' before semicolon at end.

Subsec. (a)(2)(B)(iv). Pub. L. 100–360, § 411(h)(7)(B), struck out Pub. L. 100–203, § 4077(b)(2), see 1987 Amendment note below.

Pub. L. 100–360, § 411(h)(4)(A), struck out Pub. L. 100–203, § 4073(b)(1), see 1987 Amendment note below.

Subsec. (a)(2)(F)(i). Pub. L. 100–360, § 411(g)(2)(E), added Pub. L. 100–203, § 4063(e)(2), see 1987 Amendment note below.

Subsec. (a)(2)(F)(ii). Pub. L. 100–360, § 411(i)(4) (C)(vi), added Pub. L. 100–203, § 4085(i)(22)(A), see 1987 Amendment note below.

Subsec. (b). Pub. L. 100–360, § 104(d)(3), substituted ''definitions of 'medical and other health services' and'' for ''definitions of 'spell of illness', 'medical and other health services', and''.

1987—Subsec. (a)(2)(A). Pub. L. 100–203, § 4062(d)(2)(A), inserted ''(other than items described in subparagraph (G))'' after ''services''.

Subsec. (a)(2)(B). Pub. L. 100–203, § 4062(d)(2)(B), inserted ''(other than items described in subparagraph (G))'' after ''health services''.

Subsec. (a)(2)(B)(iv). Pub. L. 100–203, § 4077(b)(2), which directed the addition of cl. (iv) relating to qualified psychologist services, was repealed by Pub. L. 100–360, § 411(h)(7)(B).

Pub. L. 100–203, § 4073(b)(1), which directed the addition of cl. (iv) relating to certified nurse-midwife services, was repealed by Pub. L. 100–360, § 411(h)(4)(A).

Subsec. (a)(2)(F)(i). Pub. L. 100–203, § 4063(e)(2), as added by Pub. L. 100–360, § 411(g)(2)(E), inserted ''(including intraocular lens in cases described in section 1395*l*(i)(2)(A)(iii) of this title)'' after ''services'' in two places.

Subsec. (a)(2)(F)(ii). Pub. L. 100–203, § 4085(i)(22)(A), as added by Pub. L. 100–360, § 411(i)(4)(C)(vi), substituted ''payment on an assignment-related basis'' for ''an assignment described in section 1395u(b)(3)(B)(ii) of this title'' in concluding provisions.

Subsec. (a)(2)(G). Pub. L. 100–203, § 4062(d)(2)(C), added subpar. (G).

1986—Subsec. (a)(2)(B)(iii). Pub. L. 99–509, § 9320(d), added cl. (iii).

Subsec. (a)(2)(C). Pub. L. 99–509, § 9337(a), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: ''outpatient physical therapy services, other than services to which the next to last sentence of section 1395x(p) of this title applies;''.

Subsec. (a)(2)(F). Pub. L. 99–509, § 9343(e)(1), inserted ''standard overhead'' in cl. (i) and concluding provisions of cl. (ii).

1984—Subsec. (a)(2)(F)(ii). Pub. L. 98–369, § 2341(b), substituted ''paragraph (1), (2), or (3) of section 1395x(r) of this title'' for ''section 1395x(r)(1) of this title''.

Subsec. (a)(2)(F)(ii)(II). Pub. L. 98–369, § 2354(b)(6), substituted ''organization'' for ''Organization''.

1982—Subsec. (a)(2)(F)(ii)(I). Pub. L. 97–248 substituted ''quality control and peer review organization (having a contract with the Secretary'' for ''Professional Standards Review Organization (designated, conditionally or otherwise,''.

1980—Subsec. (a)(2)(A). Pub. L. 96–499, § 930(g), struck out restriction on home health services of 100 visits during a calendar year.

Subsec. (a)(2)(B)(i)(II). Pub. L. 96–499, § 948(a)(2), substituted ''where the conditions specified in paragraph (7) of such section are met'' for '', unless either clause (A) or (B) of paragraph (7) of such section is met''.

Subsec. (a)(2)(E). Pub. L. 96–499, § 933(a), added subpar. (E).

Subsec. (a)(2)(F). Pub. L. 96–499, § 934(a), added subpar. (F).

1977—Subsec. (a)(1). Pub. L. 95–210, § 1(a)(1), substituted ''subparagraphs (B) and (D) of paragraph (2)'' for ''paragraph (2)(B)''.

Subsec. (a)(2)(D). Pub. L. 95–210, § 1(a)(2), added subpar. (D).

1972—Subsec. (a)(2)(B). Pub. L. 92–603, § 227(e)(1), inserted provisions relating to medical and other health services performed by a physician to a patient in a hospital which has an approved teaching program.

Subsec. (a)(2)(C). Pub. L. 92–603, § 251(a)(4), inserted '', other than services to which the next to last sentence of section 1395x(p) of this title applies''.

1968—Subsec. (a)(2)(B). Pub. L. 90–248, § 129(c)(6)(B), inserted ''and the services for which payment may be made pursuant to section 1395n(b)(2) of this title'' after ''hospital''.

Subsec. (a)(2)(C). Pub. L. 90–248, § 133(d), added subpar. (C).

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 2008 AMENDMENT

Pub. L. 110–275, title I, § 143(c), July 15, 2008, 122 Stat. 2543, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395n, 1395x, 1395y, 1395cc, and 1395nn of this title] shall apply to services furnished on or after July 1, 2009.''

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 4432(b)(5)(B) 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.

Pub. L. 105–33, title IV, § 4511(e), Aug. 5, 1997, 111 Stat. 443, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395x, 1395y, 1395cc, and 1395yy of this title] shall apply with respect to services furnished and supplies provided on and after January 1, 1998.''

Amendment by section 4603(c)(2)(B)(ii) 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.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, §4153(a)(3), Nov. 5, 1990, 104 Stat. 1388–83, provided that: ''The amendments made by paragraphs (1) and (2) [amending this section and sections 1395*l* and 1395m of this title] shall apply to items furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4155(e), Nov. 5, 1990, 104 Stat. 1388–88, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395u, and 1395x of this title] shall apply to services furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4157(d), Nov. 5, 1990, 104 Stat. 1388–89, provided that: ''The amendments made by the preceding subsections [amending this section and sections 1395x, 1395y, and 1395cc of this title] apply to services furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4161(a)(8), Nov. 5, 1990, 104 Stat. 1388–95, provided that:

''(A) Subject to subparagraphs (B) and (C), the amendments made by this section [probably means this subsection, which amended this section and sections 1320a–7b, 1395*l*, 1395x, 1395y, and 1395*oo* of this title] shall apply to services furnished on or after October 1, 1991.

''(B) In the case of a Federally qualified health care center that has elected, as of January 1, 1990, under part B of title XVIII of the Social Security Act [this part], to have the amount of payments for services under such part determined on a reasonable-charge basis, the amendment made by paragraph (3)(A) [amending this section] shall only apply on and after such date (not earlier than October 1, 1991) as the center may elect.

''(C) The amendment made by paragraph (6) [amending section 1395*oo* of this title] shall apply to cost reports for periods beginning on or after October 1, 1991.''

Pub. L. 101–508, title IV, §4162(c), Nov. 5, 1990, 104 Stat. 1388–96, provided that: ''The amendments made by subsections (a) and (b) [amending this section and sections 1395x and 1395cc of this title] shall apply with respect to partial hospitalization services provided on or after October 1, 1991.''

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 101(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 101(d) of Pub. L. 101–234, set out as a note under section 1395c 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.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 104(d)(3) of Pub. L. 100–360 effective Jan. 1, 1989, except as otherwise provided, and applicable to inpatient hospital deductible for 1989 and succeeding years, to care and services furnished on or after Jan. 1, 1989, to premiums for January 1989 and succeeding months, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 104(a) of Pub. L. 100–360, set out as a note under section 1395d of this title.

Amendment by section 203(a) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Pub. L. 100–360, title II, §205(f), July 1, 1988, 102 Stat. 731, which provided that the amendments made by section 205 of Pub. L. 100–360 [amending this section and sections 1395*l*, 1395n, 1395x, and 1395y of this title] were applicable to items and services furnished on or after January 1, 1990, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(g)(2)(E), (h)(4)(A), (7)(B), (i)(4)(C)(vi) 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 4062(d)(2) of Pub. L. 100–203 applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

Pub. L. 100–203, title IV, §4073(e), Dec. 22, 1987, 101 Stat. 1330–119, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395x, and 1396d of this title] shall be effective with respect to services performed on or after July 1, 1988.''

Pub. L. 100–203, title IV, §4077(b)(5), formerly §4077(b)(6), Dec. 22, 1987, 101 Stat. 1330–121, as renumbered by Pub. L. 100–360, title IV, §411(h)(7)(F), July 1, 1988, 102 Stat. 787, provided that: ''The amendments made by this subsection [amending this section and sections 1395*l* and 1395x of this title] shall be effective with respect to services performed on or after July 1, 1988.''

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–509, title IX, §9320(i), Oct. 21, 1986, 100 Stat. 2016, as amended by Pub. L. 100–485, title VI, §608(c)(1), Oct. 13, 1988, 102 Stat. 2412, provided that: ''Except as provided in subsection (k) [set out below], the amendments made by this section (other than subsection (a)) [amending this section and sections 1395*l*, 1395u, 1395x, 1395y, 1395aa, 1395bb, 1395cc, 1395ww, 1396a, and 1396n of this title] shall apply to services furnished on or after January 1, 1989.''

Pub. L. 99–509, title IX, §9337(e), Oct. 21, 1986, 100 Stat. 2034, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395n, 1395x, and 1395cc of this title] shall apply to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987.''

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98–369, div. B, title III, §2341(d), July 18, 1984, 98 Stat. 1094, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] apply to services furnished on or after the date of the enactment of this Act [July 18, 1984].''

Amendment by section 2354(b)(6) 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.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97–248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1320c of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by section 930(g) of Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(s)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Pub. L. 96–499, title IX, §933(h), Dec. 5, 1980, 94 Stat. 2637, provided that: ''The amendments made by this section [amending this section and sections 1395n, 1395x, 1395z, and 1395aa of this title] shall become effective with respect to a comprehensive outpatient rehabilitation facility's first accounting period which begins on or after July 1, 1981.''

Amendment by section 948(a)(2) of Pub. L. 96–499 applicable with respect to cost accounting periods begin-

ning on or after Oct. 1, 1978, see section 948(c)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–210, § 1(j), Dec. 13, 1977, 91 Stat. 1488, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395x, 1395y, and 1395aa of this title and enacting provisions set out as notes under sections 1395*l* and 1395x of this title] shall apply to services rendered on or after the first day of the third calendar month which begins after the date of enactment of this Act [Dec. 13, 1977].''

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 227(e)(1) 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.

Amendment by section 251(a)(4) of Pub. L. 92–603 applicable with respect to services furnished on or after July 1, 1973, see section 251(d)(1) of Pub. L. 92–603, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 129(c)(6)(B) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395d of this title.

Pub. L. 90–248, title I, § 133(g), Jan. 2, 1968, 81 Stat. 852, provided that: ''The amendments made by the preceding subsections of this section [amending this section and sections 1395n, 1395x, 1395aa, and 1395cc of this title] shall apply to services furnished after June 30, 1968.''

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–275, title I, § 143(d), July 15, 2008, 122 Stat. 2543, provided that: ''Nothing in this section [amending this section and sections 1395*l*, 1395n, 1395x, 1395y, 1395cc, and 1395nn of this title] shall be construed to affect existing regulations and policies of the Centers for Medicare & Medicaid Services that require physician oversight of care as a condition of payment for speech-language pathology services under part B of the Medicare program [42 U.S.C. 1395j et seq.].''

CONSTRUCTION OF 1986 AMENDMENT

Pub. L. 99–509, title IX, § 9320(j), Oct. 21, 1986, 100 Stat. 2016, provided that: ''Nothing in this section or the amendments made by this section [amending this section and sections 1395*l*, 1395u, 1395x, 1395y, 1395aa, 1395bb, 1395cc, 1395ww, 1396a, and 1396n of this title, enacting provisions set out as notes under this section, and amending provisions set out as a note under section 1395ww of this title] shall contravene provisions of State law relating to the practice of medicine or nursing or State law requirements or institutional requirements regarding the administration of anesthesia and its medical direction or supervision.''

REPORT ON IMMUNOSUPPRESSIVE DRUG BENEFIT

Pub. L. 106–113, div. B, § 1000(a)(6) [title II, § 227(d)], Nov. 29, 1999, 113 Stat. 1536, 1501A–356, which required the Secretary of Health and Human Services to submit to Congress not later than Mar. 1, 2003, a report on the operation of section 1000(a)(6) [title II, § 227] of Pub. L. 106–113, amending this section and section 1395x of this title, including an analysis of impact and recommendations regarding an appropriate cost-effective method for providing coverage of immunosuppressive drugs under the medicare program on a permanent basis, was repealed by Pub. L. 106–554, § 1(a)(6) [title I, § 113(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473.

QUALITY AND UTILIZATION OF IN-HOME CARE FOR CHRONICALLY DEPENDENT INDIVIDUALS

Pub. L. 100–360, title II, § 205(e)(2), July 1, 1988, 102 Stat. 731, directed Secretary of Health and Human Services to take appropriate efforts to assure quality and provide for appropriate utilization of in-home care for chronically dependent individuals under the amendments made by section 205 of Pub. L. 100–360 [amending this section and sections 1395*l*, 1395n, 1395x, and 1395y of this title], prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

STUDY OF ALTERNATIVE OUT-OF-HOME SERVICES

Pub. L. 100–360, title II, § 205(g), July 1, 1988, 102 Stat. 731, which required Secretary of Health and Human Services to study, and report to Congress, not later than 18 months after July 1, 1988, on advisability of providing, to chronically dependent individuals eligible for in-home care under amendments made by section 205 of Pub. L. 100–360 [amending this section and sections 1395*l*, 1395n, 1395x, and 1395y of this title], out-of-home services as alternative services to in-home care, was repealed by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

CONTINUATION OF COST PASS-THROUGH FOR CERTIFIED REGISTERED NURSE ANESTHETISTS

Pub. L. 99–509, title IX, § 9320(k), as added by Pub. L. 100–485, title VI, § 608(c)(2), Oct. 13, 1988, 102 Stat. 2412, and amended by Pub. L. 101–239, title VI, § 6132(a), Dec. 19, 1989, 103 Stat. 2222, provided that:

''(1) Subject to paragraph (2), the amendments made by this section [amending this section and sections 1395*l*, 1395u, 1395x, 1395y, 1395aa, 1395bb, 1395cc, 1395ww, 1396a, and 1396n of this title and provisions set out as a note under section 1395ww of this title] shall not apply during a year (beginning with 1989) to a hospital located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act [42 U.S.C. 1395ww(d)]) if the hospital establishes, at any time before the year[,] to the satisfaction of the Secretary of Health and Human Services that—

''(A) as of January 1, 1988, the hospital employed or contracted with a certified registered nurse anesthetist (but not more than one full-time equivalent certified registered nurse anesthetist),

''(B) in 1987 the hospital had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services that did not exceed 500 (or such higher number as the Secretary determines to be appropriate), and

''(C) each certified registered nurse anesthetist employed by, or under contract with, the hospital has agreed not to bill under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] for professional services furnished by the anesthetist at the hospital.

''(2) Paragraph (1) shall not apply in a year (after 1989) to a hospital unless the hospital establishes, before the beginning of the year, that the hospital has had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services in the previous year that did not exceed 500 (or such higher number as the Secretary determines to be appropriate).''

[Pub. L. 101–239, title VI, § 6132(b), Dec. 19, 1989, 103 Stat. 2222, provided that: ''The amendments made by this section [amending section 9320(k) of Pub. L. 99–509, set out above] shall apply to services furnished on or after January 1, 1990.'']

PAYMENT FOR SERVICES OF PHYSICIANS RENDERED IN A TEACHING HOSPITAL FOR ACCOUNTING PERIODS BEGINNING AFTER JUNE 30, 1975, AND PRIOR TO OCTOBER 1, 1978; STUDIES, REPORTS, ETC.; EFFECTIVE DATES

Pub. L. 93–233, § 15(a)(2), Dec. 31, 1973, 87 Stat. 966, provided that for the cost accounting periods beginning after June 30, 1975, and prior to Oct. 1, 1978, subsec. (a)(2)(B)(i) of this section will be administered as if subclause II of subsec. (a)(2)(B)(i) read as follows: ''(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1861(b) [42 U.S.C. 1395x(b)(6)] (including services in conjunction with the teaching programs of such hos-

pital whether or not such patient is an inpatient of such hospital), where the conditions specified in paragraph (7) of such section [42 U.S.C. 1395x(b)(7)] are met and''.

§ 1395*l*. Payment of benefits

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1395k(a)(1) of this title—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b) of this section, (B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) of this section (for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (II) under section 1395m–1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate,,[1] (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to clinical social worker services under section 1395x(s)(2)(N) of this title, the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), (G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) of this section and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D) of this section, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system, (H) with respect to services of a certified registered nurse anesthetist under section 1395x(s)(11) of this title, the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (*l*) of this section, (I) with respect to covered items (described in section 1395m(a)(13) of this title), the amounts paid shall be the amounts described in section 1395m(a)(1) of this title, and[2] (J) with respect to expenses incurred for radiologist services (as defined in section 1395m(b)(6) of this title), subject to section 1395w–4 of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1395m(b) of this title, (K) with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1395w–4 of this title for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1395x(s)(2)(M) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthet-

[1] So in original.

[2] So in original. The word ''and'' probably should not appear.

ics (as defined in section 1395m(h)(4) of this title), the amounts paid shall be the amounts described in section 1395m(h)(1) of this title, (N) with respect to expenses incurred for physicians' services (as defined in section 1395w–4(j)(3) of this title) other than personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amounts paid shall be 80 percent of the payment basis determined under section 1395w–4(a)(1) of this title, (O) with respect to services described in section 1395x(s)(2)(K) of this title (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1395w–4 of this title, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1395m(i) of this title, (Q) with respect to items or services for which fee schedules are established pursuant to section 1395u(s) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1395m(*l*) of this title and (ii) with respect to ambulance services described in section 1395m(*l*)(8) of this title, the amounts paid shall be the amounts determined under section 1395m(g) of this title for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1395x(zz) of this title)) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1395u(*o*) of this title (or, if applicable, under section 1395w–3, 1395w–3a, or 1395w–3b of this title), (T) with respect to medical nutrition therapy services (as defined in section 1395x(vv) of this title), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1395w–4(b) of this title for the same services if furnished by a physician, (U) with respect to facility fees described in section 1395m(m)(2)(B) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1395u(s) items), with respect to competitively priced items and services (described in section 1395w–3(a)(2) of this title) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1395w–3(b)(5) of this title, (W) with respect to additional preventive services (as defined in section 1395x(ddd)(1) of this title), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting ''100 percent'' for ''80 percent''), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1395w–4 of this title, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), and (Z) with respect to Federally qualified health center services for which payment is made under section 1395m(*o*) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section;

(2) in the case of services described in section 1395k(a)(2) of this title (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1395rr of this title)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1395x(kk) of this title), the amount determined under the prospective payment system under section 1395fff of this title;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1395ww of this title or section 1395yy(e)(9) of this title)—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(II) the customary charges with respect to such services,

less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1395f(b)(2) of this title, or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t) of this section, or

(iv) if (and for so long as) the conditions described in section 1395f(b)(3) of this title are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1395x(p) of this title, 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule determined under subsection (h)(1) of this section (for tests furnished before January 1, 2017) or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395cc of this title) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (II) under section 1395m–1 of this title (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395cc of this title) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1395x(s)(3) of this title (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) of this section or, for services or procedures performed on or after January 1, 1999, subsection (t) of this section;

(F) with respect to a covered osteoporosis drug (as defined in section 1395x(kk) of this title) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1395x(v) of this title;

(G) with respect to items and services described in section 1395x(s)(10)(A) of this title, the lesser of—

(i) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or,[3] if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title;

(3) in the case of services described in section 1395k(a)(2)(D) of this title—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1395x(v)(1)(A) of this title, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such services (other than for items and services described in section 1395x(s)(10)(A) of this title) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1395k(a)(2)(D) of this title that are furnished to an individual enrolled with a MA plan under part C of this subchapter pursuant to a written agreement described in section 1395w–23(a)(4) of this title, the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if ''100 percent'' were substituted for ''80 percent'' in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the pro-

[3] See 2010 Amendment note for subsec. (a)(2)(F) to (H) below.

spective payment system under section 1395m(*o*) of this title, under such section (calculated as if ''100 percent'' were substituted for ''80 percent'' in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1395w–27(e)(3)(B) of this title;

(4) in the case of facility services described in section 1395k(a)(2)(F) of this title, and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to subsection (i)(1)(A) of this section, the applicable amount as determined under paragraph (2) or (3) of subsection (i) of this section or subsection (t) of this section;

(5) in the case of covered items (described in section 1395m(a)(13) of this title) the amounts described in section 1395m(a)(1) of this title;

(6) in the case of outpatient critical access hospital services, the amounts described in section 1395m(g) of this title;

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1395m(h)(4) of this title), the amounts described in section 1395m(h) of this title;

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A of this subchapter but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A of this subchapter, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1395m(k) of this title; and

(9) in the case of services described in section 1395k(a)(2)(E) of this title that are not described in paragraph (8), the amounts described in section 1395m(k) of this title.

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1395m(0)[4] of this title.

(b) Deductible provision

Before applying subsection (a) of this section with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) of this section are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1395r(a)(1) of this title ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1395x(ddd)(3) of this title that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual.,[1] (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title)), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) of this section on an assignment-related basis, or to a provider having an agreement under section 1395cc of this title, or (B) for tests furnished before January 1, 2017, on the basis of a negotiated rate determined under subsection (h)(6) of this section, (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1395x(jj) of this title), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1395x(nn) of this title), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1395x(bbb) of this title), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1395x(pp)(1) of this title), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1395x(ww) of this title), and (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in ac-

[4] So in original. Probably should be ''1395m(*o*)''.

cordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395e(a)(2) of this title to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c) Mental disorders

(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term ''treatment'' does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

(d) Nonduplication of payments

No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1395e of this title) to have payment made with respect to such services under part A of this subchapter.

(e) Information for determination of amounts due

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f) Maximum rate of payment per visit for independent rural health clinics

In establishing limits under subsection (a) of this section on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided—

(1) in 1988, after March 31, at $46 per visit, and

(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) applicable to primary care services (as defined in section 1395u(i)(4) of this title) furnished as of the first day of that year.

(g) Physical therapy services

(1) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1395x(p) of this title and speech-language pathology services of the type described in such section through the application of section 1395x(*ll*)(2) of this title, but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1395x(p) of this title (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1395x(g) of this title and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under

which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of February 22, 2012) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(D) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1395pp of this title shall apply in the same manner as such section applies to a denial that is made by reason of section 1395y(a)(1) of this title.

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a ''therapy provider'') using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this subchapter.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this subchapter or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group[5] that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1395ddd(h) of this title for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented.

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1395m(g) of this title, the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1395m(k)(1)(B) of this title instead of being paid under section 1395m(g) of this title.

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1395m(g) of this title.

(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate

(1)(A) Subject to section 1395m(d)(1) of this title, the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1395x(*oo*) of this title consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

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[5] So in original. Probably should be preceded by ''a''.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term ''qualified hospital laboratory'' means a hospital laboratory, in a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1395u(b)(3) of this title for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before April 1, 2014, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1395u(b)(3) of this title performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017) or under section 1395m–1 of this title (for tests furnished on or after January 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this subchapter for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities rep-

resenting at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i) of this section, the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1395cc of this title, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)),[6] receives requests for testing during the year in which the test is performed[6] are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1395x(w)(1) of this title) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1395cc of this title.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1395u(j) of this title in the same manner such paragraphs apply[7] with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, in the case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4) and section 1395m–1 of this title, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical

[6] So in original. The comma after ''subclause (II))'' probably should follow ''is performed''.

[7] So in original. Probably should be ''such paragraph applies''.

cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as ''new tests'').

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term ''HCPCS'' refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be ''substantially revised'' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i) Outpatient surgery

(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1395k(a)(2)(F)(i) of this title), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of

the procedure in such a center will result in substantially less amounts paid under this subchapter than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this subchapter than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be 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.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of subsection (t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such subsection,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B) of this section; or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title.

(ii) Subject to paragraph (4), in this paragraph:

(I) The term ''cost proportion'' means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term ''ASC proportion'' means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this[8] subparagraph (A)(iii)(II), the term ''eye or eye and ear unit'' means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1395k(a)(2)(F)(i) of this title, who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $2,000. 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.

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of subsection (t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(j) Accrual of interest on balance of excess or deficit not paid

Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1395u(b)(3)(B)(ii) of this title was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid

[8] So in original. The word ''this'' probably should not appear.

or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) Hepatitis B vaccine

With respect to services described in section 1395x(s)(10)(B) of this title, the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(*l*) Fee schedule for services of certified registered nurse anesthetists

(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1395x(s)(11) of this title.

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this subchapter for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this subchapter for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A of this subchapter in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this subchapter plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1395u(b)(3) of this title.

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1395w–4(d) of this title for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1395w–4 of this title (or, in the case of services furnished during 1991, the localities used under section 1395u(b) of this title) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—[9]

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1395u(q)(1)(B) of this title for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1395w–4 of this title,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1395w–4 of this title).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the

[9] So in original. Probably should be ''are—''.

amount described in section 1395w–4(a)(5)(B) of this title with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs[10] (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this subchapter.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and 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 section 1395u(j)(1)(D) of this title.

(m) Incentive payments for physicians' services furnished in underserved areas

(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C) of this section.

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n) Payments to hospital outpatient departments for radiology; amount; definitions

(1)(A)[11] The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) of this section furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) of this section furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B) of this section, or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i) of this section), or (for procedures described in subsection (a)(2)(E)(ii) of this section), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) of this sec-

[10] So in original. Probably should be ''subparagraph''.

[11] So in original. No par. (2) has been enacted.

tion furnished on or after April 1, 1989 and for services described in subsection (a)(2)(E)(ii) of this section furnished on or after January 1, 1992) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1395u(b) of this title (or, in the case of services furnished on or after January 1, 1992, under section 1395w–4 of this title), less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title.

(ii) In this subparagraph:

(I) The term ''cost proportion'' means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) of this section for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term ''charge proportion'' means 100 percent minus the cost proportion.

(*o*) Limitation on benefit for payment for therapeutic shoes for individuals with severe diabetic foot disease

(1) In the case of shoes described in section 1395x(s)(12) of this title—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1395m(h) of this title.

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1395m(h) of this title if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1395x(s)(12) of this title may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1395m(h) of this title, a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this subchapter, the term ''shoes'' includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(p) Repealed. Pub. L. 103–432, title I, § 123(b)(2)(A)(ii), Oct. 31, 1994, 108 Stat. 4411

(q) Requests for payment to include information on referring physician

(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1395nn of this title) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion 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.

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

(r) Cap on prevailing charge; billing on assignment-related basis

(1) With respect to services described in section 1395x(s)(2)(K)(ii) of this title (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, criti-

cal access hospital, skilled nursing facility or nursing facility (as defined in section 1396r(a) of this title), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1395x(s)(2)(K)(ii) of this title may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this subchapter.

(s) Other prepaid organizations

The Secretary may not provide for payment under subsection (a)(1)(A) of this section with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term ''covered OPD services''—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A of this subchapter but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title;

(iv) does not include any therapy services described in subsection (a)(8) of this section or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(*l*) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as ''comparable with respect to the use of resources'' if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the

group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) of this section did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under subsection (b) of this section did not apply.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the ''unadjusted copayment amount'' applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the ''OPD fee schedule increase factor'' for services furnished in a year is equal to the market basket percentage increase applicable under section 1395ww(b)(3)(B)(iii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such

services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b) of this section, to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment

(A) In general

Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment

The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term ''applicable percentage'' means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority

In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCS from outlier payments

No additional payment shall be made under subparagraph (A) in the case of ambu-

latory payment classification groups established separately for drugs or biologicals.

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals

(A) In general

The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs

A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 360bb of title 21 if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy

A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products

A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) New medical devices, drugs, and biologicals

A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments

The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories

(I) In general

The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations

The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories

(I) In general

The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) Standard

Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline

Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories

The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect

A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met

A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 360e of title 21 has been approved with respect to the device, or the device has been cleared for market under section 360(k) of title 21, or the device is exempt from the requirements of section 360(k) of title 21 pursuant to subsection (*l*) or (m) of section 360 of title 21 or section 360j(g) of title 21.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment

(i) Drugs and biologicals

The payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices

Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment

Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) in the case of a drug or biological, the amount by which the amount determined under section 1395u(*o*) of this title (or if the drug or biological is covered under a competitive acquisition contract under section 1395w–3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term ''applicable percentage'' means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded

If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard

(i) In general

The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application

Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after December 8, 2003, unless—

(I) such application was being made to such drug or biological prior to December 8, 2003; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this subchapter.

(iii) Rule of construction

Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(7) Transitional adjustment to limit decline in payment

(A) Before 2002

Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002

Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003

Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions

(i) Temporary treatment for certain rural hospitals

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) Permanent treatment for cancer hospitals and children's hospitals

In the case of a hospital described in clause (iii) or (v) of section 1395ww(d)(1)(B)

of this title, for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined

In this paragraph, the ''PPS amount'' means, with respect to covered OPD services, the amount payable under this subchapter for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1395cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b) of this section.

(F) Pre-BBA amount defined

(i) In general

In this paragraph, the ''pre-BBA amount'' means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost ratio defined

For purposes of this subparagraph, the ''base payment-to-cost ratio'' for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments

The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments

Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality

The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount

(A) In general

Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount

The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount

(i) To inpatient hospital deductible amount

In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.

(ii) To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) No impact on deductibles

Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under subsection (b) of this section.

(E) Computation ignoring outlier and pass-through adjustments

The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor

If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) Special rule for ambulance services

The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1395x(v)(1)(U) of this title, or, if applicable, the fee schedule established under section 1395m(*l*) of this title.

(11) Special rules for certain hospitals

In the case of hospitals described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) Authorization of adjustment for rural hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates

(A) In general

The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(*o*) of this title, section 1395w–3a of this title, or section 1395w–3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) Specified covered outpatient drug defined

(i) In general

In this paragraph, the term ''specified covered outpatient drug'' means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r–8(k)(2) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception

Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) Annual GAO surveys in 2004 and 2005

(I) In general

The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations

Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) Subsequent secretarial surveys

The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements

The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost

In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates

Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs

(i) MedPAC report on drug APC design

The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized

The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs

For purposes of this paragraph:

(i) Sole source drugs

The term ''sole source drug'' means—

(I) a biological product (as defined under section 1395x(t)(1) of this title); or

(II) a single source drug (as defined in section 1396r–8(k)(7)(A)(iv) of this title).

(ii) Innovator multiple source drugs

The term ''innovator multiple source drug'' has the meaning given such term in section 1396r–8(k)(7)(A)(ii) of this title.

(iii) Noninnovator multiple source drugs

The term ''noninnovator multiple source drug'' has the meaning given such term in section 1396r–8(k)(7)(A)(iii) of this title.

(G) Reference average wholesale price

The term ''reference average wholesale price'' means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(*o*) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) Payment for new drugs and biologicals until HCPCS code assigned

With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) Miscellaneous provisions

(A) Application of reclassification of certain hospitals

If a hospital is being treated as being located in a rural area under section 1395ww(d)(8)(E) of this title, that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCS for drugs

The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) Special payment rule

(i) In general

In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multisource Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) Hospital described

A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1395ww(d)(2)(D) of this title);

(II) classified as a rural referral center under section 1395ww(d)(5)(C) of this title; or

(III) a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title).

(iii) Not budget neutral

In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) Application of appropriate use criteria for certain imaging services

For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1395m(q) of this title.

(F) Payment incentive for the transition from traditional X-ray imaging to digital radiography

Notwithstanding the previous provisions of this subsection:

(i) Limitation on payment for film X-ray imaging services

In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) Phased-in limitation on payment for computed radiography imaging services

In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1395w–4(b)(9)(C) of this title)—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) Application without regard to budget neutrality

The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) Implementation

In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) Quality reporting

(A) Reduction in update for failure to report

(i) In general

For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) Non-cumulative application

A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) Form and manner of submission

Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) Development of outpatient measures

(i) In general

The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) Construction

Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1395ww(b)(3)(B)(viii) of this title.

(D) Replacement of measures

For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) Availability of data

The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the op-

portunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) Authorization of adjustment for cancer hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(19) Floor on area wage adjustment factor for hospital outpatient department services in frontier States

(A) In general

Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) Limitation

This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(20) Not budget neutral application of reduced expenditures resulting from quality incentives for computed tomography

The Secretary shall not take into account the reduced expenditures that result from the application of section 1395m(p) of this title in making any budget neutrality adjustments this[12] subsection.

[12] So in original. Probably should be preceded by ''under''.

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term ''applicable items and services'' means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to clause (ii), the term ''off-campus outpatient department of a provider'' means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) Exception

For purposes of paragraph (1)(B)(v) and this paragraph, the term ''off-campus outpatient department of a provider'' shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015.

(C) Availability of payment under other payment systems

Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) Information needed for implementation

Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1395cc(j) of this title).

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(u) Incentive payments for physician scarcity areas

(1) In general

In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) Determination of ratios of physicians to medicare beneficiaries in area

Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) Number of physicians practicing in the area

The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) Number of medicare beneficiaries residing in the area

The number of individuals who are residing in the county and are entitled to benefits under part A of this subchapter or enrolled under this part, or both (in this subsection referred to as ''individuals'').

(C) Determination of ratios

(i) Primary care ratio

The ratio (in this paragraph referred to as the ''primary care ratio'') of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) Specialist care ratio

The ratio (in this paragraph referred to as the ''specialist care ratio'') of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) Ranking of counties

The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) Identification of counties

(A) In general

The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as ''primary care scarcity counties'') with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as ''specialist care scarcity counties'') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) Periodic revisions

The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) Identification of counties where service is furnished

For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) Special rule

With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, respecting—

(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) Rural census tracts

To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan

statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) Physician defined

For purposes of this paragraph, the term ''physician'' means a physician described in section 1395x(r)(1) of this title and the term ''primary care physician'' means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) Publication of list of counties; posting on website

With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1395w–4 of this title for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) Increase of FQHC payment limits

In the case of services furnished by Federally qualified health centers (as defined in section 1395x(aa)(4) of this title), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year.

(w) Methods of payment

The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) Incentive payments for primary care services

(1) In general

In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) Definitions

In this subsection:

(A) Primary care practitioner

The term ''primary care practitioner'' means an individual—

(i) who—

(I) is a physician (as described in section 1395x(r)(1) of this title) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1395x(aa)(5) of this title); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) Primary care services

The term ''primary care services'' means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) Coordination with other payments

The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z)[13] shall be determined without regard to any additional payment for the service under subsection (z)[13] and this subsection, respectively.

(4) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* of this title, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) Incentive payments for major surgical procedures furnished in health professional shortage areas

(1) In general

In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

[13] See References in Text note below.

(2) Definitions

In this subsection:

(A) General surgeon

In this subsection, the term ''general surgeon'' means a physician (as described in section 1395x(r)(1) of this title) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1395cc(j) of this title.

(B) Major surgical procedures

The term ''major surgical procedures'' means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1395w–4(b) of this title.

(3) Coordination with other payments

The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z)[13] shall be determined without regard to any additional payment for the service under subsection (z)[13] and this subsection, respectively.

(4) Application

The provisions of paragraph[14] (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z)[15] Incentive payments for participation in eligible alternative payment models

(1) Payment incentive

(A) In general

In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) Form of payment

Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) Treatment of payment incentive

Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) Coordination

The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) Qualifying APM participant

For purposes of this subsection, the term ''qualifying APM participant'' means the following:

(A) 2019 and 2020

With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 and 2022

With respect to 2021 and 2022, an eligible professional described in either of the following clauses:

(i) Medicare payment threshold option

An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) Combination all-payer and medicare payment threshold option

An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are

[14] So in original. Probably should be ''paragraphs''.

[15] So in original. Two subsecs. (z) have been enacted.

available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under subchapter XIX in a State in which no medical home or alternative payment model is available under the State program under that subchapter),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) Requirement

For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1395w–4(q)(2)(B)(i) of this title apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds[16] expected aggregate expenditures; or

(BB) with respect to beneficiaries under subchapter XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1315a(c) of this title.

(C) Beginning in 2023

With respect to 2023 and each subsequent year, an eligible professional described in either of the following clauses:

(i) Medicare payment threshold option

An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) Combination all-payer and medicare payment threshold option

An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under subchapter XIX in a State in which no medical home or alternative payment model is available under the State program under that subchapter),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) Requirement

For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1395w–4(q)(2)(B)(i) of this title apply;

[16] So in original. Probably should be ''exceed''.

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds[16] expected aggregate expenditures; or

(BB) with respect to beneficiaries under subchapter XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1315a(c) of this title.

(D) Use of patient approach

The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1395w–4(q)(1)(C)(iii) of this title by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

(3) Additional definitions

In this subsection:

(A) Covered professional services

The term ''covered professional services'' has the meaning given that term in section 1395w–4(k)(3)(A) of this title.

(B) Eligible professional

The term ''eligible professional'' has the meaning given that term in section 1395w–4(k)(3)(B) of this title and includes a group that includes such professionals.

(C) Alternative payment model (APM)

The term ''alternative payment model'' means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1315a of this title (other than a health care innovation award).

(ii) The shared savings program under section 1395jjj of this title.

(iii) A demonstration under section 1395cc–3 of this title.

(iv) A demonstration required by Federal law.

(D) Eligible alternative payment entity

The term ''eligible alternative payment entity'' means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (*o*)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1395w–4(q)(2)(B)(i) of this title; and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1315a(c) of this title.

(4) Limitation

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo*[17] of this title, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(z)[15] Medical review of spinal subluxation services

(1) In general

The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1395x(r)(5) of this title by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a[1] chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) Medical review

(A) Prior authorization medical review

(i) In general

Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1395x(r)(5) of this title that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) Ending application of prior authorization medical review

The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior

[17] So in original. Probably should be preceded by ''section''.

authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) Early request for prior authorization review permitted

Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) Type of review

The Secretary may use pre-payment review or post-payment review of services described in section 1395x(r)(5) of this title that are not subject to prior authorization medical review under subparagraph (A).

(C) Relationship to law enforcement activities

The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) No payment without prior authorization

With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) Prior authorization determination

The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1395y(a)(1)(A) of this title.

(B) Denial of payment

Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1395y(a)(1)(A) of this title.

(4) Submission of information

A chiropractor described in section 1395x(r)(5) of this title may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) Timeliness

If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) Application of limitation on beneficiary liability

Where payment may not be made as a result of the application of paragraph (2)(B), section 1395pp of this title shall apply in the same manner as such section applies to a denial that is made by reason of section 1395y(a)(1) of this title.

(7) Review by contractors

The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1395kk–1(a)(4)(G) of this title or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) Multiple services

The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) Construction

With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this chapter.

(10) Implementation

(A) Authority

The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) Administration

Chapter 35 of title 44 shall not apply to medical review under this subsection.

(Aug. 14, 1935, ch. 531, title XVIII, § 1833, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 302; amended Pub. L. 90–248, title I, §§ 129(c)(7), (8), 131(a), (b), 132(b), 135(c), Jan. 2, 1968, 81 Stat. 848–850, 853; Pub. L. 92–603, title II, §§ 204(a), 211(c)(4), 226(c)(2), 233(b), 245(d), 251(a)(2), (3), 279, 299K(a), Oct. 30, 1972, 86 Stat. 1377, 1384, 1404, 1411, 1424, 1445, 1454, 1464; Pub. L. 95–142, § 16(a), Oct. 25, 1977, 91 Stat. 1200; Pub. L. 95–210, § 1(b), Dec. 13, 1977, 91 Stat. 1485; Pub. L. 95–292, § 4(b), (c), June 13, 1978, 92 Stat. 315; Pub. L. 96–473, § 6(j), Oct. 19, 1980, 94 Stat. 2266; Pub. L. 96–499, title IX, §§ 918(a)(4), 930(h), 932(a)(1), 934(b), (d)(1), (3), 935(a), 942, 943(a), Dec. 5, 1980, 94 Stat. 2626, 2631, 2634, 2637, 2639, 2641; Pub. L. 96–611, § 1(b)(1), (2), Dec. 28, 1980, 94 Stat. 3566; Pub. L. 97–35, title XXI, §§ 2106(a), 2133(a), 2134(a), Aug. 13, 1981, 95 Stat. 792, 797; Pub. L. 97–248, title I, §§ 101(c)(2), 112(a), (b), 117(a)(2), 148(d), Sept. 3, 1982, 96 Stat. 336, 340, 355, 394; Pub. L. 98–369, div. B, title III, §§ 2303(a)–(d), 2305(a)–(d), 2308(b)(2)(B), 2321(b), (d)(4)(A), 2323(b)(1), (2), (4), 2354(b)(5), (7), July 18, 1984, 98 Stat. 1064, 1069, 1070, 1074, 1084–1086, 1100; Pub. L. 98–617, § 3(b)(2), (3), Nov. 8, 1984, 98 Stat. 3295; Pub. L. 99–272, title IX, §§ 9303(a)(1), (b)(1)–(3), 9401(b)–(2)(E), Apr. 7, 1986, 100 Stat. 188, 189, 198, 199; Pub. L. 99–509, title IX, §§ 9320(e)(1), (2), 9337(b), 9339(a)(1), (b)(1), (2), (c)(1), 9343(a), (b), (e)(2), Oct. 21, 1986, 100 Stat. 2014, 2033, 2036, 2039–2041; Pub. L. 100–203, title IV, §§ 4042(b)(2)(B), 4043(a), 4045(c)(2)(A), 4049(a)(1), 4055(a), formerly 4054(a), 4062(d)(3),

4063(b), (e)(1), 4064(a), (b)(1), (2), (c)(1), formerly (c), 4066(a), (b), 4067(a), 4068(a), 4070(a), (b)(4), 4072(b), 4073(b), formerly (b)(2), (3), 4077(b)(2), (3), formerly (b)(3), (4), 4084(a), (c)(2), 4085(b)(1), (i)(1)–(3), (21)(D)(i), (22)(B), (23), Dec. 22, 1987, 101 Stat. 1330–85, 1330–88, 1330–90, 1330–108 to 1330–115, 1330–117, 1330–118, 1330–120, 1330–121, 1330–129 to 1330–133, as amended Pub. L. 100–360, title IV, § 411(f)(2)(D), (8)(B)(i), (12)(A), (14), (g)(2)(E), (3)(A)–(C), (E), (F), (h)(3)(B), (4)(B), (C), (7)(C), (D), (F), (i)(3), (4)(C)(i), (ii), (iv), (vi), July 1, 1988, 102 Stat. 777, 779, 781, 783, 784, 786–789; Pub. L. 100–360, title I, § 104(d)(7), title II, §§ 201(a), 202(b)(1)–(3), 203(c)(1)(A)–(E), 204(d)(1), 205(c), 212(c)(2), title IV, § 411(f)(8)(C), (g)(1)(E), (2)(D), (3)(D), (4)(C), (5), (h)(1)(A), (i)(4)(B), July 1, 1988, 102 Stat. 699, 704, 722, 729, 730, 741, 779, 782–785, 789, as amended Pub. L. 100–485, title VI, § 608(d)(3)(G), Oct. 13, 1988, 102 Stat. 2414; Pub. L. 100–485, title VI, § 608(d)(4), (22)(B), (D), (23)(A), Oct. 13, 1988, 102 Stat. 2414, 2420, 2421; Pub. L. 100–647, title VIII, §§ 8421(a), 8422(a), Nov. 10, 1988, 102 Stat. 3802; Pub. L. 101–234, title II, §§ 201(a), 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101–239, title VI, §§ 6003(e)(2)(A), (g)(3)(D)(vii), 6102(c)(1), (e)(1), (5), (6)(A), (7), (f)(2), 6111(a), (b)(1), 6113(b)(3), (d), 6116(b)(1), 6131(a)(1), (b), 6133(a), 6204(b), Dec. 19, 1989, 103 Stat. 2143, 2153, 2184, 2187–2189, 2213, 2214, 2217, 2219, 2221, 2222, 2241; Pub. L. 101–508, title IV, §§ 4008(m)(2)(C), 4104(b)(1), 4118(f)(2)(D), 4151(c)(1), (2), 4153(a)(2)(B), (C), 4154(a), (b)(1), (c)(1), (e)(1), 4155(b)(2), (3), 4160, 4161(a)(3)(B), 4163(d)(1), 4206(b)(2), 4302, Nov. 5, 1990, 104 Stat. 1388–53, 1388–59, 1388–70, 1388–73, 1388–83 to 1388–87, 1388–91, 1388–93, 1388–100, 1388–116, 1388–125; Pub. L. 101–597, title IV, § 401(c)(2), Nov. 16, 1990, 104 Stat. 3035; Pub. L. 103–66, title XIII, §§ 13516(b), 13532(a), 13544(b)(2), 13551, 13555(a), Aug. 10, 1993, 107 Stat. 584, 586, 590, 592; Pub. L. 103–432, title I, §§ 123(b)(2)(A), (e), 141(a), (c)(1), 147(a), (d), (e)(2), (3), (f)(6)(C), (D), 156(a)(2)(B), 160(d)(1), Oct. 31, 1994, 108 Stat. 4411, 4412, 4424, 4425, 4429, 4430, 4432, 4440, 4443; Pub. L. 105–33, title IV, §§ 4002(j)(1)(A), 4101(b), 4102(b), 4103(b), 4104(c)(1), (2), 4201(c)(1), 4205(a)(1)(A), (2), 4315(b), 4432(b)(5)(C), 4511(b), 4512(b)(1), 4521(a), (b), 4523(a), (d)(1)(A)(i), (B)–(3), 4531(b)(1), 4541(a)(1), (c), (d)(1), 4553(a), (b), 4555, 4556(b), 4603(c)(2)(A), Aug. 5, 1997, 111 Stat. 330, 360–362, 365, 373, 376, 390, 421, 442–445, 449, 450, 454, 456, 460, 462, 463, 470; Pub. L. 106–113, div. B, § 1000(a)(6) [title II, §§ 201(a)–(e)(1), (f)–(h)(1), (i), (j), 202(a), 204(a),(b), 211(a)(3)(B), 221(a)(1), 224(a), title III, § 321(g)(2), (k)(2), title IV, §§ 401(b)(1), 403(e)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A–336 to 1501A–342, 1501A–345, 1501A–348, 1501A–351, 1501A–353, 1501A–366, 1501A–369, 1501A–371; Pub. L. 106–554, § 1(a)(6) [title I, §§ 105(c), 111(a)(1), title II, §§ 201(b)(1), 205(b), 223(c), 224(a), title IV, §§ 401(a), (b)(1), 402(a), (b), 403(a), 405(a), 406(a), 421(a), 430(a), title V, § 531(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–472, 2763A–481, 2763A–483, 2763A–489, 2763A–490, 2763A–502, 2763A–503, 2763A–505 to 2763A–508, 2763A–516, 2763A–524, 2763A–547; Pub. L. 108–173, title II, § 237(a), title III, §§ 302(b)(2), 303(i)(3)(A), title IV, §§ 411(a)(1), (b), 413(a), (b)(1), title VI, §§ 614(a), (b), 621(a)(1)–(5), (b)(1), (2), 622, 624(a)(1), 626(a)–(c), 627(a), 628, 629, 642(b), title VII, § 736(b)(1), (2), title IX, § 942(b), Dec. 8, 2003, 117 Stat. 2212, 2229, 2254, 2274, 2275, 2277, 2306–2311, 2317–2322, 2355, 2421; Pub. L. 109–171, title V, §§ 5103, 5105, 5107(a)(1), 5112(e), 5113(a), Feb. 8, 2006, 120 Stat. 40–42, 44; Pub. L. 109–432, div. B, title I, §§ 107(a), (b)(1), 109(a)(1), (b), title II, § 201, Dec. 20, 2006, 120 Stat. 2983–2986; Pub. L. 110–173, title I, §§ 102, 105, 106, 113, Dec. 29, 2007, 121 Stat. 2495, 2496, 2501; Pub. L. 110–275, title I, §§ 101(a)(2), (b)(2), 102, 141, 142, 143(b)(2), (3), 145(a)(2), (b), 147, 151(a), 184, July 15, 2008, 122 Stat. 2497, 2498, 2542, 2543, 2547, 2548, 2550, 2587; Pub. L. 111–144, § 6, Mar. 2, 2010, 124 Stat. 46; Pub. L. 111–148, title III, §§ 3103, 3114, 3121, 3138, 3401(i), (k), (*l*), title IV, §§ 4103(c)(1), (3), (4), 4104(b), (c), title V, § 5501(a)(1), (b)(1), title X, §§ 10221(a), (b)(4), 10319(g), 10324(b), 10406, 10501(i)(3)(B), (C), Mar. 23, 2010, 124 Stat. 417, 423, 439, 485–487, 555–558, 652, 653, 935, 936, 949, 960, 975, 998, 999; Pub. L. 111–152, title I, § 1105(e), Mar. 30, 2010, 124 Stat. 1049; Pub. L. 111–309, title I, §§ 104, 108, Dec. 15, 2010, 124 Stat. 3287, 3288; Pub. L. 112–78, title III, §§ 304, 308, Dec. 23, 2011, 125 Stat. 1284, 1285; Pub. L. 112–96, title III, §§ 3002(a), 3005(a), (b), 3202, Feb. 22, 2012, 126 Stat. 186–188, 193; Pub. L. 112–240, title VI, §§ 603(a)–(c), 634, Jan. 2, 2013, 126 Stat. 2347, 2355; Pub. L. 113–67, div. B, title I, § 1103, Dec. 26, 2013, 127 Stat. 1196; Pub. L. 113–93, title I, § 103, title II, §§ 216(b)(1), 218(a)(2)(A), (b)(2), Apr. 1, 2014, 128 Stat. 1041, 1059, 1064, 1069; Pub. L. 114–10, title I, § 101(e)(2), (3), title II, § 202(a), (b)(1), title V, § 514(a), Apr. 16, 2015, 129 Stat. 117, 122, 143, 171; Pub. L. 114–74, title VI, § 603, Nov. 2, 2015, 129 Stat. 597; Pub. L. 114–113, div. O, title V, §§ 502(b), 504(b)(1), Dec. 18, 2015, 129 Stat. 3019, 3021.)

AMENDMENT OF SUBSECTION (a)(1)

Pub. L. 114–113, div. O, title V, § 504(b)(1), (d), Dec. 18, 2015, 129 Stat. 3021, 3023, provided that, applicable to items furnished on or after Jan. 1, 2017, subsection (a)(1) of this section is amended as follows:

(1) by striking ''and (Z)'' and inserting ''(Z)''; and

(2) by inserting before the semicolon at the end the following: '', and (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1395m(s) of this title) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section''.

See 2015 Amendment note below.

REFERENCES IN TEXT

Section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (i)(2)(D)(i), is section 626(d) of Pub. L. 108–173, which is set out as a note under this section.

Section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989, referred to in subsec. (*l*)(1)(C), is section 9320(k) of Pub. L. 99–509, as amended, which is set out as a note under section 1395k of this title.

The amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986, referred to in subsec. (*l*)(3)(B), are amendments made by section 9320 of Pub. L. 99–509, which amended sections 1395k, 1395*l*, 1395u, 1395x, 1395y, 1395aa, 1395bb, 1395cc, 1395ww, 1396a, and 1396n of this title and provisions set out as a note under section 1395ww of this title.

Section 4521 of The Balanced Budget Act of 1997, referred to in subsec. (t)(7)(F), is section 4521 of Pub. L.

105–33, Aug. 5, 1997, 111 Stat. 444, which amended this section and enacted provisions set out as a note under this section.

Subsection (z), referred to in subsecs. (x)(3) and (y)(3), probably means the subsec. (z) of this section added by section 101(e)(2) of Pub. L. 114–10, relating to incentive payments for participation in eligible alternative payment models.

CODIFICATION

Pub. L. 111–148, §10221(a), enacted into law S. 1790, One Hundred Eleventh Congress, as reported by the Committee on Indian Affairs of the Senate in Dec. 2009, ''[e]xcept as provided in'' section 10221(b) of Pub. L. 111–148. Section 201(b) of S. 1790 would have amended this section but was stricken out by section 10221(b)(4) of Pub. L. 111–148.

AMENDMENTS

2015—Subsec. (a)(1)(AA). Pub. L. 114–113, §504(b)(1), added subpar. (AA).

Subsec. (g)(5)(A). Pub. L. 114–10, §202(a)(1), substituted ''December 31, 2017'' for ''March 31, 2015''.

Subsec. (g)(5)(C)(i). Pub. L. 114–10, §202(b)(1)(A), inserted '', subject to subparagraph (E),'' after ''manual medical review process that''.

Subsec. (g)(5)(E). Pub. L. 114–10, §202(b)(1)(B), added subpar. (E).

Subsec. (g)(6)(A). Pub. L. 114–10, §202(a)(2), substituted ''December 31, 2017'' for ''March 31, 2015'' and ''2012 through 2017'' for ''2012, 2013, 2014, or the first three months of 2015''.

Subsec. (t)(1)(B)(v). Pub. L. 114–74, §603(1), added cl. (v).

Subsec. (t)(16)(F). Pub. L. 114–113, §502(b), added subpar. (F).

Subsec. (t)(21). Pub. L. 114–74, §603(2), added par. (21).

Subsec. (x)(3). Pub. L. 114–10, §101(e)(3)(A), inserted at end ''The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.''

Subsec. (y)(3). Pub. L. 114–10, §101(e)(3)(B), inserted at end ''The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.''

Subsec. (z). Pub. L. 114–10, §514(a), added subsec. (z) relating to medical review of spinal subluxation services.

Pub. L. 114–10, §101(e)(2), added subsec. (z) relating to incentive payments for participation in eligible alternative payment models.

2014—Subsec. (a)(1)(D)(i). Pub. L. 113–93, §216(b)(1)(A)(i)–(iii), designated existing provisions as subcl. (I), substituted ''subsection (h)(1) of this section (for tests furnished before January 1, 2017)'' for ''subsection (h)(1) of this section'', and added subcl. (II).

Subsec. (a)(1)(D)(ii). Pub. L. 113–93, §216(b)(1)(A)(iv), substituted ''for tests furnished before January 1, 2017, on the basis'' for ''on the basis''.

Subsec. (a)(2)(D)(i). Pub. L. 113–93, §216(b)(1)(B)(i)–(iii), designated existing provisions as subcl. (I), substituted ''subsection (h)(1) of this section (for tests furnished before January 1, 2017)'' for ''subsection (h)(1) of this section'', and added subcl. (II).

Subsec. (a)(2)(D)(ii). Pub. L. 113–93, §216(b)(1)(B)(iv), substituted ''for tests furnished before January 1, 2017, on the basis'' for ''on the basis''.

Subsec. (b)(3)(B). Pub. L. 113–93, §216(b)(1)(C), substituted ''for tests furnished before January 1, 2017, on the basis'' for ''on the basis''.

Subsec. (g)(5)(A). Pub. L. 113–93, §103(1), substituted ''March 31, 2015'' for ''March 31, 2014''.

Subsec. (g)(6)(A). Pub. L. 113–93, §103(2), substituted ''March 31, 2015'' for ''March 31, 2014'' and ''2012, 2013, 2014, or the first three months of 2015'' for ''2012, 2013, or the first three months of 2014''.

Subsec. (h)(2)(A)(i). Pub. L. 113–93, §216(b)(1)(D), substituted ''and, for tests furnished before April 1, 2014, subject to'' for ''and subject to''.

Subsec. (h)(3). Pub. L. 113–93, §216(b)(1)(E), in introductory provisions, substituted ''fee schedules (for tests furnished before January 1, 2017) or under section 1395m–1 of this title (for tests furnished on or after January 1, 2017), subject to subsection (b)(5) of such section'' for ''fee schedules''.

Subsec. (h)(6). Pub. L. 113–93, §216(b)(1)(F), substituted ''For tests furnished before January 1, 2017, in the case'' for ''In the case''.

Subsec. (h)(7). Pub. L. 113–93, §216(b)(1)(G), substituted ''and (4) and section 1395m–1 of this title'' for ''and (4)'' and ''under this part'' for ''under this subsection''.

Subsec. (t)(16)(E). Pub. L. 113–93, §218(b)(2), added subpar. (E).

Subsec. (t)(20). Pub. L. 113–93, §218(a)(2)(A), added par. (20).

2013—Subsec. (g)(5)(A). Pub. L. 113–67, §1103(1), substituted ''March 31, 2014'' for ''December 31, 2013'' in first sentence.

Pub. L. 112–240, §603(a)(1), substituted ''December 31, 2013'' for ''December 31, 2012'' in first sentence.

Subsec. (g)(5)(D). Pub. L. 112–240, §603(c), added subpar. (D).

Subsec. (g)(6). Pub. L. 112–240, §603(b), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (g)(6)(A). Pub. L. 113–67, §1103(2), substituted ''March 31, 2014'' for ''December 31, 2013'' and '', 2013, or the first three months of 2014'' for ''or 2013''.

Pub. L. 112–240, §603(a)(2), substituted ''December 31, 2013'' for ''December 31, 2012'' and inserted ''or 2013'' after ''during 2012''.

Subsec. (t)(16)(D). Pub. L. 112–240, §634, added subpar. (D).

2012—Subsec. (g)(1), (3). Pub. L. 112–96, §3005(b)(1), substituted ''but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)'' for ''but not described in subsection (a)(8)(B) of this section''.

Subsec. (g)(5). Pub. L. 112–96, §3005(a), designated existing provisions as subpar. (A), substituted ''December 31, 2012'' for ''February 29, 2012'', inserted ''and if the requirement of subparagraph (B) is met'' after ''determined to be medically necessary'' and ''made in accordance with such requirement'' after ''receipt of the request'', and added subpars. (B) and (C).

Subsec. (g)(6). Pub. L. 112–96, §3005(b)(2), added par. (6).

Subsec. (h)(2)(A)(i). Pub. L. 112–96, §3202(1), substituted ''clause (v), subparagraph (B), and paragraph (4)'' for ''paragraph (4)''.

Subsec. (h)(2)(A)(iv). Pub. L. 112–96, §3202(2), realigned margins.

Subsec. (h)(2)(A)(v). Pub. L. 112–96, §3202(3), added cl. (v).

Subsec. (t)(7)(D)(i)(II). Pub. L. 112–96, §3002(a)(1), substituted ''January 1, 2013'' for ''March 1, 2012'' and ''or 2012'' for ''or the first two months of 2012''.

Subsec. (t)(7)(D)(i)(III). Pub. L. 112–96, §3002(a)(2), substituted ''January 1, 2013, for which'' for ''March 1, 2012, for which''.

2011—Subsec. (g)(5). Pub. L. 112–78, §304, substituted ''February 29, 2012'' for ''December 31, 2011''.

Subsec. (t)(7)(D)(i)(II). Pub. L. 112–78, §308(1), substituted ''March 1, 2012'' for ''January 1, 2012'' and ''2011, or the first two months of 2012'' for ''or 2011''.

Subsec. (t)(7)(D)(i)(III). Pub. L. 112–78, §308(2), substituted ''2009, and before March 1, 2012, for which'' for ''2009, and before January 1, 2012, for which'' and ''2010, and before March 1, 2012, the preceding'' for ''2010, and before January 1, 2012, the preceding''.

2010—Subsec. (a). Pub. L. 111–148, §10501(i)(3)(C)(ii), inserted concluding provisions.

Subsec. (a)(1)(K). Pub. L. 111–148, §3114, inserted ''(or 100 percent for services furnished on or after January 1, 2011)'' after ''1992, 65 percent''.

Subsec. (a)(1)(N). Pub. L. 111–148, §4103(c)(1)(A), inserted ''other than personalized prevention plan serv-

ices (as defined in section 1395x(hhh)(1) of this title)'' after ''(as defined in section 1395w–4(j)(3) of this title)''.

Subsec. (a)(1)(T). Pub. L. 111–148, §4104(b)(1), as amended by Pub. L. 111–148, §10406, inserted ''(or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual)'' after ''80 percent''.

Subsec. (a)(1)(W). Pub. L. 111–148, §4104(b)(2), as amended by Pub. L. 111–148, §10406, inserted ''(if such subparagraph were applied, by substituting '100 percent' for '80 percent')'' after ''subparagraph (D)'' in cl. (i) and substituted ''100 percent'' for ''80 percent'' in cl. (ii).

Subsec. (a)(1)(X). Pub. L. 111–148, §4103(c)(1)(B), (C), added subpar. (X).

Subsec. (a)(1)(Y). Pub. L. 111–148, §4104(b)(3), (4), as amended by Pub. L. 111–148, §10406, added subpar. (Y).

Subsec. (a)(1)(Z). Pub. L. 111–148, §10501(i)(3)(B), added subpar. (Z).

Subsec. (a)(2)(F) to (H). Pub. L. 111–148, §4103(c)(3)(B), which directed amendment of par. (2) by striking ''and'' at end of subpar. (F), substituting ''; and'' for comma at end of subpar. (G)(ii), and adding subpar. (H) after subpar. (G)(ii), was executed as directed despite the presence of concluding provisions following subpar. (G)(ii), which were added as part of subpar. (G) by Pub. L. 105–33, §4603(c)(2)(A)(iv).

Subsec. (a)(3)(B)(i). Pub. L. 111–148, §10501(i)(3)(C)(i)(I), inserted subcl. (I) designation after ''otherwise been provided'' and '', or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1395m(*o*) of this title, under such section (calculated as if '100 percent' were substituted for '80 percent' in such section) for such services if the individual had not been so enrolled'' after ''been so enrolled''.

Subsec. (b). Pub. L. 111–148, §4104(c)(2), inserted at end ''Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''

Subsec. (b)(1). Pub. L. 111–148, §4104(c)(1), substituted ''preventive services described in subparagraph (A) of section 1395x(ddd)(3) of this title that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual.'' for ''items and services described in section 1395x(s)(10)(A) of this title''.

Subsec. (b)(10). Pub. L. 111–148, §4103(c)(4), added par. (10).

Subsec. (g)(5). Pub. L. 111–309, §104, substituted ''and ending on December 31, 2011'' for ''and ending on March 31, 2010''.

Pub. L. 111–148, §3103, which directed substitution of ''December 31, 2010'' for ''December 31, 2009'', could not be executed because ''December 31, 2009'' did not appear subsequent to amendment by Pub. L. 111–144. See note below.

Pub. L. 111–144 substituted ''March 31, 2010'' for ''December 31, 2009''.

Subsec. (h)(2)(A)(i). Pub. L. 111–148, §3401(*l*)(1), inserted '', subject to clause (iv),'' after ''year) by'' and substituted ''and 2010'' for ''through 2013''.

Subsec. (h)(2)(A)(iv). Pub. L. 111–148, §3401(*l*)(2), added cl. (iv).

Subsec. (i)(2)(D)(v), (vi). Pub. L. 111–148, §3401(k), added cl. (v) and redesignated former cl. (v) as (vi).

Subsec. (t)(1)(B)(iv). Pub. L. 111–148, §4103(c)(3)(A), substituted '', diagnostic mammography, or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title)'' for ''and diagnostic mammography''.

Subsec. (t)(2)(D). Pub. L. 111–148, §10324(b)(1), substituted ''subject to paragraph (19), the Secretary'' for ''the Secretary''.

Subsec. (t)(3)(C)(iv). Pub. L. 111–148, §3401(i)(1), inserted ''and subparagraph (F) of this paragraph'' after ''(17)''.

Subsec. (t)(3)(F). Pub. L. 111–148, §3401(i)(2), added subpar. (F).

Subsec. (t)(3)(G). Pub. L. 111–152, §1105(e)(3), struck out cl. (i) designation and heading, redesignated subcls. (I) to (V) of former cl. (i) as cls. (i) to (v), respectively, and realigned margins.

Pub. L. 111–148, §3401(i)(2), added subpar. (G).

Subsec. (t)(3)(G)(i)(I). Pub. L. 111–148, §10319(g)(1), struck out ''and'' at end.

Subsec. (t)(3)(G)(i)(II). Pub. L. 111–152, §1105(e)(1)(A), placed subcl. (II), which was directed to be inserted after subcl. (II) by Pub. 111–148, §10319(g)(3), immediately after subcl. (I) and struck out ''and'' at end. See Amendment note below.

Pub. L. 111–148, §10319(g)(3), which directed addition of subcl. (II) ''after subclause (II)'', could not be executed. See Amendment note above.

Subsec. (t)(3)(G)(i)(III). Pub. L. 111–152, §1105(e)(1), added subcl. (III) and struck out former subcl. (III) which read as follows: ''subject to clause (ii), for each of 2014 through 2019, 0.2 percentage point.''

Pub. L. 111–148, §10319(g)(4), substituted ''2014'' for ''2012''.

Pub. L. 111–148, §10319(g)(2), redesignated subcl. (II) as (III).

Subsec. (t)(3)(G)(i)(IV), (V). Pub. L. 111–152, §1105(e)(1)(B), added subcls. (IV) and (V).

Subsec. (t)(3)(G)(ii). Pub. L. 111–152, §1105(e)(2), struck out cl. (ii). Prior to amendment, text read as follows: ''Clause (i)(II) shall be applied with respect to any of 2014 through 2019 by substituting '0.0 percentage points' for '0.2 percentage point', if for such year—

''(I) the excess (if any) of—

''(aa) the total percentage of the non-elderly insured population for the preceding year (based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Patient Protection and Affordable Care Act that, if determined in the affirmative, would clear such Act for enrollment); over

''(bb) the total percentage of the non-elderly insured population for such preceding year (as estimated by the Secretary); exceeds

''(II) 5 percentage points.''

Subsec. (t)(7)(D)(i)(II). Pub. L. 111–309, §108(1), substituted ''2012'' for ''2011'' in first sentence and ''2010, or 2011'' for ''or 2010'' in second sentence.

Pub. L. 111–148, §3121(a)(1)(B), substituted '', 2009, or 2010'' for ''or 2009''.

Pub. L. 111–148, §3121(a)(1)(A), substituted ''2011'' for ''2010''.

Subsec. (t)(7)(D)(i)(III). Pub. L. 111–309, §108(2), which directed substitution of ''January 1, 2012'' for ''January 1, 2011'', was executed by making the substitution in two places to reflect the probable intent of Congress.

Pub. L. 111–148, §3121(b), inserted at end ''In the case of covered OPD services furnished on or after January 1, 2010, and before January 1, 2011, the preceding sentence shall be applied without regard to the 100-bed limitation.''

Pub. L. 111–148, §3121(a)(2), substituted ''2009, and before January 1, 2011'' for ''2009, and before January 1, 2010''.

Subsec. (t)(18), (19). Pub. L. 111–148, §§3138, 10324(b)(2), added pars. (18) and (19).

Subsecs. (x), (y). Pub. L. 111–148, §5501(a)(1), (b)(1), added subsecs. (x) and (y).

2008—Subsec. (a)(1)(D)(iii). Pub. L. 110–275, §145(a)(2), before comma at end of subpar. (D), struck out cl. (iii), which read ''on the basis of a rate established under a demonstration project under section 1395w–3(e) of this title, the amount paid shall be equal to 100 percent of such rate''.

Subsec. (a)(1)(W). Pub. L. 110–275, §101(a)(2), added subpar. (W).

Subsec. (a)(8)(A), (B). Pub. L. 110–275, §143(b)(2), substituted '', outpatient speech-language pathology serv-

ices,'' for ''(which includes outpatient speech-language pathology services)'' in introductory provisions.

Subsec. (b)(9). Pub. L. 110–275, § 101(b)(2), added par. (9) at end of first sentence.

Subsec. (c). Pub. L. 110–275, § 102, amended subsec. (c) generally. Prior to amendment, text read as follows: ''Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section only 62½ percent of such expenses. For purposes of this subsection, the term 'treatment' does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.''

Subsec. (g)(1). Pub. L. 110–275, § 143(b)(3), inserted ''and speech-language pathology services of the type described in such section through the application of section 1395x(*ll*)(2) of this title'' after ''1395x(p) of this title'' and ''and speech-language pathology services'' after ''and physical therapy services''.

Subsec. (g)(5). Pub. L. 110–275, § 141, substituted ''December 31, 2009'' for ''June 30, 2008''.

Subsec. (h)(2)(A)(i). Pub. L. 110–275, § 145(b), inserted ''minus, for each of the years 2009 through 2013, 0.5 percentage points'' after ''city average)''.

Subsec. (t)(7)(D)(i)(II). Pub. L. 110–275, § 147(1), substituted ''January 1, 2010'' for ''January 1, 2009'' and ''For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008 or 2009.'' for ''For purposes of the previous sentence, with respect to covered OPD services furnished during 2006, 2007, or 2008, the applicable percentage shall be 95 percent, 90 percent, and 85 percent, respectively.''

Subsec. (t)(7)(D)(i)(III). Pub. L. 110–275, § 147(2), added subcl. (III).

Subsec. (t)(16)(C). Pub. L. 110–275, § 142, substituted ''January 1, 2010'' for ''July 1, 2008'' in two places.

Subsec. (v). Pub. L. 110–275, § 151(a), added subsec. (v).

Subsec. (w). Pub. L. 110–275, § 184, added subsec. (w).

2007—Subsec. (g)(5). Pub. L. 110–173, § 105, substituted ''June 30, 2008'' for ''December 31, 2007''.

Subsec. (h)(9). Pub. L. 110–173, § 113, added par. (9).

Subsec. (t)(16)(C). Pub. L. 110–173, § 106, in heading, inserted ''and therapeutic radiopharmaceuticals'' before ''at charges'', in first sentence, substituted ''July 1, 2008'' for ''January 1, 2008'' and inserted ''and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before July 1, 2008,'' after ''July 1, 2008,'' and ''or therapeutic radiopharmaceutical'' after ''the device'' and after ''each device'', and, in second sentence, inserted ''or therapeutic radiopharmaceuticals'' after ''such devices''.

Subsec. (u)(1). Pub. L. 110–173, § 102(1), substituted ''before July 1, 2008'' for ''before January 1, 2008'' in introductory provisions.

Subsec. (u)(4)(D), (E). Pub. L. 110–173, § 102(2), added subpar. (D) and redesignated former subpar. (D) as (E).

2006—Subsec. (b)(7). Pub. L. 109–171, § 5112(e), added par. (7) at end of first sentence.

Subsec. (b)(8). Pub. L. 109–171, § 5113(a), added par. (8) at end of first sentence.

Subsec. (g)(1), (3). Pub. L. 109–171, § 5107(a)(1)(A), substituted ''paragraphs (4) and (5)'' for ''paragraph (4)''.

Subsec. (g)(5). Pub. L. 109–432, § 201, substituted ''the period beginning on January 1, 2006, and ending on December 31, 2007,'' for ''2006''.

Pub. L. 109–171, § 5107(a)(1)(B), added par. (5).

Subsec. (i)(2)(A). Pub. L. 109–171, § 5103(1), inserted ''subject to subparagraph (E),'' after ''subparagraph (D),''.

Subsec. (i)(2)(D)(ii). Pub. L. 109–171, § 5103(2), inserted ''and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary'' before period at end.

Subsec. (i)(2)(D)(iv), (v). Pub. L. 109–432, § 109(b)(1), added cl. (iv) and redesignated former cl. (iv) as (v).

Subsec. (i)(2)(E). Pub. L. 109–171, § 5103(3), added subpar. (E).

Subsec. (i)(7). Pub. L. 109–432, § 109(b)(2), added par. (7).

Subsec. (t)(2)(H). Pub. L. 109–432, § 107(b)(1), inserted ''and for stranded and non-stranded devices furnished on or after July 1, 2007'' before period at end.

Subsec. (t)(3)(C)(iv). Pub. L. 109–432, § 109(a)(1)(A), inserted ''subject to paragraph (17),'' after ''this subparagraph,''.

Subsec. (t)(7)(D)(i). Pub. L. 109–171, § 5105, designated existing provisions as subcl. (I) and added subcl. (II).

Subsec. (t)(16)(C). Pub. L. 109–432, § 107(a), substituted ''2008'' for ''2007''.

Subsec. (t)(17). Pub. L. 109–432, § 109(a)(1)(B), added par. (17).

2003—Subsec. (a)(1)(D)(iii). Pub. L. 108–173, § 302(b)(2)(C), added cl. (iii).

Subsec. (a)(1)(G). Pub. L. 108–173, § 626(c), added subpar. (G).

Subsec. (a)(1)(S). Pub. L. 108–173, § 642(b), inserted ''(including intravenous immune globulin (as defined in section 1395x(zz) of this title))'' after ''with respect to drugs and biologicals''.

Pub. L. 108–173, § 303(i)(3)(A), inserted ''(or, if applicable, under section 1395w–3, 1395w–3a, or 1395w–3b of this title)'' after ''1395u(*o*) of this title''.

Subsec. (a)(1)(V). Pub. L. 108–173, § 302(b)(2)(A), (B), added subpar. (V).

Subsec. (a)(2)(E)(i). Pub. L. 108–173, § 614(b), inserted ''and, for services furnished on or after January 1, 2005, diagnostic mammography'' after ''screening mammography''.

Subsec. (a)(3). Pub. L. 108–173, § 237(a), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''in the case of services described in section 1395k(a)(2)(D) of this title, the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1395x(v)(1)(A) of this title, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such services (other than for items and services described in section 1395x(s)(10)(A) of this title) exceed 80 percent of such costs;''.

Subsec. (b). Pub. L. 108–173, § 629, substituted '', $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1395r(a)(1) of this title ending with such subsequent year (rounded to the nearest $1)'' for ''and $100 for 1991 and subsequent years'' before semicolon in first sentence.

Subsec. (g)(4). Pub. L. 108–173, § 624(a)(1), substituted ''2002, 2004, and 2005'' for ''and 2002''.

Subsec. (h)(2)(A)(ii)(IV). Pub. L. 108–173, § 628, substituted '', 1998 through 2002, and 2004 through 2008'' for ''and 1998 through 2002''.

Subsec. (h)(5)(D). Pub. L. 108–173, § 736(b)(1), substituted ''clinic,'' for ''clinic,,''.

Subsec. (h)(8). Pub. L. 108–173, § 942(b), added par. (8).

Subsec. (i)(2)(A). Pub. L. 108–173, § 626(b)(1)(A), substituted ''For services furnished prior to the implementation of the system described in subparagraph (D), the'' for ''The'' in introductory provisions.

Subsec. (i)(2)(A)(i). Pub. L. 108–173, § 626(b)(1)(B), struck out ''taken not later than January 1, 1995, and every 5 years thereafter,'' before ''of the actual audited costs''.

Subsec. (i)(2)(C). Pub. L. 108–173, § 626(a), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: ''Notwithstanding the second sentence of subparagraph (A) or the second sentence of subpara-

graph (B), if the Secretary has not updated amounts established under such subparagraphs with respect to facility services furnished during a fiscal year (beginning with fiscal year 1996), such amounts shall be 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. In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.''

Subsec. (i)(2)(D). Pub. L. 108–173, §626(b)(2), added subpar. (D).

Subsec. (m). Pub. L. 108–173, §413(b)(1), designated existing provisions as par. (1), inserted ''in a year'' after ''In the case of physicians' services furnished'' and ''as identified by the Secretary prior to the beginning of such year'' after ''as a health professional shortage area'', and added pars. (2) to (4).

Subsec. (*o*)(1)(B). Pub. L. 108–173, §627(a)(1), substituted ''no more than the amount of payment applicable under paragraph (2)'' for ''no more than the limits established under paragraph (2)''.

Subsec. (*o*)(2). Pub. L. 108–173, §627(a)(2), amended par. (2) generally, substituting provisions relating to determination of amount of payments pursuant to section 1395m of this title for provisions specifying dollar amounts of payments.

Subsec. (t)(1)(B)(iv). Pub. L. 108–173, §614(a), inserted before period at end ''and does not include screening mammography (as defined in section 1395x(jj) of this title) and diagnostic mammography''.

Subsec. (t)(2)(H). Pub. L. 108–173, §621(b)(2), which directed the amendment of par. (2) by adding a new subpar. (H) at the end, was executed by adding subpar. (H) after subpar. (G), to reflect the probable intent of Congress.

Subsec. (t)(3)(C)(ii). Pub. L. 108–173, §736(b)(2), substituted ''clause (iv)'' for ''clause (iii)''.

Subsec. (t)(5)(E). Pub. L. 108–173, §621(a)(3), added subpar. (E).

Subsec. (t)(6)(D)(i). Pub. L. 108–173, §621(a)(4), inserted ''(or if the drug or biological is covered under a competitive acquisition contract under section 1395w–3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph)'' after ''under section 1395u(*o*) of this title''.

Subsec. (t)(6)(F). Pub. L. 108–173, §622, added subpar. (F).

Subsec. (t)(7)(D)(i). Pub. L. 108–173, §411(a)(1)(A), (C), substituted ''certain'' for ''small'' in heading and ''2006'' for ''2004'' in text.

Pub. L. 108–173, §411(a)(1)(B), inserted ''or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area'' after ''100 beds''.

Subsec. (t)(9)(B). Pub. L. 108–173, §621(a)(5), inserted at end ''In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).''

Subsec. (t)(13). Pub. L. 108–173, §411(b)(2), added par. (13). Former par. (13) redesignated (16).

Subsec. (t)(14), (15). Pub. L. 108–173, §621(a)(1), added pars. (14) and (15).

Subsec. (t)(16). Pub. L. 108–173, §411(b)(1), redesignated par. (13) as (16).

Subsec. (t)(16)(B). Pub. L. 108–173, §621(a)(2), added subpar. (B).

Subsec. (t)(16)(C). Pub. L. 108–173, §621(b)(1), added subpar. (C).

Subsec. (u). Pub. L. 108–173, §413(a), added subsec. (u).

2000—Subsec. (a)(1)(D)(i). Pub. L. 106–554, §1(a)(6) [title II, §201(b)(1)], struck out ''or which are furnished on an outpatient basis by a critical access hospital'' after ''on an assignment-related basis''.

Subsec. (a)(1)(R). Pub. L. 106–554, §1(a)(6) [title II, §205(b)], substituted ''ambulance services, (i)'' for ''ambulance service,'' and inserted before comma at end ''and (ii) with respect to ambulance services described in section 1395m(*l*)(8) of this title, the amounts paid shall be the amounts determined under section 1395m(g) of this title for outpatient critical access hospital services''.

Subsec. (a)(1)(T). Pub. L. 106–554, §1(a)(6) [title I, §105(c)], added subpar. (T).

Subsec. (a)(1)(U). Pub. L. 106–554, §1(a)(6) [title II, §223(c)], added subpar. (U).

Subsec. (a)(2)(D)(i). Pub. L. 106–554, §1(a)(6) [title II, §201(b)(1)], struck out ''or which are furnished on an outpatient basis by a critical access hospital'' after ''on an assignment-related basis''.

Subsec. (f). Pub. L. 106–554, §1(a)(6) [title II, §224(a)], substituted ''hospitals'' for ''rural hospitals'' in introductory provisions.

Subsec. (g)(4). Pub. L. 106–554, §1(a)(6) [title IV, §421(a)], substituted ''2000, 2001, and 2002.'' for ''2000 and 2001.''

Subsec. (h)(4)(B)(viii). Pub. L. 106–554, §1(a)(6) [title V, §531(a)], inserted before period at end ''(or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph)''.

Subsec. (t)(2)(G). Pub. L. 106–554, §1(a)(6) [title IV, §430(a)], added subpar. (G).

Subsec. (t)(3)(C)(iii). Pub. L. 106–554, §1(a)(6) [title IV, §401(b)(1)(B)], added cl. (iii). Former cl. (iii) redesignated (iv).

Pub. L. 106–554, §1(a)(6) [title IV, §401(a)], substituted ''in each of 2000 and 2002'' for ''in each of 2000, 2001, and 2002''.

Subsec. (t)(3)(C)(iv). Pub. L. 106–554, §1(a)(6) [title IV, §401(b)(1)(A)], redesignated cl. (iii) as (iv).

Subsec. (t)(6)(A)(ii). Pub. L. 106–554, §1(a)(6) [title IV, §406(a)], inserted ''or temperature monitored cryoablation'' after ''device of brachytherapy''.

Subsec. (t)(6)(A)(iv)(II). Pub. L. 106–554, §1(a)(6) [title IV, §402(b)(1)], substituted ''the cost of the drug or biological or the average cost of the category of devices'' for ''the cost of the device, drug, or biological''.

Subsec. (t)(6)(B). Pub. L. 106–554, §1(a)(6) [title IV, §402(a)(2)], added subpar. (B) and struck out heading and text of former subpar. (B). Text read as follows: ''The payment under this paragraph with respect to a medical device, drug, or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

''(i) on the first date this subsection is implemented in the case of a drug, biological, or device described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a device, drug, or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

''(ii) in the case of a device, drug, or biological described in subparagraph (A)(iv) not described in clause (i), on the first date on which payment is made under this part for the device, drug, or biological as an outpatient hospital service.''

Subsec. (t)(6)(C). Pub. L. 106–554, §1(a)(6) [title IV, §402(a)(2)], added subpar. (C). Former subpar. (C) redesignated (D).

Subsec. (t)(6)(D). Pub. L. 106–554, §1(a)(6) [title IV, §402(b)(2)], substituted ''subparagraph (E)(iii)'' for ''subparagraph (D)(iii)'' in introductory provisions.

Pub. L. 106–554, §1(a)(6) [title IV, §402(a)(1)], redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (t)(6)(E). Pub. L. 106–554, §1(a)(6) [title IV, §402(a)(1)], redesignated subpar. (D) as (E).

Subsec. (t)(7)(D)(ii). Pub. L. 106–554, §1(a)(6) [title IV, §405(a)], in heading, inserted ''and children's hospitals'' after ''cancer hospitals'' and in text, substituted ''clause (iii) or (v) of section 1395ww(d)(1)(B) of this title'' for ''section 1395ww(d)(1)(B)(v) of this title''.

Subsec. (t)(7)(F)(ii)(I). Pub. L. 106–554, §1(a)(6) [title IV, §403(a)], inserted ''(or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report)'' after ''1996''.

Subsec. (t)(8)(C). Pub. L. 106–554, §1(a)(6) [title I, §111(a)(1)], amended heading and text of subpar. (C) generally. Prior to amendment, text read as follows: ''In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.''

Subsec. (t)(11). Pub. L. 106–554, §1(a)(6) [title IV, §405(a)(2)], substituted ''clause (iii) or (v) of section 1395ww(d)(1)(B) of this title'' for ''section 1395ww(d)(1)(B)(v) of this title'' in introductory provisions.

Subsec. (t)(12)(E). Pub. L. 106–554, §1(a)(6) [title IV, §402(b)(3)], substituted ''additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6))'' for ''additional payments (consistent with paragraph (6)(B))''.

1999—Subsec. (a)(1)(D)(i). Pub. L. 106–113, §1000(a)(6) [title IV, §403(e)(1)], inserted ''or which are furnished on an outpatient basis by a critical access hospital'' after ''on an assignment-related basis''.

Subsec. (a)(1)(O). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(2)], substituted a comma for the semicolon at end.

Subsec. (a)(2)(D)(i). Pub. L. 106–113, §1000(a)(6) [title IV, §403(e)(1)], inserted ''or which are furnished on an outpatient basis by a critical access hospital'' after ''on an assignment-related basis''.

Subsec. (g)(1), (3). Pub. L. 106–113, §1000(a)(6) [title II, §221(a)(1)(A)], substituted ''Subject to paragraph (4), in the case'' for ''In the case''.

Subsec. (g)(4). Pub. L. 106–113, §1000(a)(6) [title II, §221(a)(1)(B)], added par. (4).

Subsec. (h)(5)(A)(iii). Pub. L. 106–113, §1000(a)(6) [title III, §321(g)(2)], substituted '', critical access hospital, or skilled nursing facility,'' for ''or critical access hospital,'' and inserted ''or skilled nursing facility'' before period at end.

Subsec. (h)(7). Pub. L. 106–113, §1000(a)(6) [title II, §224(a)], added par. (7).

Subsec. (*l*)(4)(A)(i)(VII). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(3)(B)], substituted ''1395w–4(d) of this title'' for ''1395w–4(d)(3) of this title''.

Subsec. (t)(1)(B)(ii). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(1)(A)], substituted ''clause (iv)'' for ''clause (iii)'' and directed the striking out of ''but'' which was executed by striking out ''but'' after semicolon at end to reflect the probable intent of Congress.

Subsec. (t)(1)(B)(iii), (iv). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(1)(B)], added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (t)(2). Pub. L. 106–113, §1000(a)(6) [title II, §201(g)], inserted concluding provisions.

Subsec. (t)(2)(B). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(1)(C)], inserted ''and so that an implantable item is classified to the group that includes the service to which the item relates'' before semicolon at end.

Subsec. (t)(2)(C). Pub. L. 106–113, §1000(a)(6) [title II, §201(f)], inserted ''(or, at the election of the Secretary, mean)'' after ''median''.

Subsec. (t)(2)(E). Pub. L. 106–113, §1000(a)(6) [title II, §201(c)], substituted '', in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as'' for ''other adjustments, in a budget neutral manner, as determined to be necessary to ensure equitable payments, such as outlier adjustments or''.

Subsec. (t)(4). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(1)], inserted '', subject to paragraph (7),'' after ''is determined'' in introductory provisions.

Subsec. (t)(4)(C). Pub. L. 106–113, §1000(a)(6) [title II, §204(b)], inserted '', plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C)'' before period at end.

Subsec. (t)(5). Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(2)], added par. (5). Former par. (5) redesignated (7).

Subsec. (t)(6). Pub. L. 106–113, §1000(a)(6) [title II, §201(b)], added par. (6). Former par. (6) redesignated (8).

Subsec. (t)(7). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(3)], added par. (7). Former par. (7) redesignated (8).

Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(1)], redesignated par. (5) as (7). Former par. (7) redesignated (9).

Subsec. (t)(7)(D). Pub. L. 106–113, §1000(a)(6) [title II, §201(i)], added subpar. (D).

Subsec. (t)(8). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(2)], redesignated par. (7) as (8). Former par. (8) redesignated (9).

Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(1)], redesignated par. (6) as (8). Former par. (8) redesignated (10).

Subsec. (t)(8)(A). Pub. L. 106–113, §1000(a)(6) [title II, §204(a)(1)], substituted ''subparagraphs (B) and (C)'' for ''subparagraph (B)''.

Pub. L. 106–113, §1000(a)(6) [title II, §201(h)(1)(B)], inserted at end ''The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.''

Pub. L. 106–113, §1000(a)(6) [title II, §201(h)(1)(A)], substituted ''shall review not less often than annually'' for ''may periodically review''.

Subsec. (t)(8)(C) to (E). Pub. L. 106–113, §1000(a)(6) [title II, §204(a)(2), (3)], added subpar. (C) and redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsec. (t)(9). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(2)], redesignated par. (8) as (9). Former par. (9) redesignated (10).

Pub. L. 106–113, §1000(a)(6) [title II, §201(j)], substituted ''section 1395x(v)(1)(U) of this title'' for ''the matter in subsection (a)(1) of this section preceding subparagraph (A)''.

Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(1)], redesignated par. (7) as (9). Former par. (9) redesignated (11).

Subsec. (t)(10). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(2)], redesignated par. (9) as (10). Former par. (10) redesignated (11).

Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(1)], redesignated par. (8) as (10).

Subsec. (t)(11). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(2)], redesignated par. (10) as (11). Former par. (11) redesignated (12).

Pub. L. 106–113, §1000(a)(6) [title II, §201(a)(1)], redesignated par. (9) as (11).

Subsec. (t)(11)(E). Pub. L. 106–113, §1000(a)(6) [title II, §201(d)], added subpar. (E).

Subsec. (t)(12). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(2)], redesignated par. (11) as (12).

Subsec. (t)(13). Pub. L. 106–113, §1000(a)(6) [title IV, §401(b)(1)], added par. (13).

1997—Subsec. (a)(1)(A). Pub. L. 105–33, §4002(j)(1)(A), inserted ''(and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services)'' after ''prepayment basis''.

Subsec. (a)(1)(D). Pub. L. 105–33, §4104(c), inserted ''or section 1395m(d)(1) of this title'' after ''subsection (h)(1) of this section''.

Subsec. (a)(1)(O). Pub. L. 105–33, §4512(b)(1), substituted ''section 1395x(s)(2)(K) of this title'' for ''section 1395x(s)(2)(K)(ii) of this title'' and ''services furnished by physician assistants, nurse practitioners, or clinic nurse specialists'' for ''nurse practitioner or clinical nurse specialist services''.

Pub. L. 105–33, §4511(b)(1), amended subpar. (O) generally. Prior to amendment, subpar. (O) read as follows: ''with respect to services described in section

1395x(s)(2)(K)(iii) of this title (relating to nurse practitioner or clinical nurse specialist services provided in a rural area), the amounts paid shall be 80 percent of the lesser of the actual charge or the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title) if the services had been performed by a physician (subject to the limitation described in subsection (r)(2) of this section),''.

Subsec. (a)(1)(Q). Pub. L. 105–33, §4315(b), added subpar. (Q).

Subsec. (a)(1)(R). Pub. L. 105–33, §4531(b)(1), added subpar. (R).

Subsec. (a)(1)(S). Pub. L. 105–33, §4556(b), added subpar. (S).

Subsec. (a)(2). Pub. L. 105–33, §4541(a)(1)(A), inserted ''(C),'' before ''(D)'' in introductory provisions.

Subsec. (a)(2)(A). Pub. L. 105–33, §4603(c)(2)(A)(i), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''with respect to home health services (other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title)) and to items and services described in section 1395x(s)(10)(A) of this title, the lesser of—

''(i) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

''(ii) the customary charges with respect to such services,

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title;''.

Subsec. (a)(2)(B). Pub. L. 105–33, §4432(b)(5)(C), inserted ''or section 1395yy(e)(9) of this title'' after ''1395ww of this title'' in introductory provisions.

Pub. L. 105–33, §4523(d)(3), inserted ''furnished before January 1, 1999,'' after ''(i)'' in cl. (i), inserted ''before January 1, 1999,'' after ''furnished'' in cl. (ii), added cl. (iii), and redesignated former cl. (iii) as (iv).

Subsec. (a)(2)(D). Pub. L. 105–33, §4104(c)(1), inserted ''or section 1395m(d)(1) of this title'' after ''subsection (h)(1) of this section''.

Subsec. (a)(2)(E). Pub. L. 105–33, §4523(d)(2)(B), inserted ''or, for services or procedures performed on or after January 1, 1999, subsection (t) of this section'' before semicolon at end.

Subsec. (a)(2)(G). Pub. L. 105–33, §4603(c)(2)(A)(ii)–(iv), added subpar. (G).

Subsec. (a)(3). Pub. L. 105–33, §4541(a)(1)(B), substituted ''section 1395k(a)(2)(D) of this title'' for ''subparagraphs (D) and (E) of section 1395k(a)(2) of this title''.

Subsec. (a)(4). Pub. L. 105–33, §4523(d)(1)(B), inserted ''or subsection (t) of this section'' before semicolon at end.

Subsec. (a)(6). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (a)(8), (9). Pub. L. 105–33, §4541(a)(1)(C)–(E), added pars. (8) and (9).

Subsec. (b)(5). Pub. L. 105–33, §4101(b), added par. (5) at end of first sentence.

Subsec. (b)(6). Pub. L. 105–33, §4102(b), added par. (6) at end of first sentence.

Subsec. (f). Pub. L. 105–33, §4205(a)(1)(A), substituted ''rural health clinics (other than such clinics in rural hospitals with less than 50 beds)'' for ''independent rural health clinics'' in introductory provisions.

Subsec. (f)(1). Pub. L. 105–33, §4205(a)(2), inserted ''per visit'' after ''$46''.

Subsec. (g). Pub. L. 105–33, §4541(d)(1), substituted ''the amount specified in paragraph (2) for the year'' for ''$900'' in two places, redesignated first sentence as par. (1) and last sentence as par. (3), and added par. (2).

Pub. L. 105–33, §4541(c), (d)(1)(A), substituted, in first sentence, ''physical therapy services of the type described in section 1395x(p) of this title, but not described in subsection (a)(8)(B) of this section, and physical therapy services of such type which are furnished by a physician or as incident to physicians' services'' for ''services described in the second sentence of section 1395x(p) of this title'', and substituted, in last sentence, ''occupational therapy services (of the type that are described in section 1395x(p) of this title (but not described in subsection (a)(8)(B) of this section) through the operation of section 1395x(g) of this title and of such type which are furnished by a physician or as incident to physicians' services)'' for ''outpatient occupational therapy services which are described in the second sentence of section 1395x(p) of this title through the operation of section 1395x(g) of this title''.

Subsec. (h)(1)(A). Pub. L. 105–33, §4104(c)(2), substituted ''Subject to section 1395m(d)(1) of this title, the Secretary'' for ''The Secretary''.

Pub. L. 105–33, §4103(b), inserted ''(including prostate cancer screening tests under section 1395x(*oo*) of this title consisting of prostate-specific antigen blood tests)'' after ''laboratory tests''.

Subsec. (h)(2)(A)(ii)(IV). Pub. L. 105–33, §4553(a), inserted ''and 1998 through 2002'' after ''1995''.

Subsec. (h)(4)(B)(vii). Pub. L. 105–33, §4553(b)(2)(A), inserted ''and before January 1, 1998,'' after ''December 31, 1995,''.

Subsec. (h)(4)(B)(viii). Pub. L. 105–33, §4553(b)(1), (2)(B), (3), added cl. (viii).

Subsec. (h)(5)(A)(iii). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (i)(1)(A). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (i)(2)(C). Pub. L. 105–33, §4555, inserted at end ''In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.''

Subsec. (i)(3)(A). Pub. L. 105–33, §4523(d)(1)(A)(i), inserted ''before January 1, 1999,'' after ''furnished'' and struck out ''in a cost reporting period'' after ''paragraph (1)(A)''.

Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (i)(3)(B)(i)(II). Pub. L. 105–33, §4521(a), struck out ''of 80 percent'' before ''of the standard overhead amount'' and inserted before period at end '', less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title''.

Subsec. (*l*)(5). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care'' wherever appearing.

Subsec. (n)(1)(A). Pub. L. 105–33, §4523(d)(2)(A), inserted ''and before January 1, 1999,'' after ''October 1, 1988,'' and after ''October 1, 1989,''.

Subsec. (n)(1)(B)(i)(II). Pub. L. 105–33, §4521(b), struck out ''of 80 percent'' before ''of the prevailing charge'' and inserted before period at end '', less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title''.

Subsec. (r)(1). Pub. L. 105–33, §4511(b)(2)(A), substituted ''section 1395x(s)(2)(K)(ii) of this title (relating to nurse practitioner or clinical nurse specialist services)'' for ''section 1395x(s)(2)(K)(iii) of this title (relating to nurse practitioner or clinical nurse specialist services provided in a rural area)''.

Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (r)(2). Pub. L. 105–33, §4511(b)(2)(B), (D), redesignated par. (3) as (2) and struck out former par. (2) which read as follows:

''(2)(A) For purposes of subsection (a)(1)(O) of this section, the prevailing charge for services described in section 1395x(s)(2)(K)(iii) of this title may not exceed the applicable percentage (as defined in subparagraph (B)) of the prevailing charge (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title) determined for such services performed by physicians who are not specialists.

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

''(i) 75 percent in the case of services performed in a hospital, and

''(ii) 85 percent in the case of other services.''

Subsec. (r)(3). Pub. L. 105–33, §4511(b)(2)(C), (D), redesignated par. (3) as (2) and substituted ''section 1395x(s)(2)(K)(ii) of this title'' for ''section 1395x(s)(2)(K)(iii) of this title''.

Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (t). Pub. L. 105–33, §4523(a), added subsec. (t).

1994—Subsec. (a)(1)(D)(i). Pub. L. 103–432, §156(a)(2)(B)(i), struck out '', or for tests furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion)'' after ''assignment-related basis''.

Subsec. (a)(1)(G). Pub. L. 103–432, §156(a)(2)(B)(ii), struck out subpar. (G) which read as follows: ''with respect to items and services (other than clinical diagnostic laboratory tests) furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion), the amounts paid shall be 100 percent of the reasonable charges for such items and services,''.

Subsec. (a)(2)(A). Pub. L. 103–432, §156(a)(2)(B)(iii), struck out '', to items and services (other than clinical diagnostic laboratory tests) furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion),'' before ''and to items and services'' in introductory provisions.

Pub. L. 103–432, §147(f)(6)(C)(i), substituted ''health services (other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title))'' for ''health services'' in introductory provisions.

Subsec. (a)(2)(D)(i). Pub. L. 103–432, §156(a)(2)(B)(iv), substituted ''assignment-related basis or'' for ''assignment-related basis,'' and struck out '', or for tests furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion)'' after ''section 1395cc of this title''.

Subsec. (a)(2)(F). Pub. L. 103–432, §147(f)(6)(C)(ii)–(iv), added subpar. (F).

Subsec. (a)(3). Pub. L. 103–432, §156(a)(2)(B)(v), struck out ''and for items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title, or a third opinion, if the second opinion was in disagreement with the first opinion)'' after ''section 1395x(s)(10)(A) of this title''.

Subsec. (b)(2). Pub. L. 103–432, §147(f)(6)(D), inserted ''(other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title))'' after ''services''.

Subsec. (b)(4), (5). Pub. L. 103–432, §156(a)(2)(B)(vi), redesignated par. (5) as (4) and struck out former par. (4) which read as follows: ''such deductible shall not apply with respect to items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion),''.

Subsec. (h)(5)(D). Pub. L. 103–432, §123(e), substituted ''paragraph (2) of section 1395u(j)'' for ''paragraphs (2) and (3) of section 1395u(j)'' and inserted at end ''Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.''

Subsec. (i)(1). Pub. L. 103–432, §141(a)(3), inserted before period at end of last sentence '', in consultation with appropriate trade and professional organizations''.

Subsec. (i)(2)(A). Pub. L. 103–432, §141(a)(2)(A), struck out ''and may be adjusted by the Secretary, when appropriate,'' after ''annually thereafter'' in last sentence.

Subsec. (i)(2)(A)(i). Pub. L. 103–432, §141(a)(1), inserted before comma at end '', as determined in accordance with a survey (based upon a representative sample of procedures and facilities) taken not later than January 1, 1995, and every 5 years thereafter, of the actual audited costs incurred by such centers in providing such services''.

Subsec. (i)(2)(B). Pub. L. 103–432, §141(a)(2)(A), struck out ''and may be adjusted by the Secretary, when appropriate,'' after ''annually thereafter'' in last sentence.

Subsec. (i)(2)(C). Pub. L. 103–432, §141(a)(2)(B), added subpar. (C).

Subsec. (i)(3)(B)(ii). Pub. L. 103–432, §141(c)(1), in subcls. (I) and (II) substituted ''for portions of cost reporting periods'' for ''for reporting periods'' and ''and ending on or before December 31, 1990'' for ''and on or before December 31, 1990''.

Subsec. (*l*)(5)(B), (C). Pub. L. 103–432, §123(b)(2)(A)(i), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows:

''(B)(i) Payment for the services of a certified registered nurse anesthetist under this part may be made only on an assignment-related basis, and any such assignment agreed to by a certified registered nurse anesthetist shall be binding upon any other person presenting a claim or request for payment for such services.

''(ii) Except for deductible and coinsurance amounts applicable under this section, 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 of a certified registered nurse anesthetist for which payment may be made under this part only on an assignment-related basis 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. (n)(1)(B)(i)(II). Pub. L. 103–432, §147(d)(2), substituted ''April 1, 1989'' for ''January 1, 1989''.

Pub. L. 103–432, §147(d)(1), inserted ''and for services described in subsection (a)(2)(E)(ii) of this section furnished on or after January 1, 1992'' after ''January 1, 1989'' and ''(or, in the case of services furnished on or after January 1, 1992, under section 1395w–4 of this title)'' before period at end.

Subsec. (p). Pub. L. 103–432, §123(b)(2)(A)(ii), struck out subsec. (p) which read as follows: ''In the case of certified nurse-midwife services for which payment may be made under this part only pursuant to section 1395x(s)(2)(L) of this title, in the case of qualified psychologists services for which payment may be made under this part only pursuant to section 1395x(s)(2)(M) of this title, and in the case of clinical social worker services for which payment may be made under this part only pursuant to section 1395x(s)(2)(N) of this title, payment may only be made under this part for such services on an assignment-related basis. Except for deductible and coinsurance amounts applicable under this section, whoever 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 the previous sentence, 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. (q)(1). Pub. L. 103–432, §147(a), substituted ''unique physician identification number'' for ''provider number'' and struck out ''and indicate whether or not the referring physician is an interested investor (within the meaning of section 1395nn(h)(5) of this title)'' after ''for the referring physician''.

Subsec. (r). Pub. L. 103–432, §160(d)(1), redesignated subsec. (r), relating to other prepaid organizations, as (s).

Subsec. (r)(1). Pub. L. 103–432, §147(e)(2), substituted ''or ambulatory'' for ''ambulatory'' in two places and ''center'' for ''center,'' before ''with which the nurse''.

Subsec. (r)(2)(A). Pub. L. 103–432, §147(e)(3), substituted ''subsection (a)(1)(O) of this section'' for ''subsection (a)(1)(M) of this section''.

Subsec. (r)(3), (4). Pub. L. 103–432, §123(b)(2)(A)(iii), redesignated par. (4) as (3) and struck out former par. (3) which read as follows:

''(3)(A) Payment under this part for services described in section 1395x(s)(2)(K)(iii) of this title may be made only on an assignment-related basis, and any such assignment agreed to by a nurse practitioner or clinical nurse specialist shall be binding upon any other person presenting a claim or request for payment for such services.

''(B) Except for deductible and coinsurance amounts applicable under this section, 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 section 1395x(s)(2)(K)(iii) of this title in violation of subparagraph (A) 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. (s). Pub. L. 103–432, §160(d)(1), redesignated subsec. (r), relating to other prepaid organizations, as (s).

1993—Subsec. (a)(1). Pub. L. 103–66, §13544(b)(2), redesignated subpar. (M) relating to nurse practitioner and clinical nurse specialist services as (O), inserted comma before ''(O)'', transferred and inserted such subpar. to appear before semicolon at end, struck out ''and'' before ''(N)'', and inserted '', and'' and subpar. (P) following subpar. (O) and before semicolon at end.

Subsec. (g). Pub. L. 103–66, §13555(a), substituted ''$900'' for ''$750'' in two places.

Subsec. (h)(2)(A)(ii)(IV). Pub. L. 103–66, §13551(a), added subcl. (IV).

Subsec. (h)(4)(B)(iv) to (vii). Pub. L. 103–66, §13551(b), added cls. (iv) to (vii), and struck out former cl. (iv) which read as follows: ''after December 31, 1990, is equal to 88 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1).''

Subsec. (i)(3)(B)(ii). Pub. L. 103–66, §13532(a)(1), in introductory provisions substituted ''paragraph (4)'' for ''the last sentence of this clause'' and struck out concluding provisions which read as follows: ''In the case of a hospital that makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary), receives more than 30 percent of its total revenues from outpatient services and was an eye specialty hospital or an eye and ear specialty hospital on October 1, 1987, the cost proportion and ASC proportion in effect under subclauses (I) and (II) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.''

Subsec. (i)(4). Pub. L. 103–66, §13532(a)(2), added par. (4).

Subsec. (*l*)(4)(B)(i). Pub. L. 103–66, §13516(b)(1), inserted ''and before January 1, 1994,'' after ''1991,''.

Subsec. (*l*)(4)(B)(ii). Pub. L. 103–66, §13516(b)(2), inserted ''and'' at end of subcl. (II), substituted a period for the comma at end of subcl. (III), and struck out subcls. (IV) to (VII) which read as follows:

''(IV) for services furnished in 1994, $11.25,

''(V) for services furnished in 1995, $11.50,

''(VI) for services furnished in 1996, $11.70, and

''(VII) for services furnished in calendar years after 1997, the previous year's conversion factor increased by the update determined under section 1395w–4(d)(3) of this title for physician anesthesia services for that year.''

Subsec. (*l*)(4)(B)(iii). Pub. L. 103–66, §13516(b)(3), added cl. (iii).

1990—Subsec. (a)(1)(H). Pub. L. 101–508, §4118(f)(2)(D), struck out '', as the case may be'' after ''section 1395w–4 of this title''.

Subsec. (a)(1)(J). Pub. L. 101–508, §4104(b)(1), struck out ''or physician pathology services'' after ''1395m(b)(6) of this title)'' and ''or section 1395m(f) of this title, respectively'' after ''1395m(b) of this title''.

Subsec. (a)(1)(K). Pub. L. 101–508, §4155(b)(2)(A), which directed amendment of subpar. (K) by striking ''and'' at the end, could not be executed because of prior amendment by Pub. L. 101–508, §4153(a)(2)(B)(i), see below.

Pub. L. 101–508, §4153(a)(2)(B)(i), struck out ''and'' after ''by a physician),''.

Subsec. (a)(1)(L). Pub. L. 101–508, §4153(a)(2)(B)(ii), substituted ''subparagraph,'' for ''subparagraph and'' at end.

Subsec. (a)(1)(M). Pub. L. 101–508, §4155(b)(2)(B), added subpar. (M) relating to nurse practitioner and clinical nurse specialist services.

Pub. L. 101–508, §4153(a)(2)(B)(ii), added subpar. (M) relating to prosthetic devices and orthotics.

Subsec. (a)(2). Pub. L. 101–508, §4153(a)(2)(C)(i), substituted ''(H), and (I)'' for ''and (H)'' in introductory provisions.

Subsec. (a)(2)(E)(i). Pub. L. 101–508, §4163(d)(1), inserted '', but excluding screening mammography'' after ''imaging services''.

Subsec. (a)(7). Pub. L. 101–508, §4153(a)(2)(C)(ii)–(iv), added par. (7).

Subsec. (b). Pub. L. 101–508, §4302, inserted ''for calendar years before 1991 and $100 for 1991 and subsequent years'' after ''$75''.

Subsec. (b)(5). Pub. L. 101–508, §4161(a)(3)(B), added par. (5) at end of first sentence.

Subsec. (h)(2)(A)(ii). Pub. L. 101–508, §4154(a)(1), substituted ''clause (i)'' for ''any other provision of this subsection'' in introductory provisions.

Subsec. (h)(2)(A)(ii)(III). Pub. L. 101–508, §4154(a)(2)–(4), added subcl. (III).

Subsec. (h)(4)(B). Pub. L. 101–508, §4154(b)(1)(B), struck out ''and'' at end of cl. (ii), inserted ''and before January 1, 1991,'' after ''1989,'' in cl. (iii), substituted '', and'' for period at end of cl. (iii), and added cl. (iv).

Subsec. (h)(5)(A)(ii)(II). Pub. L. 101–508, §4154(e)(1)(A), substituted ''wholly owned by'' for ''a wholly-owned subsidiary of''.

Subsec. (h)(5)(A)(ii)(III). Pub. L. 101–508, §4154(e)(1)(C), substituted ''receives requests for testing during the year in which the test is performed'' for ''submits bills or requests for payment in any year''.

Pub. L. 101–508, §4154(e)(1)(B), which directed substitution of ''laboratory (but not including a laboratory described in subclause (II)),'' for ''laboratory'', was executed by making the substitution for ''laboratory'' the second time appearing to reflect the probable intent of Congress.

Subsec. (h)(5)(A)(iii). Pub. L. 101–508, §4008(m)(2)(C), which directed technical correction to Pub. L. 101–239, §6003(g)(3)(C)(vii)(I), was executed by making technical correction to Pub. L. 101–239, §6003(g)(3)(D)(vii)(I), resulting in no change in text. See 1989 Amendment note below.

Subsec. (h)(5)(C). Pub. L. 101–508, §4154(c)(1)(A), substituted ''test, including a test performed in a physician's office but excluding a test performed by a rural health clinic'' for ''test performed by a laboratory other than a rural health clinic''.

Subsec. (h)(5)(D). Pub. L. 101–508, §4154(c)(1)(B), substituted ''test, including a test performed in a physician's office but excluding a test performed by a rural health clinic,'' for ''test performed by a laboratory, other than a rural health clinic''.

Subsec. (i)(3)(B)(ii). Pub. L. 101–508, §4151(c)(1)(B), substituted ''on or after October 1, 1988, and before January 1, 1995'' for ''in fiscal year 1989 or fiscal year 1990'' in last sentence.

Subsec. (i)(3)(B)(ii)(I). Pub. L. 101–508, §4151(c)(1)(A)(i), substituted ''50 percent for reporting periods beginning on or after October 1, 1988, and on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991'' for ''and 50 percent for other cost reporting periods''.

Subsec. (i)(3)(B)(ii)(II). Pub. L. 101–508, §4151(c)(1)(A)(ii), substituted ''50 percent for reporting

periods beginning on or after October 1, 1988, and on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991'' for ''and 50 percent for other cost reporting periods''.

Subsec. (*l*)(1). Pub. L. 101–508, § 4160(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C).

Subsec. (*l*)(2). Pub. L. 101–508, § 4160(2), struck out at end ''The fee schedule shall be adjusted annually (to become effective on January 1 of each calendar year) by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for that year.''

Subsec. (*l*)(4). Pub. L. 101–508, § 4160(3), added par. (4) and struck out former par. (4) which read as follows: ''In establishing the fee schedule under paragraph (1), the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology. The Secretary may establish a nationwide fee schedule or adjust the fee schedule for geographic areas (as the Secretary may determine to be appropriate).''

Subsec. (m). Pub. L. 101–597 substituted ''health professional shortage area'' for ''health manpower shortage area''.

Subsec. (n)(1)(B)(ii)(I). Pub. L. 101–508, § 4151(c)(2), inserted before period at end '', and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991''.

Subsec. (r). Pub. L. 101–508, § 4206(b)(2), added subsec. (r) relating to other prepaid organizations.

Pub. L. 101–508, § 4155(b)(3), added subsec. (r) relating to cap on prevailing charge and billing on assignment-related basis.

1989—Subsec. (a). Pub. L. 101–234, § 202(a), repealed Pub. L. 100–360, § 212(c)(2), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 205(c)(3), 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. (a)(1)(F). Pub. L. 101–239, § 6113(b)(3)(A), added subpar. (F).

Subsec. (a)(1)(H). Pub. L. 101–239, § 6102(e)(5), inserted ''(or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title, as the case may be)'' after ''prevailing charge that would be recognized''.

Subsec. (a)(1)(J). Pub. L. 101–239, § 6102(f)(2), inserted ''or physician pathology services'' after ''1395m(b)(6) of this title)'' and ''or section 1395m(f) of this title, respectively'' after ''1395m(b) of this title''.

Pub. L. 101–239, § 6102(e)(6)(A), inserted ''subject to section 1395w–4 of this title,'' before ''the amounts''.

Subsec. (a)(1)(K). Pub. L. 101–239, § 6102(e)(7), inserted '', or, for services furnished on or after January 1, 1992, 65 percent of the fee schedule amount provided under section 1395w–4 of this title for the same service performed by a physician'' after ''for the same service performed by a physician''.

Subsec. (a)(1)(M). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 201(b)(1), 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. (a)(1)(N). Pub. L. 101–239, § 6102(e)(1)(B), added subpar. (N).

Subsec. (a)(2). Pub. L. 101–239, § 6116(b)(1)(A), substituted ''(G), and (H)'' for ''and (G)'' in introductory provisions.

Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, §§ 202(b)(2), 203(c)(1)(A)–(D), 204(d)(1), and 205(c)(1), 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. (a)(3). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 205(c)(2), 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. (a)(6). Pub. L. 101–239, § 6116(b)(1)(B)–(D), added par. (6).

Subsec. (b). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, §§ 202(b)(3), 203(c)(1)(E), 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. (c). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 201(a)(1), (4), 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. (d). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 201(a)(1)(D), (2), 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. (d)(1). Pub. L. 101–239, § 6113(d), substituted ''62½ percent of such expenses.'' for ''whichever of the following amounts is the smaller:

''(A) $1375.00, or

''(B) 62½ percent of such expenses.''

Subsec. (g). Pub. L. 101–239, § 6133(a), substituted ''$750'' for ''$500'' in two places.

Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 201(a)(3), 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. (h)(1)(B), (C). Pub. L. 101–239, § 6111(a)(1), substituted ''on or after July 1, 1984'' for ''during the period beginning on July 1, 1984, and ending on December 31, 1989. For such tests furnished on or after January 1, 1990, the fee schedule shall be established on a nationwide basis.''

Subsec. (h)(1)(D). Pub. L. 101–239, § 6003(e)(2)(A), substituted ''section 1395ww(d)(5)(D)(iii) of this title'' for ''the last sentence of section 1395ww(d)(5)(C)(ii) of this title''.

Subsec. (h)(4)(B)(ii). Pub. L. 101–239, § 6111(a)(3)(A), (B), substituted ''after March 31, 1988, and before January 1, 1990,'' for ''after March 31, 1988, and so long as a fee schedule for the test has not been established on a nationwide basis,''.

Subsec. (h)(4)(B)(iii). Pub. L. 101–239, § 6111(a)(2), (3)(C), (4), added cl. (iii).

Subsec. (h)(5)(A)(ii). Pub. L. 101–239, § 6111(b)(1), substituted ''referring laboratory but only if—'' for ''referring laboratory, and'' in introductory provisions, and added subcls. (I) through (III).

Subsec. (h)(5)(A)(iii). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(I), as amended by Pub. L. 101–508, § 4008(m)(2)(C), substituted ''hospital or rural primary care hospital,'' for ''hospital,''.

Subsec. (i)(1)(A). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(II), inserted '', rural primary care hospital,'' after ''section 1395k(a)(2)(F)(i) of this title)''.

Subsec. (i)(3)(A). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(III), inserted ''or rural primary care hospital services'' after ''facility services'' in introductory provisions.

Subsec. (*l*)(5)(A). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(IV), inserted ''rural primary care hospital,'' after ''hospital,'' in two places.

Subsec. (*l*)(5)(C). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(V), substituted ''hospital or rural primary care hospital'' for ''hospital'' in two places.

Subsec. (m). Pub. L. 101–239, § 6102(c)(1), struck out ''class 1 or class 2'' before ''health manpower shortage area'' and substituted ''10 percent'' for ''5 percent''.

Subsec. (*o*)(1). Pub. L. 101–239, § 6131(a)(1)(C), inserted ''(or inserts)'' after ''shoes'' in two places in last sentence.

Subsec. (*o*)(1)(A). Pub. L. 101–239, § 6131(a)(1)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''no payment may be made under this part for the furnishing of more than one pair of shoes for any individual for any calendar year, and''.

Subsec. (*o*)(1)(B), (2)(A). Pub. L. 101–239, §6131(a)(1)(B), substituted ''limits'' for ''limit''.

Subsec. (*o*)(2)(A)(i). Pub. L. 101–239, §6131(a)(1)(D), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: ''for the furnishing of one pair of custom molded shoes is $300''.

Subsec. (*o*)(2)(A)(ii)(II). Pub. L. 101–239, §6131(a)(1)(E), inserted ''any pairs of'' after ''$50 for''.

Subsec. (*o*)(2)(D). Pub. L. 101–239, §6131(b), added subpar. (D).

Subsec. (p). Pub. L. 101–239, §6113(b)(3)(B), substituted ''1395x(s)(2)(L) of this title,'' for ''1395x(s)(2)(L) of this title and'' and inserted ''and in the case of clinical social worker services for which payment may be made under this part only pursuant to section 1395x(s)(2)(N) of this title,'' after ''section 1395x(s)(2)(M) of this title,''.

Subsec. (q). Pub. L. 101–239, §6204(b), added subsec. (q).

1988—Subsec. (a). Pub. L. 100–360, §212(c)(2), inserted ''or, as provided in section 1395t–1(c) of this title, from the Federal Catastrophic Drug Insurance Trust Fund'' after ''Fund'' in introductory provisions.

Pub. L. 100–360, §205(c)(3), inserted provision at end relating to payment for in-home care for chronically dependent individuals.

Subsec. (a)(1)(D)(i). Pub. L. 100–360, §411(i)(4)(C)(i), amended Pub. L. 100–203, §4085(i)(1)(A), see 1987 Amendment note below.

Subsec. (a)(1)(F). Pub. L. 100–360, §411(f)(12)(A), (14), added and renumbered Pub. L. 100–203, §4055(a)(1), see 1987 Amendment note below.

Pub. L. 100–360, §411(i)(4)(C)(iv), made technical amendment to directory language of Pub. L. 100–203, §4085(i)(21)(D)(i), see 1987 Amendment note below.

Pub. L. 100–360, §411(i)(4)(C)(ii), repealed Pub. L. 100–203, §4085(i)(1)(B), see 1987 Amendment note below.

Pub. L. 100–360, §411(h)(4)(B)(i), (ii), redesignated and amended directory language of Pub. L. 100–203, §4073(b)(1)(A), see 1987 Amendment note below.

Subsec. (a)(1)(G). Pub. L. 100–360, §411(h)(7)(C)(ii), repealed Pub. L. 100–203, §4077(b)(3)(A), see 1987 Amendment note below.

Pub. L. 100–360, §411(h)(4)(B)(iii), repealed Pub. L. 100–203, §4073(b)(2)(B), see 1987 Amendment note below.

Subsec. (a)(1)(H). Pub. L. 100–360, §411(h)(7)(C)(ii), repealed Pub. L. 100–203, §4077(b)(3)(B), see 1987 Amendment note below.

Pub. L. 100–360, §411(g)(1)(E), which directed the amendment of subpar. (H) by striking ''and'' before ''(I)'' could not be executed because of the prior amendment by section 4049(a)(1) of Pub. L. 100–203, see 1987 Amendment note below.

Pub. L. 100–360, §411(i)(3), added Pub. L. 100–203, §4084(c)(2), see 1987 Amendment note below.

Subsec. (a)(1)(J). Pub. L. 100–360, §411(f)(8)(B)(i), made technical amendment to directory language of Pub. L. 100–203, §4049(a)(1), see 1987 Amendment note below.

Pub. L. 100–360, §411(f)(8)(C), substituted ''section 1395m(b)(6) of this title'' for ''section 1395m(b)(5) of this title''.

Subsec. (a)(1)(K). Pub. L. 100–360, §411(h)(7)(C)(iii), (F), redesignated and amended Pub. L. 100–203, §4077(b)(2)(A), see 1987 Amendment note below.

Pub. L. 100–360, §411(h)(4)(B)(i), (iv), (v), redesignated and amended Pub. L. 100–203, §4073(b)(1)(B), see 1987 Amendment note below.

Subsec. (a)(1)(L). Pub. L. 100–360, §411(h)(7)(C)(i), (iv), (v), (F), redesignated and amended Pub. L. 100–203, §4077(b)(2)(B), see 1987 Amendment note below.

Subsec. (a)(1)(M). Pub. L. 100–360, §202(b)(1), added subpar. (M) relating to expenses incurred for covered outpatient drugs.

Subsec. (a)(2). Pub. L. 100–360, §205(c)(1), inserted ''(A)(ii),'' after ''subparagraphs'' in introductory provisions.

Pub. L. 100–360, §202(b)(2), inserted ''(other than covered outpatient drugs)'' after ''in the case of services'' in introductory provisions.

Subsec. (a)(2)(B). Pub. L. 100–360, §203(c)(1)(A), substituted ''(E), or (F)'' for ''or (E)'' in introductory provisions.

Subsec. (a)(2)(D)(i). Pub. L. 100–360, §411(i)(4)(C)(i), amended Pub. L. 100–203, §4085(i)(1)(A), see 1987 Amendment note below.

Subsec. (a)(2)(E)(i). Pub. L. 100–360, §204(d)(1), inserted '', but excluding screening mammography'' after ''imaging services''.

Subsec. (a)(2)(F). Pub. L. 100–360, §203(c)(1)(B)–(D), added subpar. (F) relating to home intravenous drug therapy services.

Subsec. (a)(3). Pub. L. 100–360, §205(c)(2), substituted ''subparagraphs (A)(ii), (D),'' for ''subparagraphs (D)''.

Subsec. (b). Pub. L. 100–360, §104(d)(7), as added by Pub. L. 100–485, §608(d)(3)(G), inserted at end ''The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395e(a)(2) of this title to blood or blood cells furnished the individual in the year.''

Subsec. (b)(1). Pub. L. 100–360, §202(b)(3)(A), inserted ''or for covered outpatient drugs'' after ''section 1395x(s)(10)(A) of this title''.

Subsec. (b)(2). Pub. L. 100–360, §203(c)(1)(E), substituted ''services and home intravenous drug therapy services'' for ''services''.

Pub. L. 100–360, §202(b)(3)(B), inserted ''or with respect to covered outpatient drugs'' after ''home health services''.

Subsec. (b)(3) to (5). Pub. L. 100–360, §411(f)(12)(A), (14), added and renumbered Pub. L. 100–203, §4055(a)(2), see 1987 Amendment note below.

Subsec. (c). Pub. L. 100–360, §201(a)(4), added subsec. (c) relating to limitation on out-of-pocket catastrophic cost-sharing, adjustment, buy-out plans, and conditions for payments with respect to plans other than buy-out plans. Former subsec. (c) redesignated (d)(1).

Pub. L. 100–360, §411(h)(1)(A), substituted ''monitoring or changing drug prescriptions'' for ''prescribing or monitoring prescription drugs'' in last sentence.

Pub. L. 100–360, §201(a)(1)(A), as amended by Pub. L. 100–485, §608(d)(4), substituted ''subsections (a) through (c)'' for ''subsections (a) and (b)'' in introductory provisions.

Pub. L. 100–360, §201(a)(1)(B), (C), redesignated former pars. (1) and (2) as subpars. (A) and (B) and substituted ''this paragraph'' for ''this subsection'' in last sentence.

Subsec. (d)(1). Pub. L. 100–360, §201(a)(1)(D), redesignated former subsec. (c) as subsec. (d)(1). Former subsec. (d) redesignated subsec. (d)(2).

Subsec. (d)(2). Pub. L. 100–360, §201(a)(2), redesignated former subsec. (d) as subsec. (d)(2).

Subsec. (f). Pub. L. 100–360, §411(g)(5), substituted ''MEI (as defined in section 1395u(i)(3) of this title) applicable to primary care services (as defined in section 1395u(i)(4) of this title)'' for ''medicare economic index (referred to in the fourth sentence of section 1395u(b)(3) of this title) applicable to physicians' services''.

Subsec. (g). Pub. L. 100–360, §201(a)(3), substituted ''subsections (a) through (c) of this section'' for ''subsections (a) and (b) of this section'' in two places.

Subsec. (h)(1)(D). Pub. L. 100–360, §411(g)(3)(E), (F), amended and redesignated Pub. L. 100–203, §4064(c)(1), see 1987 Amendment note below.

Subsec. (h)(2)(A)(i). Pub. L. 100–360, §411(g)(3)(A), added Pub. L. 100–203, §4064(a)(1), see 1987 Amendment note below.

Subsec. (h)(2)(A)(ii). Pub. L. 100–360, §411(g)(3)(A), added Pub. L. 100–203, §4064(a)(3), see 1987 Amendment note below.

Subsec. (h)(2)(A)(iii). Pub. L. 100–360, §411(g)(3)(B), (C), amended Pub. L. 100–203, §4064(b)(1), see 1987 Amendment note below.

Subsec. (h)(2)(B). Pub. L. 100–360, §411(g)(3)(A), added Pub. L. 100–203, §4064(a)(2), see 1987 Amendment note below.

Subsec. (h)(3). Pub. L. 100–647, §8421(a), inserted at end ''In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the person-

nel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this subchapter for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.''

Subsec. (h)(4)(B)(ii). Pub. L. 100–360, § 411(g)(3)(D), inserted ''after'' before ''March 31, 1988''.

Subsec. (h)(5)(A). Pub. L. 100–360, § 411(i)(4)(C)(vi), added Pub. L. 100–203, § 4085(i)(22)(B), see 1987 Amendment note below.

Subsec. (h)(5)(C). Pub. L. 100–360, § 411(i)(4)(C)(vi), added Pub. L. 100–203, § 4085(i)(22)(B), see 1987 Amendment note below.

Subsec. (h)(5)(D). Pub. L. 100–360, § 411(i)(4)(B), substituted ''A person may not bill for a clinical diagnostic laboratory test performed by a laboratory, other than a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence'' for ''If a person knowingly and willfully and on a repeated basis bills an individual enrolled under this part for charges for a clinical diagnostic laboratory test for which payment may only be made on an assignment-related basis under subparagraph (C)'' and ''paragraphs (2) and (3) of section 1395u(j) of this title in the same manner such paragraphs apply with respect to a physician'' for ''section 1395u(j)(2) of this title''.

Subsec. (i)(2)(A)(iii). Pub. L. 100–360, § 411(g)(2)(D), substituted ''insertion'' for ''implantation'' and inserted ''or subsequent to'' after ''during''.

Subsec. (i)(4). Pub. L. 100–360, § 411(f)(12)(A), (14), added and renumbered Pub. L. 100–203, § 4055(a)(3), see 1987 Amendment note below.

Subsec. (i)(6). Pub. L. 100–485, § 608(d)(22)(B), substituted ''Any person, including'' for ''Any person, other than''.

Pub. L. 100–360, § 411(g)(2)(E), added Pub. L. 100–203, § 4063(e)(1), see 1987 Amendment note below.

Subsec. (*l*)(2). Pub. L. 100–360, § 411(f)(2)(D), added Pub. L. 100–203, § 4042(b)(2)(B), see 1987 Amendment note below.

Subsec. (*l*)(3)(B). Pub. L. 100–647, § 8422(a), inserted ''plus applicable coinsurance'' after ''would have been paid''.

Subsec. (*l*)(5)(B)(ii). Pub. L. 100–360, § 411(i)(4)(C)(vi), added Pub. L. 100–203, § 4085(i)(23), see 1987 Amendment note below.

Subsec. (n)(1)(A). Pub. L. 100–360, § 411(g)(4)(C)(i), as amended by Pub. L. 100–485, § 608(d)(22)(D), substituted ''for services described in subsection (a)(2)(E)(i) of this section furnished under this part on or after October 1, 1988, and for services described in subsection (a)(2)(E)(ii) of this section furnished under this part on or after October 1, 1989,'' for ''beginning on or after October 1, 1988 under this part for services described in subsection (a)(2)(E) of this section'' in introductory provisions.

Subsec. (n)(1)(B)(i)(II). Pub. L. 100–360, § 411(g)(4)(C)(ii), inserted ''or (for services described in subsection (a)(2)(E)(i) of this section furnished on or after January 1, 1989) the fee schedule amount established'' after ''the prevailing charge''.

Subsec. (n)(1)(B)(ii). Pub. L. 100–360, § 411(g)(4)(C)(iii), amended subcls. (I) and (II) generally. Prior to amendment, subcls. (I) and (II) read as follows:

''(I) The term 'cost proportion' means 65 percent for all or any part of cost reporting periods which occur in fiscal year 1989 and 50 percent for other cost reporting periods.

''(II) The term 'charge proportion' means 35 percent for all or any parts of cost reporting periods which occur in fiscal year 1989 and 50 percent for other cost reporting periods.''

Subsec. (*o*). Pub. L. 100–360, § 411(h)(3)(B), as amended by Pub. L. 100–485, § 608(d)(23)(A), amended Pub. L. 100–203, § 4072(b), see 1987 Amendment note below.

Subsec. (p). Pub. L. 100–360, § 411(h)(7)(D), (F), redesignated and amended Pub. L. 100–203, § 4077(b)(3), see 1987 Amendment note below.

Pub. L. 100–360, § 411(h)(4)(C), redesignated and amended Pub. L. 100–203, § 4073(b)(2), see 1987 Amendment note below.

1987—Subsec. (a)(1)(D)(i). Pub. L. 100–203, § 4085(i)(1)(A), as amended by Pub. L. 100–360, § 411(i)(4)(C)(i), substituted ''on an assignment-related basis,'' for ''on the basis of an assignment described in section 1395u(b)(3)(B)(ii) of this title, under the procedure described in section 1395gg(f)(1) of this title,''.

Subsec. (a)(1)(F). Pub. L. 100–203, § 4055(a)(1), formerly § 4054(a)(1), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), struck out subpar. (F) which read as follows: ''with respect to expenses incurred for services described in subsection (i)(4) of this section under the conditions specified in such subsection, the amounts paid shall be the reasonable charge for such services,''.

Pub. L. 100–203, § 4085(i)(21)(D)(i), as amended by Pub. L. 100–360, § 411(i)(4)(C)(iv), amended Pub. L. 99–509, § 9343(e)(2)(A), see 1986 Amendment note below.

Pub. L. 100–203, § 4085(i)(1)(B), which directed striking out ''and'' at end, was repealed by Pub. L. 100–360, § 411(i)(4)(C)(ii).

Pub. L. 100–203, § 4073(b)(1)(A), formerly § 4073(b)(2)(A), as redesignated and amended by Pub. L. 100–360, § 411(h)(4)(B)(i), (ii), struck out ''and'' at end.

Subsec. (a)(1)(G). Pub. L. 100–203, § 4077(b)(3)(A), which directed striking out ''and'' at end, was repealed by Pub. L. 100–360, § 411(h)(7)(C)(ii).

Pub. L. 100–203, § 4073(b)(2)(B), which directed substituting ''services,'' for ''services; and'', was repealed by Pub. L. 100–360, § 411(h)(4)(B)(iii).

Pub. L. 100–203, § 4062(d)(3)(A)(i), substituted ''services,'' for ''services; and''.

Subsec. (a)(1)(H). Pub. L. 100–203, § 4077(b)(3)(B), which directed substituting ''services,'' for ''services; and'', was repealed by Pub. L. 100–360, § 411(h)(7)(C)(ii).

Pub. L. 100–203, § 4084(c)(2), as added by Pub. L. 100–360, § 411(i)(3), substituted ''least of the actual charge, the prevailing charge that would be recognized if the services had been performed by an anesthesiologist,'' for ''lesser of the actual charge''.

Pub. L. 100–203, § 4062(d)(3)(A)(ii), inserted ''and'' before the subpar. (I) added by section 4062(d)(3)(A)(ii) of Pub. L. 100–203, see below.

Pub. L. 100–203, § 4049(a)(1), struck out ''and'' before the subpar. (I) added by section 4062(d)(3)(A)(ii) of Pub. L. 100–203, see below.

Subsec. (a)(1)(I). Pub. L. 100–203, § 4062(d)(3)(A)(ii), added subpar. (I).

Subsec. (a)(1)(J). Pub. L. 100–203, § 4049(a)(1), as amended by Pub. L. 100–360, § 411(f)(8)(B)(i), added subpar. (J).

Subsec. (a)(1)(K). Pub. L. 100–203, § 4077(b)(2)(A), formerly § 4077(b)(3)(C), as redesignated and amended by Pub. L. 100–360, § 411(h)(7)(C)(iii), (F), inserted ''and'' after ''performed by a physician),''.

Pub. L. 100–203, § 4073(b)(1)(B), formerly § 4073(b)(2)(C), as redesignated and amended by Pub. L. 100–360, § 411(h)(4)(B)(i), (iv), (v), added subpar. (K), formerly (I), relating to amounts paid with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title.

Subsec. (a)(1)(L). Pub. L. 100–203, § 4077(b)(2)(B), formerly § 4077(b)(3)(D), as redesignated and amended by Pub. L. 100–360, § 411(h)(7)(C)(i), (iv), (v), (F), added subpar. (L), formerly (J), relating to amounts paid with respect to qualified psychologist services under section 1395x(s)(2)(M) of this title.

Subsec. (a)(2). Pub. L. 100–203, § 4062(d)(3)(B)(i), inserted reference to subpar. (G).

Subsec. (a)(2)(A). Pub. L. 100–203, § 4062(d)(3)(B)(ii), struck out ''(other than durable medical equipment)'' after ''home health services''.

Subsec. (a)(2)(B). Pub. L. 100–203, § 4066(b), inserted reference to subpar. (E).

Subsec. (a)(2)(D)(i). Pub. L. 100–203, § 4085(i)(1)(A), as amended by Pub. L. 100–360, § 411(i)(4)(C)(i), substituted ''on an assignment-related basis,'' for ''on the basis of an assignment described in section 1395u(b)(3)(B)(ii) of this title, under the procedure described in section 1395gg(f)(1) of this title,''.

Subsec. (a)(2)(E). Pub. L. 100–203, § 4066(a)(1), added subpar. (E).

Subsec. (a)(5). Pub. L. 100–203, § 4062(d)(3)(C)–(E), added par. (5).

Subsec. (b)(3). Pub. L. 100–203, § 4055(a)(2), formerly § 4054(a)(2), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), redesignated par. (4) as (3) and struck out former par. (3) which read as follows: ''such total amount shall not include expenses incurred for services the amount of payment for which is determined under subsection (a)(1)(F) of this section,''.

Pub. L. 100–203, § 4085(i)(21)(D)(i), amended Pub. L. 99–509, § 9343(e)(2)(A), see 1986 Amendment note below.

Subsec. (b)(4). Pub. L. 100–203, § 4055(a)(2), formerly § 4054(a)(2), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (b)(4)(A). Pub. L. 100–203, § 4085(i)(1)(C), substituted ''on an assignment-related basis'' for ''on the basis of an assignment described in section 1395u(b)(3)(B)(ii) of this title, under the procedure described in section 1395gg(f)(1) of this title''.

Subsec. (b)(5). Pub. L. 100–203, § 4055(a)(2), formerly § 4054(a)(2), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), redesignated par. (5) as (4).

Subsec. (c). Pub. L. 100–203, § 4070(b)(4), inserted ''or partial hospitalization services that are not directly provided by a physician'' before period at end of last sentence.

Pub. L. 100–203, § 4070(a)(2), inserted sentence at end defining ''treatment''.

Subsec. (c)(1). Pub. L. 100–203, § 4070(a)(1), substituted ''$1375.00'' for ''$312.50''.

Subsec. (f). Pub. L. 100–203, § 4067(a), added subsec. (f).

Subsec. (h)(1)(C). Pub. L. 100–203, § 4085(i)(2), inserted before period at end '', and ending on December 31, 1989. For such tests furnished on or after January 1, 1990, the fee schedule shall be established on a nationwide basis''.

Subsec. (h)(1)(D). Pub. L. 100–203, § 4064(c)(1), formerly § 4064(c), as amended and redesignated by Pub. L. 100–360, § 411(g)(3)(E), (F), inserted '', in a sole community hospital (as defined in the last sentence of section 1395ww(d)(5)(C)(ii) of this title),''.

Subsec. (h)(2). Pub. L. 100–203, § 4064(c), which had directed that ''laboratory in a sole community hospital'' be substituted for ''hospital laboratory'' in subsec. (h)(2), was redesignated § 4064(c)(1) by section 411(g)(3)(F) of Pub. L. 100–360 and amended by section 411(g)(3)(E) of Pub. L. 100–360 to provide for amendment of subsec. (h)(1)(D) instead of subsec. (h)(2).

Subsec. (h)(2)(A)(i). Pub. L. 100–203, § 4064(a)(1), as added by Pub. L. 100–360, § 411(g)(3)(A), inserted ''(A)(i)'' after ''(2)''.

Subsec. (h)(2)(A)(ii). Pub. L. 100–203, § 4064(a)(3), as added by Pub. L. 100–360, § 411(g)(3)(A), added cl. (ii).

Subsec. (h)(2)(A)(iii). Pub. L. 100–203, § 4064(b)(1), as amended by Pub. L. 100–360, § 411(g)(3)(B), (C), set out as cl. (iii) provisions formerly set out in an otherwise undesignated sentence in par. (2) relating to the rebasing of fee schedules for certain automated and similar tests for 1988 and for the continuation of such reduced fee schedules as the base for 1989 and subsequent years.

Subsec. (h)(2)(B). Pub. L. 100–203, § 4064(a)(2), as added by Pub. L. 100–360, § 411(g)(3)(A), inserted subpar. (B) designation preceding second sentence and redesignated former subpars. (A) and (B) of par. (2) as cls. (i) and (ii).

Subsec. (h)(4)(B)(i). Pub. L. 100–203, § 4064(b)(2)(A), substituted ''April'' for ''January''.

Subsec. (h)(4)(B)(ii). Pub. L. 100–203, § 4064(b)(2)(B), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ''after December 31, 1987, and so long as a fee schedule for the test has not been established on a nationwide basis, is equal to 110 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1).''

Subsec. (h)(5)(A). Pub. L. 100–203, § 4085(i)(22)(B), as added by Pub. L. 100–360, § 411(i)(4)(C)(vi), substituted ''on an assignment-related basis'' for ''on the basis of an assignment described in section 1395u(b)(3)(B)(ii) of this title, under the procedure described in section 1395gg(f)(1) of this title,'' in introductory provisions.

Subsec. (h)(5)(A)(iii). Pub. L. 100–203, § 4085(i)(3), added cl. (iii).

Subsec. (h)(5)(C). Pub. L. 100–203, § 4085(i)(22)(B), as added by Pub. L. 100–360, § 411(i)(4)(C)(vi), substituted ''on an assignment-related basis'' for ''on the basis of an assignment described in section 1395u(b)(3)(B)(ii) of this title, in accordance with section 1395u(b)(6)(B) of this title, under the procedure described in section 1395gg(f)(1) of this title,''.

Subsec. (h)(5)(D). Pub. L. 100–203, § 4085(b)(1), added subpar. (D).

Subsec. (i)(2)(A)(iii). Pub. L. 100–203, § 4063(b), added cl. (iii).

Subsec. (i)(3)(B)(ii). Pub. L. 100–203, § 4068(a)(1), substituted ''Subject to the last sentence of this clause, in'' for ''In''.

Pub. L. 100–203, § 4068(a)(2), inserted sentence at end relating to cost and ASC proportions in the case of an eye or eye and ear specialty hospital.

Subsec. (i)(4). Pub. L. 100–203, § 4055(a)(3), formerly § 4054(a)(3), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), struck out par. (4) which read as follows: ''In the case of services (including all pre- and post-operative services) described in paragraphs (1) and (2)(A) of section 1395x(s) of this title and furnished in connection with surgical procedures (specified pursuant to paragraph (1) of this subsection) in a physician's office, an ambulatory surgical center described in such paragraph, or a hospital outpatient department, payment for such services shall be determined in accordance with subsection (a)(1)(F) of this section if the physician accepts an assignment described in section 1395u(b)(3)(B)(ii) of this title with respect to payment for such services.''

Subsec. (i)(6). Pub. L. 100–203, § 4063(e)(1), as added by Pub. L. 100–360, § 411(g)(2)(E), added par. (6).

Subsec. (*l*)(2). Pub. L. 100–203, § 4084(a)(1), substituted ''1985 and such other data as the Secretary determines necessary'' for ''1985''.

Pub. L. 100–203, § 4042(b)(2)(B), as added by Pub. L. 100–360, § 411(f)(2)(D), substituted ''1395u(i)(3)'' for ''1395u(b)(4)(E)(ii)''.

Subsec. (*l*)(5)(A). Pub. L. 100–203, § 4084(a)(2), substituted ''group practice, or ambulatory surgical center'' for ''or group practice'' in two places.

Subsec. (*l*)(5)(B)(ii). Pub. L. 100–203, § 4085(i)(23), 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. (*l*)(6). Pub. L. 100–203, § 4045(c)(2)(A)(i), (ii), struck out subpar. (A) designation and substituted ''after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1395u(j)(1)(D) of this title.'' for ''(subject to subparagraph (D)), the physician may not charge the individual more than the limiting charge (as defined in subparagraph (B)) 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.''

Pub. L. 100–203, § 4045(c)(2)(A)(iii), struck out subpars. (B) to (D) which read as follows:

''(B) In subparagraph (A), 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 subparagraph (A).

''(C) If a physician knowingly and willfully imposes charges in violation of subparagraph (A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

''(D) This paragraph 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. (m). Pub. L. 100–203, § 4043(a), added subsec. (m).

Subsec. (n). Pub. L. 100–203, § 4066(a)(2), added subsec. (n).

Subsec. (*o*). Pub. L. 100–203, § 4072(b), as amended by Pub. L. 100–360, § 411(h)(3)(B), as amended by Pub. L. 100–485, § 608(d)(23)(A), added subsec. (*o*) [originally added as subsec. (f)].

Subsec. (p). Pub. L. 100–203, § 4077(b)(3), formerly § 4077(b)(4), as redesignated and amended by Pub. L. 100–360, § 411(h)(7)(D), (F), inserted ''and in the case of qualified psychologists services for which payment may be made under this part only pursuant to section 1395x(s)(2)(M) of this title''.

Pub. L. 100–203, § 4073(b)(2), formerly § 4073(b)(3), as redesignated and amended by Pub. L. 100–360, § 411(h)(4)(C), added subsec. (p) [originally added as subsec. (m)] and inserted provision relating to monetary penalty for whoever knowingly and willfully presents, or causes to be presented, to an enrolled individual a bill or request for payment for described services.

1986—Subsec. (a)(1)(D). Pub. L. 99–272, § 9401(b)(2)(B), substituted '', under the procedure described in section 1395gg(f)(1) of this title, or for tests furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion)'' for ''or under the procedure described in section 1395gg(f)(1) of this title''.

Subsec. (a)(1)(D)(i). Pub. L. 99–272, § 9303(b)(1), inserted '', the limitation amount for that test determined under subsection (h)(4)(B) of this section,'' after ''lesser of the amount determined under such fee schedule''.

Subsec. (a)(1)(F). Pub. L. 99–509, § 9343(e)(2)(A), as amended by Pub. L. 100–203, § 4085(i)(21)(D)(i), substituted ''(i)(4)'' for ''(i)(3)''.

Subsec. (a)(1)(G). Pub. L. 99–272, § 9401(b)(2)(A), added subpar. (G).

Subsec. (a)(1)(H). Pub. L. 99–509, § 9320(e)(1), added subpar. (H).

Subsec. (a)(2)(A). Pub. L. 99–272, § 9401(b)(2)(C), inserted '', to items and services (other than clinical diagnostic laboratory tests) furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion),'' after ''(other than durable medical equipment)''.

Subsec. (a)(2)(D). Pub. L. 99–272, § 9401(b)(2)(D), substituted ''to a provider having an agreement under section 1395cc of this title, or for tests furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion)'' for ''or to a provider having an agreement under section 1395cc of this title''.

Subsec. (a)(2)(D)(i). Pub. L. 99–272, § 9303(b)(1), inserted '', the limitation amount for that test determined under subsection (h)(4)(B) of this section,'' after ''lesser of the amount determined under such fee schedule''.

Subsec. (a)(3). Pub. L. 99–272, § 9401(b)(2)(E), inserted ''and for items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title, or a third opinion, if the second opinion was in disagreement with the first opinion'' after ''1395x(s)(10)(A) of this title''.

Subsec. (a)(4). Pub. L. 99–509, § 9343(a)(1)(A), amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''in the case of facility services described in subparagraph (F) of section 1395k(a)(2) of this title, the applicable amount described in paragraph (2) of subsection (i) of this section.''

Subsec. (b)(3). Pub. L. 99–509, § 9343(e)(2)(A), as amended by Pub. L. 100–203, § 4085(i)(21)(D)(i), which directed that par. (3) be amended by striking ''or under subsection (i)(2) or (i)(4) of this section'', was executed by striking ''or under subsection (i)(2) or (i)(5) of this section'', to reflect the probable intent of Congress and an earlier amendment by Pub. L. 99–509, § 9343(a)(2), see below.

Pub. L. 99–509, § 9343(a)(2), substituted ''(i)(5)'' for ''(i)(4)''.

Subsec. (b)(5). Pub. L. 99–272, § 9401(b)(1), added par. (5).

Subsec. (g). Pub. L. 99–509, § 9337(b), substituted ''second sentence'' for ''next to last sentence'', and inserted at end ''In the case of outpatient occupational therapy services which are described in the second sentence of section 1395x(p) of this title through the operation of section 1395x(g) of this title, with respect to expenses incurred in any calendar year, no more than $500 shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.''

Subsec. (h)(1)(B). Pub. L. 99–509, § 9339(b)(1), substituted ''December 31, 1989'' and ''January 1, 1990'' for ''December 31, 1987'' and ''January 1, 1988'', respectively.

Pub. L. 99–509, § 9339(a)(1)(A), substituted ''qualified hospital laboratory (as defined in subparagraph (D))'' for ''hospital laboratory''.

Pub. L. 99–272, § 9303(a)(1)(A), substituted ''December 31, 1987'' for ''June 30, 1987'' and ''January 1, 1988'' for ''July 1, 1987''.

Subsec. (h)(1)(C). Pub. L. 99–509, § 9339(a)(1)(B), substituted ''qualified hospital laboratory (as defined in subparagraph (D))'' for ''hospital laboratory'', struck out '', and ending on December 31, 1987'' after ''July 1, 1984'', and struck out ''For such tests furnished on or after January 1, 1988, the fee schedule under subparagraph (A) shall not apply with respect to clinical diagnostic laboratory tests performed by a hospital laboratory for outpatients of such hospital.'' which constituted second sentence.

Pub. L. 99–272, § 9303(a)(1)(A), substituted ''December 31, 1987'' for ''June 30, 1987'' and ''January 1, 1988'' for ''July 1, 1987''.

Subsec. (h)(1)(D). Pub. L. 99–509, § 9339(a)(1)(C), added subpar. (D).

Subsec. (h)(2). Pub. L. 99–509, § 9339(b)(2), struck out ''(or, effective January 1, 1988, for the United States)'' after ''applicable region, State, or area''.

Pub. L. 99–509, § 9339(a)(1)(D), substituted ''qualified hospital laboratory (as defined in paragraph (1)(D))'' for ''hospital laboratory''.

Pub. L. 99–272, § 9303(a)(1), substituted ''January 1, 1988'' for ''July 1, 1987'', and inserted ''(to become effective on January 1 of each year)'' after ''adjusted annually''.

Subsec. (h)(3). Pub. L. 99–509, § 9339(c)(1), inserted subpar. (A) designation after ''provide for and establish'', and added subpar. (B).

Subsec. (h)(4). Pub. L. 99–272, § 9303(b)(2), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (h)(5)(C). Pub. L. 99–272, § 9303(b)(3), substituted ''laboratory other than'' for ''laboratory which is independent of a physician's office or''.

Subsec. (i)(1). Pub. L. 99–509, § 9343(b)(2), inserted at end ''The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years.''

Subsec. (i)(2). Pub. L. 99–509, § 9343(e)(2)(B), inserted ''80 percent of'' before ''a standard overhead amount'' in introductory provisions of subpars. (A) and (B).

Pub. L. 99–509, § 9343(b)(1), substituted ''shall be reviewed and updated not later than July 1, 1987, and annually thereafter'' for ''shall be reviewed periodically'' in concluding provisions of subpars. (A) and (B).

Subsec. (i)(3) to (5). Pub. L. 99–509, §9343(a)(1)(B), added par. (3) and redesignated former pars. (3) and (4) as (4) and (5), respectively.

Subsec. (*l*). Pub. L. 99–509, §9320(e)(2), added subsec. (*l*).

1984—Subsec. (a)(1). Pub. L. 98–369, §2354(b)(7), struck out ''and'' at the end.

Subsec. (a)(1)(B). Pub. L. 98–369, §2323(b)(1), substituted ''section 1395x(s)(10)(A) of this title'' for ''section 1395x(s)(10) of this title''.

Subsec. (a)(1)(D). Pub. L. 98–369, §2303(a), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: ''with respect to diagnostic tests performed in a laboratory for which payment is made under this part to the laboratory, the amounts paid shall be equal to 100 percent of the negotiated rate for such tests (as determined pursuant to subsection (h) of this section),''.

Subsec. (a)(1)(F), (G). Pub. L. 98–369, §2305(a), redesignated subpar. (G) as (F), and struck out former subpar. (F) which related to payment of reasonable charges for preadmission diagnostic services furnished by a physician to individuals enrolled under this part which are furnished in the outpatient department of a hospital within seven days of such individual's admission to the same hospital or another hospital or furnished in the physician's office within seven days of such individual's admission to a hospital as an inpatient.

Subsec. (a)(2). Pub. L. 98–369, §2305(c), struck out ''and in paragraph (5) of this subsection'' after ''of such section''.

Subsec. (a)(2)(A). Pub. L. 98–617, §3(b)(2), inserted '', or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision),''.

Pub. L. 98–369, §2354(b)(5), realigned margin of subpar. (A).

Pub. L. 98–369, §2321(b)(1), inserted in provision preceding cl. (i) ''(other than durable medical equipment)''.

Pub. L. 98–369, §2323(b)(1), substituted ''section 1395x(s)(10)(A) of this title'' for ''section 1395x(s)(10) of this title''.

Subsec. (a)(2)(B). Pub. L. 98–369, §2354(b)(5), realigned margin of subpar. (B).

Pub. L. 98–369, §2321(b)(2), inserted in provision preceding cl. (i) ''items and'' after ''to other''.

Pub. L. 98–369, §2303(b)(1), inserted ''or (D)'' after ''subparagraph (C)''.

Subsec. (a)(2)(B)(ii). Pub. L. 98–369, §2308(b)(2)(B), inserted '', or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause),''.

Subsec. (a)(2)(D). Pub. L. 98–369, §2303(b)(2)–(4), added subpar. (D).

Subsec. (a)(3). Pub. L. 98–369, §2323(b)(1), substituted ''section 1395x(s)(10)(A) of this title'' for ''section 1395x(s)(10) of this title''.

Subsec. (a)(5). Pub. L. 98–369, §2305(b), struck out par. (5) which related to payment of reasonable costs for preadmission diagnostic services described in section 1395x(s)(2)(C) of this title furnished to an individual by the outpatient department of a hospital within seven days of such individual's admission to the same hospital as an inpatient or to another hospital.

Subsec. (b)(1). Pub. L. 98–369, §2323(b)(2), substituted ''section 1395x(s)(10)(A) of this title'' for ''section 1395x(s)(10) of this title''.

Subsec. (b)(3). Pub. L. 98–369, §2305(d), substituted ''subsection (a)(1)(F)'' for ''subsection (a)(1)(G)''.

Subsec. (b)(4). Pub. L. 98–369, §2303(c), added par. (4).

Subsec. (f). Pub. L. 98–369, §2321(d)(4)(A), transferred subsec. (f) to part C of this subchapter and redesignated its provisions as section 1889 of the Social Security Act, which is classified to section 1395zz of this title.

Subsec. (h). Pub. L. 98–369, §2303(d), amended subsec. (h) generally, substituting provisions directing the Secretary to establish fee schedules for clinical diagnostic laboratory tests at a percentage of the prevailing charge level and nominal fees to cover costs in collecting samples and authorizing the Secretary to make adjustments in the fee schedule, setting forth the recipients of payments, and authorizing the Secretary to establish a negotiated payment rate for provision authorizing the Secretary to establish a negotiated rate of payment with the laboratory which would be considered the full charge for such tests.

Subsec. (h)(5)(C). Pub. L. 98–617, §3(b)(3), inserted a comma before ''under the procedure described in section''.

Subsec. (i)(3). Pub. L. 98–369, §2305(d), substituted ''subsection (a)(1)(F)'' for ''subsection (a)(1)(G)''.

Subsec. (k). Pub. L. 98–369, §2323(b)(4), added subsec. (k).

1982—Subsec. (a)(1)(B). Pub. L. 97–248, §112(a)(1), substituted provisions that with respect to items and services described in section 1395x(s)(10) of this title, amounts paid shall be 100 percent of reasonable charges for such items and services for provision that with respect to expenses incurred for radiological or pathological services for which payment could be made under this part, furnished to any inpatient of a hospital by a physician in field of radiology or pathology who had in effect an agreement with Secretary by which the physician agreed to accept an assignment (as provided for in section 1395u(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part, the amounts paid would be equal to 100 percent of the reasonable charges for such services.

Subsec. (a)(1)(H). Pub. L. 97–248, §112(a)(2), (3), struck out subpar. (H) which provided that, with respect to items and services described in section 1395x(s)(10) of this title, the amount of benefits paid would be 100 percent of reasonable charges for such items and services.

Subsec. (a)(2)(B). Pub. L. 97–248, §101(c)(2), inserted ''and except as may be provided in section 1395ww of this title''.

Subsec. (b)(1). Pub. L. 97–248, §112(b), struck out subpar. (A) provision that total amount of expenses shall not include expenses incurred for radiological or pathological services furnished an individual as an inpatient of a hospital by a physician in field of radiology or pathology who has an agreement with Secretary by which physician agrees to accept an assignment (as provided for in section 1395u(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients under this part, and redesignated subpar. (B) provisions as par. (1).

Subsec. (i)(1). Pub. L. 97–248, §148(d), struck out requirement of consultation with National Professional Standards Review Council.

Subsec. (j). Pub. L. 97–248, §117(a)(2), added subsec. (j).

1981—Subsec. (a)(2)(A). Pub. L. 97–35, §2106(a), substituted provisions that with respect to home health services and to items and services described in section 1395x(s)(10) of this title, the lesser of reasonable cost of such services as determined under section 1395x(v) of this title or customary charges with respect to such services, or if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title for provisions that with respect to home health services and to items and services described in section 1395x(s)(10) of this title, the reasonable cost of such services, as determined under section 1395x(v) of this title.

Subsec. (a)(2)(B). Pub. L. 97–35, §2106(a), substituted new formula in cls. (i) to (iii) with respect to other services for provisions providing for reasonable costs of such services less the amount a provider may charge as described in section 1395cc(a)(2)(A) of this title and that in no case may payment for such other services exceed 80 percent of such costs.

Subsec. (b). Pub. L. 97–35, §§2133(a), 2134(a), redesignated pars. (2) to (4) as (1) to (3), and struck out former par. (1), which provided that amount of deductible for such calendar year as so determined shall first be re-

duced by amount of any expenses incurred by such individual in last three months of preceding calendar year and applied toward such individual's deductible under this section for such preceding year.

Pub. L. 97–35, § 2134(a), substituted ''by a deductible of $75'' for ''by a deductible of $60''.

1980—Subsec. (a)(1)(B). Pub. L. 96–499, § 943(a), inserted ''who has in effect an agreement with the Secretary by which the physician agrees to accept an assignment (as provided for in section 1395u(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part'' after ''radiology or pathology''.

Subsec. (a)(1)(D). Pub. L. 96–499, § 918(a)(4), substituted ''subsection (h)'' for ''subsection (g)''.

Subsec. (a)(1)(F). Pub. L. 96–499, § 932(a)(1)(B), added subpar. (F).

Subsec. (a)(1)(G). Pub. L. 96–499, § 934(d)(1), added subpar. (G).

Subsec. (a)(1)(H). Pub. L. 96–611, § 1(b)(1)(A), (B), added subpar. (H).

Subsec. (a)(2). Pub. L. 96–611, § 1(b)(1)(C), inserted in subpar. (A) ''and to items and services described in section 1395x(s)(10) of this title''.

Pub. L. 96–499, § 942, authorized payment of reasonable cost of home health services and prescribed formulae for determining payment amounts for services other than home health services.

Subsec. (a)(3). Pub. L. 96–611, § 1(b)(1)(D), inserted ''(other than for items and services described in section 1395x(s)(10) of this title)''.

Pub. L. 96–499, § 942, prescribed a formula for determining payment amounts for services described in subpars. (D) and (E) of section 1395k(a)(2) of this title.

Subsec. (a)(4), (5). Pub. L. 96–499, § 942, added pars. (4) and (5).

Subsec. (b)(2). Pub. L. 96–611, § 1(b)(2), inserted ''(A)'' after ''expenses incurred'' and added subpar. (B).

Pub. L. 96–499, § 943(a), inserted ''who has in effect an agreement with the Secretary by which the physician agrees to accept an assignment (as provided for in section 1395u(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part''.

Subsec. (b)(3). Pub. L. 96–499, § 930(h)(2), added par. (3).

Subsec. (b)(4). Pub. L. 96–499, § 934(d)(3), added par. (4).

Subsec. (g). Pub. L. 96–499, § 935(a), substituted ''$500'' for ''$100''.

Subsec. (h). Pub. L. 96–473 redesignated subsec. (g) as added by section 279(b) of Pub. L. 92–603 as (h), which for purposes of codification had been editorially set out as subsec. (h), thereby requiring no change in text. See 1972 Amendment note below.

Subsec. (i). Pub. L. 96–499, § 934(b), added subsec. (i).

1978—Subsec. (a)(1)(E). Pub. L. 95–292, § 4(b)(2), added subpar. (E).

Subsec. (a)(2). Pub. L. 95–292, § 4(c), inserted ''(unless otherwise specified in section 1395rr of this title)'' after ''and with respect to other services'' in provisions preceding subpar. (A).

1977—Subsec. (a)(2). Pub. L. 95–210, § 1(b)(2), inserted parenthetical provisions preceding subpar. (A) excepting those services described in subpar. (D) of section 1395k(a)(2) of this title.

Subsec. (a)(3). Pub. L. 95–210, § 1(b)(1), (3), (4), added par. (3).

Subsec. (f)(1). Pub. L. 95–142 substituted provisions relating to determinations by Secretary with respect to presumptions regarding purchase price or practicality of buying or renting durable medical equipment, for provisions relating to purchase price of durable medical equipment authorized to be paid by Secretary.

Subsec. (f)(2). Pub. L. 95–142 substituted provisions relating to waiver of coinsurance amount in purchase of used durable medical equipment, for provisions relating to reimbursement procedures established by Secretary in cases of rental of durable medical equipment.

Subsec. (f)(3), (4). Pub. L. 95–142 added pars. (3) and (4).

1972—Subsec. (a). Pub. L. 92–603, § 226(c)(2), inserted reference to section 1395mm of this title in provisions preceding par. (1).

Subsec. (a)(1). Pub. L. 92–603, §§ 211(c)(4), 279(a), added subpars. (C) and (D).

Subsec. (a)(2). Pub. L. 92–603, §§ 233(b), 251(a)(3), 299K(a), substituted subpars. (A) and (B) for provisions relating to the amount payable by reference to section 1395x(v) of this title, added subpar. (C), and in provisions preceding subpar. (A), inserted ''with respect to home health services, 100 percent, and with respect to other services,'' before ''80 percent''.

Subsec. (b). Pub. L. 92–603, § 204(a), substituted ''$60'' for ''$50''.

Subsec. (f). Pub. L. 92–603, § 245(d), designated existing provisions as par. (1)(A) and added par. (1)(B) and (2).

Subsec. (g). Pub. L. 92–603, § 251(a)(2), added subsec. (g).

Subsec. (h). Pub. L. 92–603, § 279(b), added subsec. (h). Subsec. was in the original (g) and was changed to accommodate subsec. (g) as added by section 251(a)(2) of Pub. L. 92–603.

1968—Subsec. (a)(1). Pub. L. 90–248, § 131(a)(1), (2), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (b). Pub. L. 90–248, §§ 129(c)(7), 131(b), struck out reference in par. (1) to expenses regarded under former par. (2) as incurred for services furnished in last three months of preceding year, struck out former par. (2) which provided that amount of any deduction imposed by section 1395e(a)(2)(A) of this title for outpatient hospital diagnostic services furnished in any calendar year is to be regarded as an incurred expense for such year; and added par. (2).

Pub. L. 90–248, § 135(c), inserted last sentence providing that there shall be a deductible equal to expenses incurred for first three pints of whole blood (or equivalent quantities of packed red blood cells as defined under regulations) furnished to an individual during a calendar year which deductible is to be appropriately reduced to extent that such blood has been replaced, and such blood will be deemed to have been replaced when institution or person furnishing such blood is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells) furnished individual to which three pint deductible applies.

Subsec. (d). Pub. L. 90–248, § 129(c)(8), struck out reference to subsection (a)(2)(A) of section 1395e of this title.

Subsec. (f). Pub. L. 90–248, § 132(b), added subsec. (f).

EFFECTIVE DATE OF 2015 AMENDMENT

Pub. L. 114–113, div. O, title V, § 504(d), Dec. 18, 2015, 129 Stat. 3023, provided that: ''The amendments made by this section [amending this section and sections 1395m and 1395x of this title] shall apply to items furnished on or after January 1, 2017.''

Pub. L. 114–10, title II, § 202(b)(2), Apr. 16, 2015, 129 Stat. 144, provided that: ''The amendments made by this subsection [amending this section] shall apply with respect to requests described in section 1833(g)(5)(C)(i) of the Social Security Act (42 U.S.C. 1395*l*(g)(5)(C)(i)) with respect to which the Secretary of Health and Human Services has not conducted medical review under such section by a date (not later than 90 days after the date of the enactment of this Act [Apr. 16, 2015]) specified by the Secretary.''

EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112–96, title III, § 3005(e), Feb. 22, 2012, 126 Stat. 189, provided that: ''The requirement of subparagraph (B) of section 1833(g)(5) of the Social Security Act (42 U.S.C. 1395*l*(g)(5)), as added by subsection (a), shall apply to services furnished on or after March 1, 2012.''

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title IV, § 4103(e), Mar. 23, 2010, 124 Stat. 557, provided that: ''The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to services furnished on or after January 1, 2011.''

Pub. L. 111–148, title IV, §4104(d), Mar. 23, 2010, 124 Stat. 558, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] shall apply to items and services furnished on or after January 1, 2011.''

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §101(c), July 15, 2008, 122 Stat. 2498, provided that: ''The amendments made by this section [amending this section and sections 1395x and 1395y of this title] shall apply to services furnished on or after January 1, 2009.''

Amendment by section 143(b)(2), (3), of Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395k of this title.

Pub. L. 110–275, title I, §145(a)(3), July 15, 2008, 122 Stat. 2547, provided that: ''The amendments made by this subsection [amending this section and section 1395w–3 of this title] shall take effect on the date of the enactment of this Act [July 15, 2008].''

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §109(c), Dec. 20, 2006, 120 Stat. 2985, provided that: ''The amendments made by this section [amending this section and section 1395ww of this title] shall apply to payment for services furnished on or after January 1, 2009.''

Pub. L. 109–171, title V, §5112(f), Feb. 8, 2006, 120 Stat. 44, provided that: ''The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to services furnished on or after January 1, 2007.''

Pub. L. 109–171, title V, §5113(c), Feb. 8, 2006, 120 Stat. 44, provided that: ''The amendments made by this section [amending this section and section 1395m of this title] shall apply to services furnished on or after January 1, 2007.''

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 237(a) of Pub. L. 108–173 applicable to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1320a–7b of this title.

Pub. L. 108–173, title IV, §411(a)(2), Dec. 8, 2003, 117 Stat. 2274, provided that: ''The amendment made by paragraph (1)(B) [amending this section] shall apply with respect to cost reporting periods beginning on and after January 1, 2004.''

Pub. L. 108–173, title IV, §413(b)(2), Dec. 8, 2003, 117 Stat. 2277, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to physicians' services furnished on or after January 1, 2005.''

Pub. L. 108–173, title VI, §614(c), Dec. 8, 2003, 117 Stat. 2306, provided that: ''The amendments made by this section [amending this section] shall apply—

''(1) in the case of screening mammography, to services furnished on or after the date of the enactment of this Act [Dec. 8, 2003]; and

''(2) in the case of diagnostic mammography, to services furnished on or after January 1, 2005.''

Pub. L. 108–173, title VI, §621(a)(6), Dec. 8, 2003, 117 Stat. 2310, provided that: ''The amendments made by this subsection [amending this section] shall apply to items and services furnished on or after January 1, 2004.''

Pub. L. 108–173, title VI, §627(c), Dec. 8, 2003, 117 Stat. 2321, provided that: ''The amendments made by this section [amending this section and sections 1395m and 1395u of this title] shall apply to items furnished on or after January 1, 2005.''

Pub. L. 108–173, title VI, §642(c), Dec. 8, 2003, 117 Stat. 2322, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] shall apply to items furnished administered [sic] on or after January 1, 2004.''

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, §1(a)(6) [title I, §105(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–472, provided that: ''The amendments made by this section [amending this section and sections 1395u and 1395x of this title] shall apply to services furnished on or after January 1, 2002.''

Pub. L. 106–554, §1(a)(6) [title I, §111(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply with respect to services furnished on or after April 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title II, §201(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: ''The amendment made—

''(1) by subsection (a) [amending section 1395m of this title] shall apply to services furnished on or after the date of the enactment of BBRA [Pub. L. 106–113, §1000(a)(6), approved Nov. 29, 1999];

''(2) by subsection (b)(1) [amending this section] shall apply as if included in the enactment of section 403(e)(1) of BBRA (113 Stat. 1501A–371) [Pub. L. 106–113, §1000(a)(6) [title IV, §403(e)(1)]]; and

''(3) by subsection (b)(2) [amending provisions set out as a note under section 1395m of this title] shall apply as if included in the enactment of section 403(d)(2) of BBRA (113 Stat. 1501A–371) [Pub. L. 106–113, §1000(a)(6) [title IV, §403(d)(2)], set out as a note under section 1395m of this title].''

Pub. L. 106–554, §1(a)(6) [title II, §205(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–483, provided that: ''The amendments made by this section [amending this section and section 1395m of this title] shall apply to services furnished on or after the date of the enactment of this Act [Dec. 21, 2000].''

Pub. L. 106–554, §1(a)(6) [title II, §223(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–490, provided that: ''The amendments made by subsections (b) and (c) [amending this section and section 1395m of this title] shall be effective for services furnished on or after October 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title II, §224(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–490, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title IV, §401(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–503, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect as if included in the enactment of BBA [Pub. L. 105–33].''

Pub. L. 106–554, §1(a)(6) [title IV, §402(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–505, provided that: ''The amendments made by this section [amending this section] take effect on the date of the enactment of this Act [Dec. 21, 2000].''

Pub. L. 106–554, §1(a)(6) [title IV, §403(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–506, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of BBRA [Pub. L. 106–113, §1000(a)(6)].''

Pub. L. 106–554, §1(a)(6) [title IV, §405(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–507, provided that: ''The amendments made by subsection (a) [amending this section] shall apply as if included in the enactment of section 202 of BBRA [Pub. L. 106–113, §1000(a)(6) [title II, §202]] (113 Stat. 1501A–342).''

Pub. L. 106–554, §1(a)(6) [title IV, §406(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–508, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to devices furnished on or after April 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title IV, §430(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–525, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] apply to items and services furnished on or after July 1, 2001.''

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(h)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–340, provided that: ''The Secretary of Health and Human Services shall first conduct the annual review under the amendment made by paragraph (1)(A) [amending this section] in 2001 for application in 2002 and the amendment made by

paragraph (1)(B) [amending this section] takes effect on the date of the enactment of this Act [Nov. 29, 1999].''

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(m)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, provided that: ''Except as provided in this section, the amendments made by this section [amending this section and sections 1395m and 1395x of this title] shall be effective as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33].''

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §202(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–344, provided that: ''The amendments made by this section [amending this section] shall be effective as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33].''

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §204(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–345, provided that: ''The amendments made by this section [amending this section] apply as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33] and shall only apply to procedures performed for which payment is made on the basis of the prospective payment system under section 1833(t) of the Social Security Act [42 U.S.C. 1395*l*(t)].''

Amendment by section 1000(a)(6) [title III, §321(g)(2), (k)(2)] 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.

Amendment by section 1000(a)(6) [title IV, §401(b)(1)] of Pub. L. 106–113 effective Jan. 1, 2000, see section 1000(a)(6) [title IV, §401(c)] of Pub. L. 106–113, set out as a note under section 1395i–4 of this title.

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §403(e)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–371, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [Nov. 29, 1999].''

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–33, title IV, §4002(j)(1)(B), Aug. 5, 1997, 111 Stat. 330, provided that: ''The amendment made by subparagraph (A) [amending this section] applies to new contracts entered into after the date of enactment of this Act [Aug. 5, 1997] and, with respect to contracts in effect as of such date, shall apply to payment for services furnished after December 31, 1998.''

Pub. L. 105–33, title IV, §4101(d), Aug. 5, 1997, 111 Stat. 360, provided that: ''The amendments made by this section [amending this section and section 1395m of this title] shall apply to items and services furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4102(e), Aug. 5, 1997, 111 Stat. 361, provided that: ''The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to items and services furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4103(e), Aug. 5, 1997, 111 Stat. 362, provided that: ''The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to items and services furnished on or after January 1, 2000.''

Pub. L. 105–33, title IV, §4104(e), Aug. 5, 1997, 111 Stat. 366, provided that: ''The amendments made by this section [amending this section and sections 1395m, 1395w–4, 1395x, and 1395y of this title] shall apply to items and services furnished on or after January 1, 1998.''

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.

Pub. L. 105–33, title IV, §4205(a)(1)(B), Aug. 5, 1997, 111 Stat. 376, provided that: ''The amendment made by subparagraph (A) [amending this section] applies to services furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4315(c), Aug. 5, 1997, 111 Stat. 390, provided that: ''The amendments made by this section [amending this section and section 1395u of this title] to the extent such amendments substitute fee schedules for reasonable charges, shall apply to particular services as of the date specified by the Secretary of Health and Human Services.''

Amendment by section 4432(b)(5)(C) 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 4511(b) of Pub. L. 105–33 applicable with respect to services furnished and supplies provided on and after Jan. 1, 1998, see section 4511(e) of Pub. L. 105–33, set out as a note under section 1395k of this title.

Pub. L. 105–33, title IV, §4512(d), Aug. 5, 1997, 111 Stat. 444, provided that: ''The amendments made by this section [amending this section and sections 1395u and 1395x of this title] shall apply with respect to services furnished and supplies provided on and after January 1, 1998.''

Pub. L. 105–33, title IV, §4521(c), Aug. 5, 1997, 111 Stat. 444, provided that: ''The amendments made by this section [amending this section] shall apply to services furnished during portions of cost reporting periods occurring on or after October 1, 1997.''

Pub. L. 105–33, title IV, §4523(d)(1)(A)(ii), Aug. 5, 1997, 111 Stat. 449, provided that: ''The amendment made by clause (i) [amending this section] shall apply to services furnished on or after January 1, 1999.''

Pub. L. 105–33, title IV, §4531(b)(3), Aug. 5, 1997, 111 Stat. 452, provided that: ''The amendments made by this subsection [amending this section and section 1395m of this title] shall apply to services furnished on or after January 1, 2000.''

Pub. L. 105–33, title IV, §4541(e), Aug. 5, 1997, 111 Stat. 457, provided that:

''(1) The amendments made by subsections (a)(1), (a)(2), and (b) [amending this section and sections 1395m and 1395y of this title] apply to services furnished on or after January 1, 1998, including portions of cost reporting periods occurring on or after such date, except that section 1834(k) of the Social Security Act [42 U.S.C. 1395m(k)] (as added by subsection (a)(2)) shall not apply to services described in section 1833(a)(8)(B) of such Act [42 U.S.C. 1395*l*(a)(8)(B)] (as added by subsection (a)(1)) that are furnished during 1998.

''(2) The amendments made by subsections (a)(3) and (c) [amending this section and section 1395cc of this title] apply to services furnished on or after January 1, 1999.

''(3) The amendments made by subsection (d)(1) [amending this section] apply to expenses incurred on or after January 1, 1999.''

Pub. L. 105–33, title IV, §4556(d), Aug. 5, 1997, 111 Stat. 463, provided that: ''The amendments made by subsections (a) and (b) [amending this section and section 1395u of this title] shall apply to drugs and biologicals furnished on or after January 1, 1998.''

Amendment by section 4603(c)(2)(A) 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.

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, §123(f)(1), (2), Oct. 31, 1994, 108 Stat. 4412, provided that:

''(1) ENFORCEMENT; MISCELLANEOUS AND TECHNICAL AMENDMENTS.—The amendments made by subsections (a) and (e) [amending this section and section 1395w–4 of this title] shall apply to services furnished on or after the date of the enactment of this Act [Oct. 31, 1994]; except that the amendments made by subsection (a) [amending section 1395w–4 of this title] shall not apply to services of a nonparticipating supplier or other person furnished before January 1, 1995.

''(2) PRACTITIONERS.—The amendments made by subsection (b) [amending this section and section 1395u of this title] shall apply to services furnished on or after January 1, 1995.''

Pub. L. 103–432, title I, §141(c)(2), Oct. 31, 1994, 108 Stat. 4425, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].''

Amendment by section 147(a), (e)(2), (3), (f)(6)(C), (D) of Pub. L. 103–432 effective as if included in the enactment of Pub. L. 101–508, see section 147(g) of Pub. L. 103–432, set out as a note under section 1320a–3a of this title.

Pub. L. 103–432, title I, §147(d)(1), (2), Oct. 31, 1994, 108 Stat. 4429, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 101–239.

Amendment by section 156(a)(2)(B) of Pub. L. 103–432 applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103–432, set out as a note under section 1320c–3 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, §13532(b), Aug. 10, 1993, 107 Stat. 587, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to portions of cost reporting periods beginning on or after January 1, 1994.''

Pub. L. 103–66, title XIII, §13544(b)(3), Aug. 10, 1993, 107 Stat. 590, provided that: ''The amendments made by this subsection [amending this section and section 1395m of this title] shall apply to items furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, §13555(b), Aug. 10, 1993, 107 Stat. 592, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1994.''

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, §4104(d), Nov. 5, 1990, 104 Stat. 1388–59, provided that: ''The amendments made by this section [amending this section and sections 1395m and 1395w–4 of this title] shall apply to services furnished on or after January 1, 1991.''

Amendment by section 4153(a)(2)(B), (C) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(a)(3) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Pub. L. 101–508, title IV, §4154(b)(2), Nov. 5, 1990, 104 Stat. 1388–85, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to tests furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4154(c)(2), Nov. 5, 1990, 104 Stat. 1388–85, provided that: ''The amendment made by paragraph (1)(A) [amending this section] shall take effect as if included in the enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985 [Pub. L. 99–272], and the amendment made by paragraph (1)(B) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].''

Pub. L. 101–508, title IV, §4154(e)(5), Nov. 5, 1990, 104 Stat. 1388–86, as amended by Pub. L. 103–432, title I, §147(f)(2), Oct. 31, 1994, 108 Stat. 4431, provided that: ''The amendments made by paragraphs (1)(A), (1)(B), (2), and (4) [amending this section, section 1395w–2 of this title, and provisions set out as a note below] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239], and the amendment made by paragraph (1)(C) [amending this section] shall take effect January 1, 1991.''

Amendment by section 4155(b)(2), (3) 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.

Amendment by section 4161(a)(3)(B) of Pub. L. 101–508 applicable to services furnished on or after Oct. 1, 1991, see section 4161(a)(8) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Pub. L. 101–508, title IV, §4163(e), Nov. 5, 1990, 104 Stat. 1388–100, as amended by Pub. L. 103–432, title I, §147(f)(5)(B), Oct. 31, 1994, 108 Stat. 4431, provided that: ''Except as provided in subsection (d)(3) [enacting provisions set out as a note under section 1395y of this title], the amendments made by this section [amending this section and sections 1395m, 1395x, 1395y, 1395z, 1395aa, and 1395bb of this title] shall apply to screening mammography performed on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4206(e)(2), Nov. 5, 1990, 104 Stat. 1388–117, provided that: ''The amendments made by subsection (b) [amending this section and section 1395mm of this title] shall apply to contracts under section 1876 of the Social Security Act [42 U.S.C. 1395mm] and payments under section 1833(a)(1)(A) of such Act [42 U.S.C. 1395*l*(a)(1)(A)] as of first day of the first month beginning more than 1 year after the date of the enactment of this Act [Nov. 5, 1990].''

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6102(c)(2), Dec. 19, 1989, 103 Stat. 2185, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to services furnished on or after January 1, 1991.''

Pub. L. 101–239, title VI, §6102(f)(3), Dec. 19, 1989, 103 Stat. 2189, provided that: ''The amendments made by this subsection [amending this section and section 1395m of this title] shall apply to services furnished on or after January 1, 1991.''

Pub. L. 101–239, title VI, §6102(g), Dec. 19, 1989, 103 Stat. 2189, provided that: ''Except as otherwise provided in this section, this section, and the amendments made by this section [enacting section 1395w–4 of this title, amending this section and sections 1395m, 1395u, and 1395rr of this title, and enacting provisions set out as notes under this section and sections 1395m, 1395u, and 1395w–4 of this title], shall take effect on the date of the enactment of this Act [Dec. 19, 1989].''

Pub. L. 101–239, title VI, §6111(b)(2), Dec. 19, 1989, 103 Stat. 2214, as amended by Pub. L. 101–508, title IV, §4154(e)(4), Nov. 5, 1990, 104 Stat. 1388–86, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply with respect to clinical diagnostic laboratory tests performed on or after May 1, 1990.''

Pub. L. 101–239, title VI, §6113(e), Dec. 19, 1989, 103 Stat. 2217, provided that: ''The amendments made by this section [amending this section and section 1395x of this title], and the provisions of subsection (c) [set out below], shall apply to services furnished on or after July 1, 1990, and the amendments made by subsection (d) [amending this section] shall apply to expenses incurred in a year beginning with 1990.''

Pub. L. 101–239, title VI, §6131(c), Dec. 19, 1989, 103 Stat. 2221, provided that:

''(1) The amendments made by this section [amending this section and section 1395x of this title] shall apply with respect to therapeutic shoes and inserts furnished on or after July 1, 1989.

''(2) In applying the amendments made by this section, the increase under subparagraph (C) of section 1833(*o*)(2) of the Social Security Act [42 U.S.C. 1395*l*(*o*)(2)(C)] shall apply to the dollar amounts specified under subparagraph (A) of such section (as amended by this section) in the same manner as the increase would have applied to the dollar amounts specified under subparagraph (A) of such section (as in effect before the date of the enactment of this Act [Dec. 19, 1989]).''

Pub. L. 101–239, title VI, §6133(b), Dec. 19, 1989, 103 Stat. 2222, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1990.''

Amendment by section 6204(b) of Pub. L. 101–239 effective with respect to referrals made on or after Jan. 1, 1992, see section 6204(c) of Pub. L. 101–239, set out as a note under section 1395nn 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.

Amendment by section 202(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–647, title VIII, § 8422(b), Nov. 10, 1988, 102 Stat. 3802, provided that: ''The amendment made by subsection (a) [amending this section] shall become effective as if included in the amendment made by section 9320(e)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509].''

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) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 202(b)(1)–(3) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100–360, set out as a note under section 1395u of this title.

Amendment by section 203(c)(1)(A)–(E) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Amendment by section 204(d)(1) of Pub. L. 100–360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 205(c) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100–360, set out as a note under section 1395k of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(f)(2)(D), (8)(B)(i), (C), (12)(A), (14), (g)(1)(E), (2)(D), (E), (3)(A)–(F), (4)(C), (5), (h)(1)(A), (3)(B), (4)(B), (C), (7)(C), (D), (F), (i)(3), (4)(B)–(C)(ii), (iv), and (vi) 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

Pub. L. 100–203, title IV, § 4043(c), Dec. 22, 1987, 101 Stat. 1330–86, provided that: ''The amendments made by this [sic] subsection (a) [amending this section] shall apply with respect to services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act [42 U.S.C. 1395ww(d)(2)(D)]) on or after January 1, 1989, and to other services furnished on or after January 1, 1991.''

Amendment by section 4045(c)(2)(A) of Pub. L. 100–203 applicable to items and services furnished on or after Apr. 1, 1988, see section 4045(d) of Pub. L. 100–203, set out as a note under section 1395u of this title.

Amendment by section 4049(a)(1) of Pub. L. 100–203 applicable to services performed on or after Apr. 1, 1989, see section 4049(b)(2) of Pub. L. 100–203, as amended, set out as a note under section 1395m of this title.

Pub. L. 100–203, title IV, § 4055(b), formerly § 4054(b), as added and renumbered by Pub. L. 100–360, title IV, § 411(f)(12)(A), (14), July 1, 1988, 102 Stat. 781, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988.''

Amendment by section 4062(d)(3) of Pub. L. 100–203 applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

Pub. L. 100–203, title IV, § 4063(c), Dec. 22, 1987, 101 Stat. 1330–110, provided that: ''The amendments made by this section [amending this section and section 1395u of this title] shall apply to items furnished on or after July 1, 1988.''

Pub. L. 100–203, title IV, § 4064(b)(3), Dec. 22, 1987, 101 Stat. 1330–110, provided that: ''The amendments made by paragraphs (1) and (2) [amending this section] shall apply with respect to services furnished on or after April 1, 1988.''

Pub. L. 100–203, title IV, § 4064(c)(2), as added by Pub. L. 100–360, title IV, § 411(g)(3)(F), July 1, 1988, 102 Stat. 784, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply with respect to diagnostic laboratory tests furnished on or after April 1, 1988.''

Pub. L. 100–203, title IV, § 4066(c), Dec. 22, 1987, 101 Stat. 1330–113, provided that: ''The amendments made by subsection (a) [amending this section] shall apply with respect to outpatient hospital radiology services furnished on or after October 1, 1988, and other diagnostic procedures performed on or after October 1, 1989.''

Pub. L. 100–203, title IV, § 4067(c), Dec. 22, 1987, 101 Stat. 1330–113, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988.''

Pub. L. 100–203, title IV, § 4068(c), Dec. 22, 1987, 101 Stat. 1330–114, provided that: ''The amendments made by subsection (a) [amending this section] shall be effective as if included in the amendment made by section 9343(a)(1)(B) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509].''

Pub. L. 100–203, title IV, § 4070(c)(1), Dec. 22, 1987, 101 Stat. 1330–115, provided that: ''The amendment made by subsection (a)(1) [amending this section] shall apply with respect to calendar years beginning with 1988; except that with respect to 1988, any reference in section 1833(c) of the Social Security Act [42 U.S.C. 1395*l*(c)], as amended by subsection (a), to '$1375.00' is deemed a reference to '$562.50'. The amendment made by subsection (a)(2) [amending this section] shall apply to services furnished on or after January 1, 1989.''

For effective date of amendment by section 4072(b) of Pub. L. 100–203, see section 4072(e) of Pub. L. 100–203, set out as a note under section 1395x of this title.

Amendment by section 4073(b) of Pub. L. 100–203 effective with respect to services performed on or after July 1, 1988, see section 4073(e) of Pub. L. 100–203, set out as a note under section 1395k of this title.

Amendment by section 4077(b)(2), (3) of Pub. L. 100–203 effective with respect to services performed on or after July 1, 1988, see section 4077(b)(5) of Pub. L. 100–203, set out as a note under section 1395k of this title.

Pub. L. 100–203, title IV, § 4084(b), Dec. 22, 1987, 101 Stat. 1330–129, provided that: ''The amendments made by subsection (a) [amending this section] shall apply as if included in the amendment made by section 9320(e)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509].''

Pub. L. 100–203, title IV, § 4084(c)(3), as added by Pub. L. 100–360, title IV, § 411(i)(3), July 1, 1988, 102 Stat. 788, provided that: ''The amendments made by this subsection [amending this section and section 1395x of this title] shall apply to services furnished after December 31, 1988.''

Pub. L. 100–203, title IV, § 4085(b)(2), Dec. 22, 1987, 101 Stat. 1330–130, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to procedures performed on or after January 1, 1988.''

Pub. L. 100–203, title IV, § 4085(i)(21), Dec. 22, 1987, 101 Stat. 1330–133, provided that the amendment to section 9343 of Pub. L. 99–509 by section 4085(i)(21)(D) of Pub. L. 100–203, amending this section and provisions set out as an Effective Date of 1986 Amendments note below, is effective as if included in the enactment of Pub. L. 99–509.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 9320(e)(1), (2) 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.

Amendment by section 9337(b) of Pub. L. 99–509 applicable to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987, see section 9337(e) of Pub. L. 99–509, set out as a note under section 1395k of this title.

Pub. L. 99–509, title IX, §9339(a)(2), Oct. 21, 1986, 100 Stat. 2036, provided that: ''The amendments made by this subsection [amending this section] apply to clinical diagnostic laboratory tests performed on or after January 1, 1987.''

Pub. L. 99–509, title IX, §9339(c)(2), Oct. 21, 1986, 100 Stat. 2037, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to samples collected on or after January 1, 1987.''

Pub. L. 99–509, title IX, §9343(h), Oct. 21, 1986, 100 Stat. 2042, as amended by Pub. L. 100–203, title IV, §4085(i)(21)(D)(ii), (iii), Dec. 22, 1987, 101 Stat. 1330–134; Pub. L. 100–360, title IV, §411(i)(4)(C)(v), July 1, 1988, 102 Stat. 789, provided that:

''(1) The amendments made by subsection (a)(1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1987.

''(2) The amendments made by subsections (b)(1) and (c) [amending this section and sections 1395y and 1395cc of this title] shall apply to services furnished after June 30, 1987.

''(3) The Secretary of Health and Human Services shall first provide, under the amendment made by subsection (b)(2) [amending this section], for the review and update of procedure lists within 6 months after the date of the enactment of this Act [Oct. 21, 1986].

''(4) The amendments made by subsection (d) [amending section 1320c–3 of this title] shall apply to contracts entered into or renewed after January 1, 1987.''

Pub. L. 99–272, title IX, §9303(a)(2), Apr. 7, 1986, 100 Stat. 188, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to clinical laboratory diagnostic tests performed on or after July 1, 1986.''

Pub. L. 99–272, title IX, §9303(b)(5)(A), (B), Apr. 7, 1986, 100 Stat. 189, provided that:

''(A) The amendments made by paragraphs (1) and (2) [amending this section] shall apply to clinical diagnostic laboratory tests performed on or after July 1, 1986.

''(B) The amendment made by paragraph (3) [amending this section] shall apply to clinical diagnostic laboratory tests performed on or after January 1, 1987.''

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.

Pub. L. 98–369, div. B, title III, §2303(j), July 18, 1984, 98 Stat. 1067, provided that:

''(1) Except as provided in paragraphs (2) and (3), the amendments made by this section [amending this section and sections 1395u, 1395cc, 1396a, and 1396b of this title and enacting provisions set out as notes under this section and section 1395u of this title] shall apply to clinical diagnostic laboratory tests furnished on or after July 1, 1984.

''(2) The amendments made by subsection (g)(2) [amending section 1396b of this title] shall apply to payments for calendar quarters beginning on or after October 1, 1984.

''(3) The amendments made by this section shall not apply to clinical diagnostic laboratory tests furnished to inpatients of a provider operating under a waiver granted pursuant to section 602(k) of the Social Security Amendments of 1983 [section 602(k) of Pub. L. 98–21, set out as a note under section 1395y of this title]. Payment for such services shall be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] at 80 percent (or 100 percent in the case of such tests for which payment is made on the basis of an assignment described in section 1842(b)(3)(B)(ii) of the Social Security Act [42 U.S.C. 1395u(b)(3)(B)(ii)] or under the procedure described in section 1870(f)(1) of such Act [42 U.S.C. 1395gg(f)(1)]) of the reasonable charge for such service. The deductible under section 1833(b) of such Act [42 U.S.C. 1395*l*(b)] shall not apply to such tests if payment is made on the basis of such an assignment or procedure.''

Pub. L. 98–369, div. B, title III, §2305(e), July 18, 1984, 98 Stat. 1070, provided that: ''The amendments made by this section [amending this section and enacting provisions set out below] shall apply to services performed after the date of the enactment of this Act [July 18, 1984].''

Amendment by section 2321(b), (d)(4)(A) of Pub. L. 98–369 applicable to items and services furnished on or after July 18, 1984, see section 2321(g) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Pub. L. 98–369, div. B, title III, §2323(d), July 18, 1984, 98 Stat. 1086, provided that: ''The amendments made by this section [amending this section and sections 1395x, 1395cc, and 1395rr of this title and enacting provisions set out below] apply to services furnished on or after September 1, 1984.''

Amendment by section 2354(b)(5), (7) 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.

EFFECTIVE DATE OF 1982 AMENDMENT

Pub. L. 97–248, title I, §112(c), Sept. 3, 1982, 96 Stat. 340, provided that: ''The amendments made by this section [amending this section] shall apply with respect to items and services furnished on or after October 1, 1982.''

Amendment by section 117(a)(2) of Pub. L. 97–248 applicable to final determinations made on or after Sept. 3, 1982, see section 117(b) of Pub. L. 97–248, set out as a note under section 1395g of this title.

Amendment by section 148(d) of Pub. L. 97–248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1320c of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXI, §2106(c), Aug. 13, 1981, 95 Stat. 792, provided that: ''The amendment made by subsection (a) [amending this section] is effective as of December 5, 1980, and the amendment made by subsection (b)(2) [amending section 1395q(b) of this title], is effective as of April 1, 1981.''

Pub. L. 97–35, title XXI, §2133(b), Aug. 13, 1981, 95 Stat. 797, provided that: ''The amendments made by subsection (a) [amending this section] first apply to the deductible for calendar year 1982 with respect to expenses incurred on or after October 1, 1981.''

Pub. L. 97–35, title XXI, §2134(b), Aug. 13, 1981, 95 Stat. 797, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect on January 1, 1982, and shall apply to the deductible for calendar years beginning with 1982.''

EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96–611, §2, Dec. 28, 1980, 94 Stat. 3567, provided that: ''The amendments made by this Act [probably should be the amendments made by section 1 of this Act, which amended this section and sections 1395x, 1395y, 1395aa, and 1395cc of this title] shall take effect on, and apply to services furnished on or after, July 1, 1981.''

Amendment by section 930(h) of Pub. L. 96–499, effective with respect to services furnished on or after July 1, 1981, see section 930(s)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Pub. L. 96–499, title IX, §935(b), Dec. 5, 1980, 94 Stat. 2639, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to expenses incurred in calendar years beginning with calendar year 1982.''

Pub. L. 96–499, title IX, §943(b), Dec. 5, 1980, 94 Stat. 2642, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished after the sixth calendar month beginning

after the date of the enactment of this Act [Dec. 5, 1980].''

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 on 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 1977 AMENDMENT

Amendment by Pub. L. 95–210 applicable to services rendered on or after first day of third calendar month which begins after Dec. 31, 1977, see section 1(j) of Pub. L. 95–210, set out as a note under section 1395k of this title.

Pub. L. 95–142, § 16(b), Oct. 25, 1977, 91 Stat. 1201, provided that: ''The amendment made by subsection (a) [amending this section] shall apply with respect to durable medical equipment purchased or rented on or after October 1, 1977.''

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–603, title II, § 204(c), Oct. 30, 1972, 86 Stat. 1377, provided that: ''The amendments made by this section [amending this section and section 1395n of this title] shall be effective with respect to calendar years after 1972 (except that, for purposes of applying clause (1) of the first sentence of section 1833(b) of the Social Security Act [42 U.S.C. 1395*l*(b)], such amendments shall be deemed to have taken effect on January 1, 1972).''

Amendment by section 211(c)(4) 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 226(c)(2) of Pub. L. 92–603 effective with respect to services provided on or after July 1, 1973, see section 226(f) of Pub. L. 92–603, set out as an Effective Date note under section 1395mm of this title.

Amendment by section 233(b) of Pub. L. 92–603 applicable to services furnished by hospitals, extended care facilities, and home health agencies in accounting periods beginning after Dec. 31, 1972, see section 233(f) of Pub. L. 92–603, set out as a note under section 1395f of this title. See, also, Pub. L. 93–233, § 16, Dec. 31, 1973, 87 Stat. 967, set out as a note under section 1395f of this title.

Amendment by section 251(a)(2), (3) of Pub. L. 92–603 applicable with respect to services furnished on or after July 1, 1973, see section 251(d)(1) of Pub. L. 92–603, set out as a note under section 1395x of this title.

Pub. L. 92–603, title II, § 299K(b), Oct. 30, 1972, 86 Stat. 1464, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished by home health agencies in accounting periods beginning after December 31, 1972.''

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 129(c)(7), (8) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395d of this title.

Pub. L. 90–248, title I, § 131(c), Jan. 2, 1968, 81 Stat. 850, provided that: ''The amendments made by this section [amending this section] shall apply with respect to services furnished after March 31, 1968.''

Pub. L. 90–248, title I, § 132(c), Jan. 2, 1968, 81 Stat. 850, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] shall apply only with respect to items purchased after December 31, 1967.''

Amendment by section 135(c) of Pub. L. 90–248 applicable with respect to payment for blood (or packed red blood cells) furnished an individual after Dec. 31, 1967, see section 135(d) of Pub. L. 90–248, set out as a note under section 1395e of this title.

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–275, title I, § 101(a)(4), July 15, 2008, 122 Stat. 2497, provided that: ''Nothing in the provisions of, or amendments made by, this subsection [amending this section and sections 1395x and 1395y of this title] shall be construed to provide coverage under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] of items and services for the treatment of a medical condition that is not otherwise covered under such title.''

CONSTRUCTION REGARDING LIMITING INCREASES IN COST-SHARING

Pub. L. 106–554, § 1(a)(6) [title I, § 111(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473, provided that: ''Nothing in this Act [H.R. 5661, as enacted by section 1(a)(6) of Pub. L. 106–554, see Tables for classification] or the Social Security Act [this chapter] shall be construed as preventing a hospital from waiving the amount of any coinsurance for outpatient hospital services under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] that may have been increased as a result of the implementation of the prospective payment system under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)).''

IMPROVING DOCUMENTATION OF SERVICES

Pub. L. 114–10, title V, § 514(b), Apr. 16, 2015, 129 Stat. 173, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with stakeholders (including the American Chiropractic Association) and representatives of medicare administrative contractors (as defined in section 1874A(a)(3)(A) of the Social Security Act (42 U.S.C. 1395kk–1(a)(3)(A))), develop educational and training programs to improve the ability of chiropractors to provide documentation to the Secretary of services described in section 1861(r)(5) [42 U.S.C. 1395x(r)(5)] in a manner that demonstrates that such services are, in accordance with section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)), reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

''(2) TIMING.—The Secretary shall make the educational and training programs described in paragraph (1) publicly available not later than January 1, 2016.

''(3) FUNDING.—The Secretary shall use funds made available under paragraph (10) of section 1893(h) of the Social Security Act (42 U.S.C. 1395ddd(h)), as added by section 505, to carry out this subsection.''

MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT

Pub. L. 112–242, title I, § 101, Jan. 10, 2013, 126 Stat. 2374, provided that:

''(a) ESTABLISHMENT.—The Secretary shall establish and implement a demonstration project under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globin for the treatment of primary immune deficiency diseases.

''(b) DURATION AND SCOPE.—

''(1) DURATION.—Beginning not later than one year after the date of enactment of this Act [Jan. 10, 2013], the Secretary shall conduct the demonstration project for a period of 3 years.

''(2) SCOPE.—The Secretary shall enroll not more than 4,000 Medicare beneficiaries who have been diag-

nosed with primary immunodeficiency disease for participation in the demonstration project. A Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time.

''(c) COVERAGE.—Except as otherwise provided in this section, items and services for which payment may be made under the demonstration program shall be treated and covered under part B of title XVIII of the Social Security Act in the same manner as similar items and services covered under such part.

''(d) PAYMENT.—The Secretary shall establish a per visit payment amount for items and services needed for the in-home administration of intravenous immune globin based on the national per visit low-utilization payment amount under the prospective payment system for home health services established under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

''(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] as may be necessary to carry out the demonstration project.

''(f) STUDY AND REPORT TO CONGRESS.—

''(1) INTERIM EVALUATION AND REPORT.—Not later than three years after the date of enactment of this Act, the Secretary shall submit to Congress a report that contains an interim evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

''(2) FINAL EVALUATION AND REPORT.—Not later than one year after the date of completion of the demonstration project, the Secretary shall submit to Congress a report that contains the following:

''(A) A final evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

''(B) An analysis of the appropriateness of implementing a new methodology for payment for intravenous immune globulins in all care settings under part B of title XVIII of the Social Security Act (42 U.S.C. 1395k [1395j] et seq.).

''(C) An update to the report entitled 'Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)', issued in February 2007 by the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

''(g) FUNDING.—There shall be made available to the Secretary to carry out the demonstration project not more than $45,000,000 from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

''(h) DEFINITIONS.—In this section:

''(1) DEMONSTRATION PROJECT.—The term 'demonstration project' means the demonstration project conducted under this section.

''(2) MEDICARE BENEFICIARY.—The term 'Medicare beneficiary' means an individual who is enrolled for benefits under part B of title XVIII of the Social Security Act.

''(3) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.''

IMPLEMENTATION OF 2013 AMENDMENT

Pub. L. 112–240, title VI, §603(d), Jan. 2, 2013, 126 Stat. 2347, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, and the amendments made by, this section [amending this section] by program instruction or otherwise.''

IMPLEMENTATION OF 2012 AMENDMENT

Pub. L. 112–96, title III, §3005(d), Feb. 22, 2012, 126 Stat. 189, provided that: ''The Secretary of Health and Human Services shall implement such claims processing edits and issue such guidance as may be necessary to implement the amendments made by this section [amending this section and section 1395u of this title] in a timely manner. Notwithstanding any other provision of law, the Secretary may implement the amendments made by this section by program instruction. Of the amount of funds made available to the Secretary for fiscal year 2012 for program management for the Centers for Medicare & Medicaid Services, not to exceed $9,375,000 shall be available for such fiscal year and the first 3 months of fiscal year 2013 to carry out section 1833(g)(5)(C) of the Social Security Act [42 U.S.C. 1395*l*(g)(5)(C)] (relating to manual medical review), as added by subsection (a).''

COLLECTION OF ADDITIONAL DATA

Pub. L. 112–96, title III, §3005(g), Feb. 22, 2012, 126 Stat. 189, provided that:

''(1) STRATEGY.—The Secretary of Health and Human Services shall implement, beginning on January 1, 2013, a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services subject to the limitations of section 1833(g) of the Social Security Act (42 U.S.C. 1395*l*(g)). Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes.

''(2) CONSULTATION.—In proposing and implementing such strategy, the Secretary shall consult with relevant stakeholders.''

TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS

Pub. L. 111–148, title III, §3113, Mar. 23, 2010, 124 Stat. 422, provided that:

''(a) DEMONSTRATION PROJECT.—

''(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a demonstration project under part B [of] title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] under which separate payments are made under such part for complex diagnostic laboratory tests provided to individuals under such part. Under the demonstration project, the Secretary shall establish appropriate payment rates for such tests.

''(2) COVERED COMPLEX DIAGNOSTIC LABORATORY TEST DEFINED.—In this section, the term 'complex diagnostic laboratory test' means a diagnostic laboratory test—

''(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;

''(B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics;

''(C) which is billed using a Health Care Procedure Coding System (HCPCS) code other than a not otherwise classified code under such Coding System;

''(D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

''(E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

''(3) SEPARATE PAYMENT DEFINED.—In this section, the term 'separate payment' means direct payment to a laboratory (including a hospital-based or independent laboratory) that performs a complex diagnostic laboratory test with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital if the test is performed after such period of hospitalization and if separate payment would not otherwise be made under title XVIII of the Social Security Act by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i) of the such [sic] Act (42 U.S.C. 1395y(a)(14); 42 U.S.C. 1395cc(a)(1)(H)(i)).

''(b) DURATION.—Subject to subsection (c)(2), the Secretary shall conduct the demonstration project under this section for the 2-year period beginning on July 1, 2011.

''(c) PAYMENTS AND LIMITATION.—Payments under the demonstration project under this section shall—

''(1) be made from the Federal Supplemental [probably should be ''Supplementary''] Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t); and

''(2) may not exceed $100,000,000.

''(d) REPORT.—Not later than 2 years after the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project. Such report shall include—

''(1) an assessment of the impact of the demonstration project on access to care, quality of care, health outcomes, and expenditures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] (including any savings under such title); and

''(2) such recommendations as the Secretary determines appropriate.

''(e) IMPLEMENTATION FUNDING.—For purposes of administering this section (including preparing and submitting the report under subsection (d)), the Secretary shall provide for the transfer, from the Federal Supplemental [probably should be ''Supplementary''] Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000. Amounts transferred under the preceding sentence shall remain available until expended.''

TREATMENT OF CERTIFIED REGISTERED NURSE ANESTHETISTS

Pub. L. 110–275, title I, §139(b), July 15, 2008, 122 Stat. 2541, provided that: ''With respect to items and services furnished on or after January 1, 2010, the Secretary of Health and Human Services shall make appropriate adjustments to payments under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for teaching certified registered nurse anesthetists to implement a policy with respect to teaching certified registered nurse anesthetists that—

''(1) is consistent with the adjustments made by the special rule for teaching anesthesiologists under section 1848(a)(6) of the Social Security Act [42 U.S.C. 1395w–4(a)(6)], as added by subsection (a); and

''(2) maintains the existing payment differences between teaching anesthesiologists and teaching certified registered nurse anesthetists.''

IMPLEMENTATION OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §107(b)(2), Dec. 20, 2006, 120 Stat. 2983, provided that: ''The Secretary of Health and Human Services may implement the amendment made by paragraph (1) [amending this section] by program instruction or otherwise.''

Pub. L. 109–171, title V, §5107(a)(2), Feb. 8, 2006, 120 Stat. 42, provided that: ''The Secretary of Health and Human Services shall waive such provisions of law and regulation (including those described in section 110(c) of Public Law 108–173 [set out as a note under section 1395w–101 of this title]) as are necessary to implement the amendments made by paragraph (1) [amending this section] on a timely basis and, notwithstanding any other provision of law, may implement such amendments by program instruction or otherwise. There shall be no administrative or judicial review under section 1869 or section 1878 of the Social Security Act (42 U.S.C. 1395ff and 1395*oo*), or otherwise of the process (including the establishment of the process) under section 1833(g)(5) of such Act [42 U.S.C. 1395*l*(g)(5)], as added by paragraph (1).''

IMPLEMENTATION OF CLINICALLY APPROPRIATE CODE EDITS IN ORDER TO IDENTIFY AND ELIMINATE IMPROPER PAYMENTS FOR THERAPY SERVICES

Pub. L. 109–171, title V, §5107(b), Feb. 8, 2006, 120 Stat. 43, provided that: ''By not later than July 1, 2006, the Secretary of Health and Human Services shall implement clinically appropriate code edits with respect to payments under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for physical therapy services, occupational therapy services, and speech-language pathology services in order to identify and eliminate improper payments for such services, including edits of clinically illogical combinations of procedure codes and other edits to control inappropriate billings.''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable 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, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY

Pub. L. 108–173, title III, §305(b), Dec. 8, 2003, 117 Stat. 2255, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

''(2) REPORT.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).''

TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED TO HOSPITAL OUTPATIENTS IN CERTAIN RURAL AREAS

Pub. L. 108–173, title IV, §416, Dec. 8, 2003, 117 Stat. 2282, as amended by Pub. L. 109–432, div. B, title I, §105, Dec. 20, 2006, 120 Stat. 2981; Pub. L. 110–173, title I, §107, Dec. 29, 2007, 121 Stat. 2496; Pub. L. 111–148, title III, §3122, Mar. 23, 2010, 124 Stat. 423; Pub. L. 111–309, title I, §109, Dec. 15, 2010, 124 Stat. 3288, provided that:

''(a) IN GENERAL.—Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395*l*) and section 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in the case of a clinical diagnostic laboratory test covered under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] that is furnished during a cost reporting period described in subsection (b) by a hospital with fewer than 50 beds that is located in a qualified rural area (identified under paragraph (12)(B)(iii) of section 1834(*l*) of the Social Security Act (42 U.S.C. 1395m(*l*)), as added by section 414(c)) as part of outpatient services of the hospital, the amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

''(b) APPLICATION.—A cost reporting period described in this subsection is a cost reporting period beginning during the period beginning on July 1, 2004, and ending on June 30, 2008 or during the 2-year period beginning on July 1, 2010.

''(c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERVICES.—For purposes of subsection (a), in determining whether clinical diagnostic laboratory services are furnished as part of outpatient services of a hospital, the Secretary [of Health and Human Services] shall apply the same rules that are used to determine whether clinical diagnostic laboratory services are furnished as an outpatient critical access hospital service under

section 1834(g)(4) of the Social Security Act (42 U.S.C. 1395m(g)(4)).''

[Pub. L. 109–432, div. B, title I, §105, Dec. 20, 2006, 120 Stat. 2981, provided that the amendment made by that section to section 416(b) of Pub. L. 108–173, set out above, is effective as if included in the enactment of section 416 of Pub. L. 108–173.]

GAO REPORT ON PAYMENTS FOR BRACHYTHERAPY DEVICES

Pub. L. 108–173, title VI, §621(b)(3), Dec. 8, 2003, 117 Stat. 2311, provided that: ''The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(16)(C) of the Social Security Act [42 U.S.C. 1395*l*(t)(16)(C)], as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary [of Health and Human Services] a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.''

MORATORIUM ON PHYSICAL THERAPY SERVICES CAPS IN 2003

Pub. L. 108–173, title VI, §624(a)(2), Dec. 8, 2003, 117 Stat. 2317, provided that: ''For the period beginning on the date of the enactment of this Act [Dec. 8, 2003] and ending of [sic] December 31, 2003, the Secretary [of Health and Human Services] shall not apply the provisions of paragraphs (1), (2), and (3) of section 1833(g) [42 U.S.C. 1395*l*(g)] to expenses incurred with respect to services described in such paragraphs during such period. Nothing in the preceding sentence shall be construed as affecting the application of such paragraphs by the Secretary before the date of the enactment of this Act.''

PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES

Pub. L. 108–173, title VI, §624(b), Dec. 8, 2003, 117 Stat. 2317, provided that: ''Not later than March 31, 2004, the Secretary [of Health and Human Services] shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 457) [set out as a note under this section] (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Appendix F, 113 Stat. 1501A–352), as enacted into law by section 1000(a)(6) of Public Law 106–113 [set out as a note under this section] (relating to utilization patterns for outpatient therapy).''

GAO STUDY OF AMBULATORY SURGICAL CENTER PAYMENTS

Pub. L. 108–173, title VI, §626(d), Dec. 8, 2003, 117 Stat. 2319, provided that:

''(1) STUDY.—

''(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)). The study shall also examine how accurately ambulatory payment categories reflect procedures furnished in ambulatory surgical centers.

''(B) CONSIDERATION OF ASC DATA.—In conducting the study under paragraph (1), the Comptroller General shall consider data submitted by ambulatory surgical centers regarding the matters described in clauses (i) through (iii) of paragraph (2)(B).

''(2) REPORT AND RECOMMENDATIONS.—

''(A) REPORT.—Not later than January 1, 2005, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

''(B) RECOMMENDATIONS.—The report submitted under subparagraph (A) shall include recommendations on the following matters:

''(i) The appropriateness of using the groups of covered services and relative weights established under the outpatient prospective payment system as the basis of payment for ambulatory surgical centers.

''(ii) If the relative weights under such hospital outpatient prospective payment system are appropriate for such purpose—

''(I) whether the payment rates for ambulatory surgical centers should be based on a uniform percentage of the payment rates or weights under such outpatient system; or

''(II) whether the payment rates for ambulatory surgical centers should vary, or the weights should be revised, based on specific procedures or types of services (such as ophthalmology and pain management services).

''(iii) Whether a geographic adjustment should be used for payment of services furnished in ambulatory surgical centers, and if so, the labor and nonlabor shares of such payment.''

DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICALS

Pub. L. 108–173, title VI, §641, Dec. 8, 2003, 117 Stat. 2321, provided that:

''(a) DEMONSTRATION PROJECT.—The Secretary [of Health and Human Services] shall conduct a demonstration project under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] under which payment is made for drugs or biologicals that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q)), or both, for which payment is made under such part. Such project shall provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as cost-sharing applies with respect to part D [part D of this subchapter] drugs under standard prescription drug coverage (as defined in section 1860D–2(b) of the Social Security Act [42 U.S.C. 1395w–102(b)], as added by section 101(a)).

''(b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in sites selected by the Secretary.

''(c) DURATION.—The Secretary shall conduct the demonstration project for the 2-year period beginning on the date that is 90 days after the date of the enactment of this Act [Dec. 8, 2003], but in no case may the project extend beyond December 31, 2005.

''(d) LIMITATION.—Under the demonstration project over the duration of the project, the Secretary may not provide—

''(1) coverage for more than 50,000 patients; and

''(2) more than $500,000,000 in funding.

''(e) REPORT.—Not later than July 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to reduced physicians' services and hospital outpatient departments services for administration of the biological.''

PAYMENT FOR PANCREATIC ISLET CELL INVESTIGATIONAL TRANSPLANTS FOR MEDICARE BENEFICIARIES IN CLINICAL TRIALS

Pub. L. 108–173, title VII, §733, Dec. 8, 2003, 117 Stat. 2352, provided that:

''(a) CLINICAL TRIAL.—

''(1) IN GENERAL.—The Secretary [of Health and Human Services], acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation which includes medicare beneficiaries.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such

sums as may be necessary to conduct the clinical investigation under paragraph (1).

''(b) MEDICARE PAYMENT.—Not earlier than October 1, 2004, the Secretary shall pay for the routine costs as well as transplantation and appropriate related items and services (as described in subsection (c)) in the case of medicare beneficiaries who are participating in a clinical trial described in subsection (a) as if such transplantation were covered under title XVIII of such Act [42 U.S.C. 1395 et seq.] and as would be paid under part A or part B of such title [42 U.S.C. 1395c et seq., 1395j et seq.] for such beneficiary.

''(c) SCOPE OF PAYMENT.—For purposes of subsection (b):

''(1) The term 'routine costs' means reasonable and necessary routine patient care costs (as defined in the Centers for Medicare & Medicaid Services Coverage Issues Manual, section 30–1), including immunosuppressive drugs and other followup care.

''(2) The term 'transplantation and appropriate related items and services' means items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the Centers for Medicare & Medicaid Services Coverage Issues Manual.

''(3) The term 'medicare beneficiary' means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.], or enrolled under part B of such title [42 U.S.C. 1395j et seq.], or both.

''(d) CONSTRUCTION.—The provisions of this section shall not be construed—

''(1) to permit payment for partial pancreatic tissue or islet cell transplantation under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] other than payment as described in subsection (b); or

''(2) as authorizing or requiring coverage or payment conveying—

''(A) benefits under part A of such title [42 U.S.C. 1395c et seq.] to a beneficiary not entitled to such part A; or

''(B) benefits under part B of such title [42 U.S.C. 1395j et seq.] to a beneficiary not enrolled in such part B.''

GAO STUDY OF REDUCTION IN MEDIGAP PREMIUM LEVELS RESULTING FROM REDUCTIONS IN COINSURANCE

Pub. L. 106–554, §1(a)(6) [title I, §111(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473, provided that: ''The Comptroller General of the United States shall work, in concert with the National Association of Insurance Commissioners, to evaluate the extent to which the premium levels for medicare supplemental policies reflect the reductions in coinsurance resulting from the amendment made by subsection (a) [amending this section]. Not later than April 1, 2004, the Comptroller General shall submit to Congress a report on such evaluation and the extent to which the reductions in beneficiary coinsurance effected by such amendment have resulted in actual savings to medicare beneficiaries.''

MEDPAC STUDY ON LOW-VOLUME, ISOLATED RURAL HEALTH CARE PROVIDERS

Pub. L. 106–554, §1(a)(6) [title II, §225], Dec. 21, 2000, 114 Stat. 2763, 2763A–490, provided that:

''(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the effect of low patient and procedure volume on the financial status of low-volume, isolated rural health care providers participating in the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a) indicating—

''(1) whether low-volume, isolated rural health care providers are having, or may have, significantly decreased medicare margins or other financial difficulties resulting from any of the payment methodologies described in subsection (c);

''(2) whether the status as a low-volume, isolated rural health care provider should be designated under the medicare program and any criteria that should be used to qualify for such a status; and

''(3) any changes in the payment methodologies described in subsection (c) that are necessary to provide appropriate reimbursement under the medicare program to low-volume, isolated rural health care providers (as designated pursuant to paragraph (2)).

''(c) PAYMENT METHODOLOGIES DESCRIBED.—The payment methodologies described in this subsection are the following:

''(1) The prospective payment system for hospital outpatient department services under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)).

''(2) The fee schedule for ambulance services under section 1834(*l*) of such Act (42 U.S.C. 1395m(*l*)).

''(3) The prospective payment system for inpatient hospital services under section 1886 of such Act (42 U.S.C. 1395ww).

''(4) The prospective payment system for routine service costs of skilled nursing facilities under section 1888(e) of such Act (42 U.S.C. 1395yy(e)).

''(5) The prospective payment system for home health services under section 1895 of such Act (42 U.S.C. 1395fff).''

SPECIAL RULE FOR PAYMENT FOR 2001

Pub. L. 106–554, §1(a)(6) [title IV, §401(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–503, provided that: ''Notwithstanding the amendment made by subsection (a) [amending this section], for purposes of making payments under section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t)) for covered OPD services furnished during 2001, the medicare OPD fee schedule amount under such section—

''(1) for services furnished on or after January 1, 2001, and before April 1, 2001, shall be the medicare OPD fee schedule amount for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

''(2) for services furnished on or after April 1, 2001, and before January 1, 2002, shall be the fee schedule amount (as determined taking into account the amendment made by subsection (a)), increased by a transitional percentage allowance equal to 0.32 percent (to account for the timing of implementation of the full market basket update).''

TRANSITION PROVISIONS APPLICABLE TO SUBSECTION (t)(6)(B)

Pub. L. 106–554, §1(a)(6) [title IV, §402(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–506, provided that:

''(1) IN GENERAL.—In the case of a medical device provided as part of a service (or group of services) furnished during the period before initial categories are implemented under subparagraph (B)(i) of section 1833(t)(6) of the Social Security Act [42 U.S.C. 1395*l*(t)(6)(B)(i)] (as amended by subsection (a)), payment shall be made for such device under such section in accordance with the provisions in effect before the date of the enactment of this Act [Dec. 21, 2000]. In addition, beginning on the date that is 30 days after the date of the enactment of this Act, payment shall be made for such a device that is not included in a program memorandum described in such subparagraph if the Secretary of Health and Human Services determines that the device (including a device that would have been included in such program memoranda but for the requirement of subparagraph (A)(iv)(I) of that section) is likely to be described by such an initial category.

''(2) APPLICATION OF CURRENT PROCESS.—Notwithstanding any other provision of law, the Secretary shall continue to accept applications with respect to medical devices under the process established pursuant

to paragraph (6) of section 1833(t) of the Social Security Act [42 U.S.C. 1395*l*(t)(6)] (as in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]) through December 1, 2000, and any device—

''(A) with respect to which an application was submitted (pursuant to such process) on or before such date; and

''(B) that meets the requirements of clause (ii) or (iv) of subparagraph (A) of such paragraph (as determined pursuant to such process),

shall be treated as a device with respect to which an initial category is required to be established under subparagraph (B)(i) of such paragraph (as amended by subsection (a)(2)).''

STUDY ON STANDARDS FOR SUPERVISION OF PHYSICAL THERAPIST ASSISTANTS

Pub. L. 106–554, §1(a)(6) [title IV, §421(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that:

''(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the implications—

''(A) of eliminating the 'in the room' supervision requirement for medicare payment for services of physical therapy assistants who are supervised by physical therapists; and

''(B) of such requirement on the cap imposed under section 1833(g) of the Social Security Act (42 U.S.C. 1395*l*(g)) on physical therapy services.

''(2) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Secretary shall submit to Congress a report on the study conducted under paragraph (1).''

DELAY IN IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM FOR AMBULATORY SURGICAL CENTERS

Pub. L. 106–554, §1(a)(6) [title IV, §424(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: ''The Secretary of Health and Human Services may not implement a revised prospective payment system for services of ambulatory surgical facilities under section 1833(i) of the Social Security Act (42 U.S.C. 1395*l*(i)) before January 1, 2002.''

MEDPAC STUDY AND REPORT ON MEDICARE REIMBURSEMENT FOR SERVICES PROVIDED BY CERTAIN PROVIDERS

Pub. L. 106–554, §1(a)(6) [title IV, §434], Dec. 21, 2000, 114 Stat. 2763, 2763A–526, provided that:

''(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the appropriateness of the current payment rates under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for services provided by a—

''(1) certified nurse-midwife (as defined in subsection (gg)(2) of section 1861 of such Act (42 U.S.C. 1395x));

''(2) physician assistant (as defined in subsection (aa)(5)(A) of such section);

''(3) nurse practitioner (as defined in such subsection); and

''(4) clinical nurse specialist (as defined in subsection (aa)(5)(B) of such section).

The study shall separately examine the appropriateness of such payment rates for orthopedic physician assistants, taking into consideration the requirements for accreditation, training, and education.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a), together with any recommendations for legislation that the Commission determines to be appropriate as a result of such study.''

MEDPAC STUDY ON ACCESS TO OUTPATIENT PAIN MANAGEMENT SERVICES

Pub. L. 106–554, §1(a)(6) [title IV, §438], Dec. 21, 2000, 114 Stat. 2763, 2763A–528, provided that:

''(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the barriers to coverage and payment for outpatient interventional pain medicine procedures under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]. Such study shall examine—

''(1) the specific barriers imposed under the medicare program on the provision of pain management procedures in hospital outpatient departments, ambulatory surgery centers, and physicians' offices; and

''(2) the consistency of medicare payment policies for pain management procedures in those different settings.

''(b) REPORT.—Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study.''

ESTABLISHMENT OF CODING AND PAYMENT PROCEDURES FOR NEW CLINICAL DIAGNOSTIC LABORATORY TESTS AND OTHER ITEMS ON A FEE SCHEDULE

Pub. L. 106–554, §1(a)(6) [title V, §531(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–547, provided that: ''Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall establish procedures for coding and payment determinations for the categories of new clinical diagnostic laboratory tests and new durable medical equipment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM.''

REPORT ON PROCEDURES USED FOR ADVANCED, IMPROVED TECHNOLOGIES

Pub. L. 106–554, §1(a)(6) [title V, §531(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–547, provided that: ''Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall submit to Congress a report that identifies the specific procedures used by the Secretary under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] to adjust payments for clinical diagnostic laboratory tests and durable medical equipment which are classified to existing codes where, because of an advance in technology with respect to the test or equipment, there has been a significant increase or decrease in the resources used in the test or in the manufacture of the equipment, and there has been a significant improvement in the performance of the test or equipment. The report shall include such recommendations for changes in law as may be necessary to assure fair and appropriate payment levels under such part for such improved tests and equipment as reflects increased costs necessary to produce improved results.''

CONGRESSIONAL INTENTION REGARDING BASE AMOUNTS IN APPLYING HOPD PPS

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(*l*)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, provided that: ''With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1833(t) of the Social Security Act [42 U.S.C. 1395*l*(t)(3)(A)(ii)], as added by section 4523(a) of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33], Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.''

STUDY AND REPORT TO CONGRESS REGARDING SPECIAL TREATMENT OF RURAL AND CANCER HOSPITALS IN PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §203], Nov. 29, 1999, 113 Stat. 1536, 1501A–344, provided that:

''(a) STUDY.—

''(1) IN GENERAL.—The Medicare Payment Advisory Commission (referred to in this section as 'MedPAC') shall conduct a study to determine the appropriate-

ness (and the appropriate method) of providing payments to hospitals described in paragraph (2) for covered OPD services (as defined in paragraph (1)(B) of section 1833(t) of the Social Security Act (42 U.S.C. 1395*l*(t))) based on the prospective payment system established by the Secretary in accordance with such section.

''(2) HOSPITALS DESCRIBED.—The hospitals described in this paragraph are the following:

''(A) A medicare-dependent, small rural hospital (as defined in section 1886(d)(5)(G)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)(iv))).

''(B) A sole community hospital (as defined in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C. 1395ww(d)(5)(D)(iii))).

''(C) Rural health clinics (as defined in section 1861(aa)(2) of such Act (42 U.S.C. 1395x(aa)(2)).

''(D) Rural referral centers (as so classified under section 1886(d)(5)(C) of such Act (42 U.S.C. 1395ww(d)(5)(C)).

''(E) Any other rural hospital with not more than 100 beds.

''(F) Any other rural hospital that the Secretary determines appropriate.

''(G) A hospital described in section 1886(d)(1)(B)(v) of such Act (42 U.S.C. 1395ww(d)(1)(B)(v)).

''(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Nov. 29, 1999], MedPAC shall submit a report to the Secretary of Health and Human Services and Congress on the study conducted under subsection (a), together with any recommendations for legislation that MedPAC determines to be appropriate as a result of such study.

''(c) COMMENTS.—Not later than 60 days after the date on which MedPAC submits the report under subsection (b) to the Secretary of Health and Human Services, the Secretary shall submit comments on such report to Congress.''

GAO STUDY ON RESOURCES REQUIRED TO PROVIDE SAFE AND EFFECTIVE OUTPATIENT CANCER THERAPY

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §213], Nov. 29, 1999, 113 Stat. 1536, 1501A–350, provided that:

''(a) STUDY.—The Comptroller General of the United States shall conduct a nationwide study to determine the physician and non-physician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services under the medicare program. In making such determination, the Comptroller General shall—

''(1) determine the adequacy of practice expense relative value units associated with the utilization of those clinical resources;

''(2) determine the adequacy of work units in the practice expense formula; and

''(3) assess various standards to assure the provision of safe outpatient cancer therapy services.

''(b) REPORT TO CONGRESS.—The Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding practice expense adjustments to the payment methodology under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], including the development and inclusion of adequate work units to assure the adequacy of payment amounts for safe outpatient cancer therapy services. The study shall also include an estimate of the cost of implementing such recommendations.''

FOCUSED MEDICAL REVIEWS OF CLAIMS DURING MORATORIUM PERIOD

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §221(a)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–351, as amended by Pub. L. 106–554, §1(a)(6) [title IV, §421(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that: ''During years in which paragraph (4) of section 1833(g) of the Social Security Act (42 U.S.C. 1395*l*(g)) applies, the Secretary of Health and Human Services shall conduct focused medical reviews of claims for reimbursement for services described in paragraph (1) or (3) of such section, with an emphasis on such claims for services that are provided to residents of skilled nursing facilities.''

STUDY AND REPORT ON UTILIZATION

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §221(d)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, provided that:

''(1) STUDY.—

''(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study which compares—

''(i) utilization patterns (including nationwide patterns, and patterns by region, types of settings, and diagnosis or condition) of outpatient physical therapy services, outpatient occupational therapy services, and speech-language pathology services that are covered under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395) [42 U.S.C. 1395 et seq.] and provided on or after January 1, 2000; with

''(ii) such patterns for such services that were provided in 1998 and 1999.

''(B) REVIEW OF CLAIMS.—In conducting the study under this subsection the Secretary of Health and Human Services shall review a statistically significant number of claims for reimbursement for the services described in subparagraph (A).

''(2) REPORT.—Not later than June 30, 2001, the Secretary of Health and Human Services shall submit a report to Congress on the study conducted under paragraph (1), together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.''

PHASE-IN OF PPS FOR AMBULATORY SURGICAL CENTERS

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §226], Nov. 29, 1999, 113 Stat. 1536, 1501A–354, as amended by Pub. L. 106–554, §1(a)(6) [title IV, §424(b), (c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, 2763A–519, provided that: ''If the Secretary of Health and Human Services implements a revised prospective payment system for services of ambulatory surgical facilities under section 1833(i) of the Social Security Act (42 U.S.C. 1395*l*(i)), prior to incorporating data from the 1999 Medicare cost survey or a subsequent cost survey, such system shall be implemented in a manner so that—

''(1) in the first year of its implementation, only a proportion (specified by the Secretary and not to exceed one-fourth) of the payment for such services shall be made in accordance with such system and the remainder shall be made in accordance with current regulations; and

''(2) in each of the following 2 years a proportion (specified by the Secretary and not to exceed one-half and three-fourths, respectively) of the payment for such services shall be made under such system and the remainder shall be made in accordance with current regulations.

By not later than January 1, 2003, the Secretary shall incorporate data from a 1999 medicare cost survey or a subsequent cost survey for purposes of implementing or revising such system.''

MEDPAC STUDY ON POSTSURGICAL RECOVERY CARE CENTER SERVICES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §229(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–356, provided that:

''(1) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study on the cost-effectiveness and efficacy of covering under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] services of a post-surgical recovery care center (that provides an intermediate level of recovery care following surgery). In conducting such study, the Commission shall consider data on these centers gathered in demonstration projects.

''(2) REPORT.—Not later than 1 year after the date of the enactment of this Act [Nov. 29,1999], the Commis-

sion shall submit to Congress a report on such study and shall include in the report recommendations on the feasibility, costs, and savings of covering such services under the medicare program.''

MEDICARE REIMBURSEMENT FOR TELEHEALTH SERVICES

Pub. L. 105–33, title IV, §4206, Aug. 5, 1997, 111 Stat. 377, as amended by Pub. L. 106–554, §1(a)(6) [title II, §223(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, provided that:

''(a) IN GENERAL.—For services furnished on and after January 1, 1999, and before October 1, 2001, the Secretary of Health and Human Services shall make payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) in accordance with the methodology described in subsection (b) for professional consultation via telecommunications systems with a physician (as defined in section 1861(r) of such Act (42 U.S.C. 1395x(r)) or a practitioner (described in section 1842(b)(18)(C) of such Act (42 U.S.C. 1395u(b)(18)(C)) furnishing a service for which payment may be made under such part to a beneficiary under the medicare program residing in a county in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) that is designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)), notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary.

''(b) METHODOLOGY FOR DETERMINING AMOUNT OF PAYMENTS.—Taking into account the findings of the report required under section 192 of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 1988), the findings of the report required under paragraph (c), and any other findings related to the clinical efficacy and cost-effectiveness of telehealth applications, the Secretary shall establish a methodology for determining the amount of payments made under subsection (a) within the following parameters:

''(1) The payment shall [be] shared between the referring physician or practitioner and the consulting physician or practitioner. The amount of such payment shall not be greater than the current fee schedule of the consulting physician or practitioner for the health care services provided.

''(2) The payment shall not include any reimbursement for any telephone line charges or any facility fees, and a beneficiary may not be billed for any such charges or fees.

''(3) The payment shall be made subject to the coinsurance and deductible requirements under subsections (a)(1) and (b) of section 1833 of the Social Security Act (42 U.S.C. 1395*l*).

''(4) The payment differential of section 1848(a)(3) of such Act (42 U.S.C. 1395w–4(a)(3)) shall apply to services furnished by non-participating physicians. The provisions of section 1848(g) of such Act (42 U.S.C. 1395w–4(g)) and section 1842(b)(18) of such Act (42 U.S.C. 1395u(b)(18)) shall apply. Payment for such service shall be increased annually by the update factor for physicians' services determined under section 1848(d) of such Act (42 U.S.C. 1395w–4(d)).

''(c) SUPPLEMENTAL REPORT.—Not later than January 1, 1999, the Secretary shall submit a report to Congress which shall contain a detailed analysis of—

''(1) how telemedicine and telehealth systems are expanding access to health care services;

''(2) the clinical efficacy and cost-effectiveness of telemedicine and telehealth applications;

''(3) the quality of telemedicine and telehealth services delivered; and

''(4) the reasonable cost of telecommunications charges incurred in practicing telemedicine and telehealth in rural, frontier, and underserved areas.

''(d) EXPANSION OF TELEHEALTH SERVICES FOR CERTAIN MEDICARE BENEFICIARIES.—

''(1) IN GENERAL.—Not later than January 1, 1999, the Secretary shall submit a report to Congress that examines the possibility of making payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) for professional consultation via telecommunications systems with such a physician or practitioner furnishing a service for which payment may be made under such part to a beneficiary described in paragraph (2), notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary.

''(2) BENEFICIARY DESCRIBED.—A beneficiary described in this paragraph is a beneficiary under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who does not reside in a rural area (as so defined) that is designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)), who is homebound or nursing homebound, and for whom being transferred for health care services imposes a serious hardship.

''(3) REPORT.—The report described in paragraph (1) shall contain a detailed statement of the potential costs and savings to the medicare program of making the payments described in that paragraph using various reimbursement schemes.''

REPORT ON COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES

Pub. L. 105–33, title IV, §4541(d)(2), Aug. 5, 1997, 111 Stat. 457, as amended by Pub. L. 106–113, div. B, §1000(a)(6) [title II, §221(c)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A–351, provided that: ''Not later than January 1, 2001, the Secretary of Health and Human Services shall submit to Congress a report that includes recommendations on—

''(A) the establishment of a mechanism for assuring appropriate utilization of outpatient physical therapy services, outpatient occupational therapy services, and speech-language pathology services that are covered under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395) [42 U.S.C. 1395 et seq.]; and

''(B) the establishment of an alternative payment policy for such services based on classification of individuals by diagnostic category, functional status, prior use of services (in both inpatient and outpatient settings), and such other criteria as the Secretary determines appropriate, in place of the uniform dollar limitations specified in section 1833(g) of such Act [42 U.S.C. 1395*l*(g)], as amended by paragraph (1).

The recommendations shall include how such a mechanism or policy might be implemented in a budget-neutral manner.''

[Pub. L. 106–113, div. B, §1000(a)(6) [title II, §221(c)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, provided that: ''The amendment made by paragraph (1) [amending section 4541(d)(2) of Pub. L. 105–33, set out above] shall take effect as if included in the enactment of section 4541 of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33].'']

STUDY AND REPORT ON CLINICAL LABORATORY TESTS

Pub. L. 105–33, title IV, §4553(c), Aug. 5, 1997, 111 Stat. 460, provided that:

''(1) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study of payments under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for clinical laboratory tests. The study shall include a review of the adequacy of the current methodology and recommendations regarding alternative payment systems. The study shall also analyze and discuss the relationship between such payment systems and access to high quality laboratory tests for medicare beneficiaries, including availability and access to new testing methodologies.

''(2) REPORT TO CONGRESS.—The Secretary shall, not later than 2 years after the date of enactment of this section [Aug. 5, 1997], report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate the results of the study described in paragraph (1), including any recommendations for legislation.''

ADJUSTMENTS TO PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES

Pub. L. 103–432, title I, §141(b), Oct. 31, 1994, 108 Stat. 4425, provided that:

''(1) ESTABLISHMENT OF PROCESS FOR REVIEW OF AMOUNTS.—Not later than 1 year after the date of the enactment of this Act [Oct. 31, 1994], the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall develop and implement a process under which interested parties may request review by the Secretary of the appropriateness of the reimbursement amount provided under section 1833(i)(2)(A)(iii) of the Social Security Act [42 U.S.C. 1395*l*(i)(2)(A)(iii)] with respect to a class of new technology intraocular lenses. For purposes of the preceding sentence, an intraocular lens may not be treated as a new technology lens unless it has been approved by the Food and Drug Administration.

''(2) FACTORS CONSIDERED.—In determining whether to provide an adjustment of payment with respect to a particular lens under paragraph (1), the Secretary shall take into account whether use of the lens is likely to result in reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

''(3) NOTICE AND COMMENT.—The Secretary shall publish notice in the Federal Register from time to time (but no less often than once each year) of a list of the requests that the Secretary has received for review under this subsection, and shall provide for a 30-day comment period on the lenses that are the subjects of the requests contained in such notice. The Secretary shall publish a notice of the Secretary's determinations with respect to intraocular lenses listed in the notice within 90 days after the close of the comment period.

''(4) EFFECTIVE DATE OF ADJUSTMENT.—Any adjustment of a payment amount (or payment limit) made under this subsection shall become effective not later than 30 days after the date on which the notice with respect to the adjustment is published under paragraph (3).''

STUDY OF MEDICARE COVERAGE OF PATIENT CARE COSTS ASSOCIATED WITH CLINICAL TRIALS OF NEW CANCER THERAPIES

Pub. L. 103–432, title I, §142, Oct. 31, 1994, 108 Stat. 4426, directed Secretary of Health and Human Services to conduct a study, and to submit a report to Congress not later than 2 years after Oct. 31, 1994, of effects of expressly covering under medicare program patient care costs for beneficiaries enrolled in clinical trials of new cancer therapies, where protocol for the trial has been approved by the National Cancer Institute or met similar scientific and ethical standards, including approval by an institutional review board.

STUDY OF ANNUAL CAP ON AMOUNT OF MEDICARE PAYMENT FOR OUTPATIENT PHYSICAL THERAPY AND OCCUPATIONAL THERAPY SERVICES

Pub. L. 103–432, title I, §143, Oct. 31, 1994, 108 Stat. 4426, directed Secretary of Health and Human Services to submit to Congress, not later than Jan. 1, 1996, study and report on appropriateness of continuing annual limitation on amount of payment for outpatient services of independently practicing physical and occupational therapists under medicare program, which was to include such recommendations for changes in such annual limitation as Secretary found appropriate.

AMBULATORY SURGICAL CENTER SERVICES; INFLATION UPDATE

Pub. L. 103–66, title XIII, §13531, Aug. 10, 1993, 107 Stat. 586, provided that: ''The Secretary of Health and Human Services shall not provide for any inflation update in the payment amounts under subparagraphs (A) and (B) of section 1833(i)(2) of the Social Security Act [42 U.S.C. 1395*l*(i)(2)(A), (B)] for fiscal year 1994 or for fiscal year 1995.''

FREEZE IN ALLOWANCE FOR INTRAOCULAR LENSES

Pub. L. 103–66, title XIII, §13533, Aug. 10, 1993, 107 Stat. 587, provided that: ''Notwithstanding section 1833(i)(2)(A)(iii) of the Social Security Act [42 U.S.C. 1395*l*(i)(2)(A)(iii)], the amount of payment determined under such section for an intraocular lens inserted subsequent to or during cataract surgery in an ambulatory surgical center on or after January 1, 1994, and before January 1, 1999, shall be equal to $150.''

Pub. L. 101–508, title IV, §4151(c)(3), Nov. 5, 1990, 104 Stat. 1388–73, as amended by Pub. L. 103–432, title I, §141(d), Oct. 31, 1994, 108 Stat. 4426, provided that: ''Notwithstanding section 1833(i)(2)(A)(iii) of the Social Security Act [42 U.S.C. 1395*l*(i)(2)(A)(iii)], the amount of payment determined under such section for an intraocular lens inserted during or subsequent to cataract surgery furnished to an individual in an ambulatory surgical center on or after the date of the enactment of this Act [Nov. 5, 1990] and on or before December 31, 1992, shall be equal to $200.''

[Pub. L. 103–432, title I, §141(d), Oct. 31, 1994, 108 Stat. 4426, provided that the amendment made by that section to section 4151(c)(3) of Pub. L. 101–508, set out above, is effective as if included in the enactment of Pub. L. 101–508.]

REDUCTION IN PAYMENTS UNDER PART B DURING FINAL TWO MONTHS OF 1990

Pub. L. 101–508, title IV, §4158, Nov. 5, 1990, 104 Stat. 1388–89, provided that:

''(a) IN GENERAL.—Notwithstanding any other provision of law (including any other provision of this Act, other than subsection (b)(4)), payments under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for items and services furnished during the period beginning on November 1, 1990, and ending on December 31, 1990, shall be reduced by 2 percent, in accordance with subsection (b).

''(b) SPECIAL RULES FOR APPLICATION OF REDUCTION.—

''(1) PAYMENT ON THE BASIS OF COST REPORTING PERIODS.—In the case in which payment for services of a provider of services is made under part B of such title on a basis relating to the reasonable cost incurred for the services during a cost reporting period of the provider, the reduction made under subsection (a) shall be applied to payment for costs for such services incurred at any time during each cost reporting period of the provider any part of which occurs during the period described in such subsection, but only in the same proportion as the fraction of the cost reporting period that occurs during such period.

''(2) NO INCREASE IN BENEFICIARY CHARGES IN ASSIGNMENT-RELATED CASES.—If a reduction in payment amounts is made under subsection (a) for items or services for which payment under part B of such title is made on an assignment-related basis (as defined in section 1842(i)(1) of the Social Security Act [42 U.S.C. 1395u(i)(1)]), the person furnishing the items or services shall be considered to have accepted payment of the reasonable charge for the items or services, less any reduction in payment amount made under subsection (a), as payment in full.

''(3) TREATMENT OF PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS.—Subsection (a) shall not apply to payments under risk-sharing contracts under section 1876 of the Social Security Act [42 U.S.C. 1395mm] or under similar contracts under section 402 of the Social Security Amendments of 1967 [Pub. L. 90–248, enacting section 1395b–1 of this title and

amending section 1395*ll* of this title] or section 222 of the Social Security Amendments of 1972 [Pub. L. 92–603, amending sections 1395b–1 and 1395*ll* of this title and enacting provisions set out as a note under section 1395b–1 of this title].''

EFFECT ON STATE LAW

Conscientious objections of health care provider under State law unaffected by enactment of subsecs. (a)(1)(Q) and (f) of this section, see section 4206(c) of Pub. L. 101–508, set out as a note under section 1395cc of this title.

DEVELOPMENT OF CRITERIA REGARDING CONSULTATION WITH A PHYSICIAN

Pub. L. 101–239, title VI, §6113(c), Dec. 19, 1989, 103 Stat. 2217, as amended by Pub. L. 103–432, title I, §147(b), Oct. 31, 1994, 108 Stat. 4429, provided that: ''The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for qualified psychologist services and clinical social worker services for which payment may be made directly to the psychologist or clinical social worker under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] under which such a psychologist or clinical social worker must agree to consult with a patient's attending physician in accordance with such criteria.''

[Pub. L. 103–432, title I, §147(b), Oct. 31, 1994, 108 Stat. 4429, provided that the amendment made by that section to section 6113(c) of Pub. L. 101–239, set out above, is effective with respect to services furnished on or after Jan. 1, 1991.]

STUDY OF REIMBURSEMENT FOR AMBULANCE SERVICES

Pub. L. 101–239, title VI, §6136, Dec. 19, 1989, 103 Stat. 2222, directed Secretary of Health and Human Services to conduct a study to determine adequacy and appropriateness of payment amounts under this subchapter for ambulance services and, not later than one year after Dec. 19, 1989, submit a report to Congress on results of the study, with report to include such recommendations for changes in medicare payment policy with respect to ambulance services as may be needed to ensure access by medicare beneficiaries to quality ambulance services in metropolitan and rural areas.

PROPAC STUDY OF PAYMENTS FOR SERVICES IN HOSPITAL OUTPATIENT DEPARTMENTS

Pub. L. 101–239, title VI, §6137, Dec. 19, 1989, 103 Stat. 2223, directed Prospective Payment Assessment Commission to conduct a study on payment under this subchapter for hospital outpatient services and, not later than July 1, 1990, and not later than Mar. 1, 1991, to submit reports to Congress on specified portions of the study, with the reports to include such recommendations as the Commission deemed appropriate, prior to repeal by Pub. L. 103–432, title I, §147(c)(1), Oct. 31, 1994, 108 Stat. 4429.

BUDGET NEUTRALITY

Pub. L. 100–647, title VIII, §8421(b), Nov. 10, 1988, 102 Stat. 3802, provided that: ''The Secretary of Health and Human Services shall adjust the fees for transportation and personnel established under section 1833(h)(3)(B) of the Social Security Act [42 U.S.C. 1395*l*(h)(3)(B)] for tests not covered under the amendment made by subsection (a) [amending this section] in such manner that the total cost of fees under such section is the same as would have been the case without such amendment.''

ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

For requirement that Secretary of Health and Human Services modify contracts under subsection (a)(1)(A) of this section to take into account amendments made by Pub. L. 100–360 and that such organizations make appropriate adjustments in their agreements with medicare beneficiaries to take into account such amendments, see section 222 of Pub. L. 100–360, set out as a note under section 1395mm of this title.

STUDY AND REPORT TO CONGRESS RESPECTING INCENTIVE PAYMENTS FOR PHYSICIANS' SERVICES FURNISHED IN UNDERSERVED AREAS

Pub. L. 100–203, title IV, §4043(b), Dec. 22, 1987, 101 Stat. 1330–86, directed Secretary of Health and Human Services to study and report to Congress, by not later than Jan. 1, 1990, on feasibility of making additional payments described in section 1395*l*(m) of this title with respect to physician services performed in health manpower shortage areas located in urban areas, prior to repeal by Pub. L. 101–508, title IV, §4118(g)(1), Nov. 5, 1990, 104 Stat. 1388–70.

FEE SCHEDULES FOR PHYSICIAN PATHOLOGY SERVICES

Pub. L. 100–203, title IV, §4050, Dec. 22, 1987, 101 Stat. 1330–92, directed Secretary of Health and Human Services to develop a relative value scale and fee schedules with updating index for payment of physician pathology services under this part, and to report to committees of Congress not later than Apr. 1, 1989, on the scale, schedules, and index, prior to repeal by Pub. L. 101–508, title IV, §4104(b)(3), Nov. 5, 1990, 104 Stat. 1388–59.

APPLYING COPAYMENT AND DEDUCTIBLE TO CERTAIN OUTPATIENT PHYSICIANS' SERVICES

Pub. L. 100–203, title IV, §4054, Dec. 22, 1987, 101 Stat. 1330–98, relating to payment under part B of title XVIII of the Social Security Act (this part) for physicians' services specified in subsec. (i) of this section and furnished on or after Apr. 1, 1988, in an ambulatory surgical center or hospital outpatient department on an assignment-related basis, was negated in the amendment of section 4054 by Pub. L. 100–360, title IV, §411(f)(12)(A), July 1, 1988, 102 Stat. 781.

OTHER PHYSICIAN PAYMENT STUDIES

Pub. L. 100–203, title IV, §4056(c), formerly §4055(c), Dec. 22, 1987, 101 Stat. 1330–99, as renumbered by Pub. L. 100–360, title IV, §411(f)(14), July 1, 1988, 102 Stat. 781, provided directed Secretary to (1) conduct a study of changes in the payment system for physicians' services, under part B, that would be required for the implementation of a national fee schedule for such services furnished on or after Jan. 1, 1990, and report to Congress on such study by not later than July 1, 1989, (2) conduct a study of issues relating to the volume and intensity of physicians' services under part B and submit to Congress an interim report on such study not later than May 1, 1988, and a final report on such study not later than May 1, 1989, and (3) conduct a survey to determine distribution of (A) the liabilities and expenditures for health care services of individuals entitled to benefits under this subchapter, including liabilities for charges (not paid on an assignment-related basis) in excess of the reasonable charge recognized, and (B) the collection rates among different classes of physicians for such liabilities, including collection rates for required coinsurance and for charges (not paid on an assignment-related basis) in excess of the reasonable charge recognized, report to Congress on such study by not later than July 1, 1990.

STUDY OF PAYMENT FOR CHEMOTHERAPY IN PHYSICIANS' OFFICES

Pub. L. 100–203, title IV, §4056(d), formerly §4055(d), Dec. 22, 1987, 101 Stat. 1330–99, as renumbered by Pub. L. 100–360, title IV, §411(f)(14), July 1, 1988, 102 Stat. 781, directed Secretary to study ways of modifying part B to permit adequate payment under such part for costs associated with providing chemotherapy to cancer patients in physicians' offices, with the Secretary to report to Congress on results of study by not later than Apr. 1, 1989, prior to repeal by Pub. L. 105–362, title VI, §601(b)(7), Nov. 10, 1998, 112 Stat. 3286.

CLINICAL DIAGNOSTIC LABORATORY TESTS; LIMITATION ON CHANGES IN FEE SCHEDULES

Pub. L. 100–203, title IV, § 4064(a), Dec. 22, 1987, 101 Stat. 1330–110, which provided 3-month freeze in fee schedules for clinical laboratory diagnostic laboratory tests under part B of title XVIII of the Social Security Act (this part) and directed the Secretary of Health and Human Services to not adjust the fee schedules established under subsec. (h) of this section to take into account any increase in the consumer price index, was negated in the amendment of section 4064(a) by Pub. L. 100–360, title IV, § 411(g)(3)(A), July 1, 1988, 102 Stat. 783.

GAO STUDY OF FEE SCHEDULES

Pub. L. 100–203, title IV, § 4064(b)(4), Dec. 22, 1987, 101 Stat. 1330–110, directed Comptroller General to conduct a study of level of fee schedules established for clinical diagnostic laboratory services under subsec. (h)(2) of this section to determine, based on costs of, and revenues received for, such tests the appropriateness of such schedules, with Comptroller General to report to Congress on results of such study by not later than Jan. 1, 1990, and with provision that suppliers of such tests which fail to provide Comptroller General with reasonable access to necessary records to carry out study being subject to exclusion from the medicare program under section 1320a–7(a) of this title.

AMOUNTS PAID FOR INDEPENDENT RURAL HEALTH CLINIC SERVICES

Pub. L. 100–203, title IV, § 4067(b), Dec. 22, 1987, 101 Stat. 1330–113, provided that: ''The Secretary of Health and Human Services shall report to Congress, by not later than March 1, 1989, on the adequacy of the amounts paid under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for rural health clinic services provided by independent rural health clinics.''

REPORT ON ESTABLISHMENT OF NATIONAL FEE SCHEDULES FOR PAYMENT OF CLINICAL DIAGNOSTIC LABORATORY TESTS

Pub. L. 99–509, title IX, § 9339(b)(3), Oct. 21, 1986, 100 Stat. 2036, directed Secretary of Health and Human Services to report to Congress, by not later than Apr. 1, 1988, on advisability and feasibility of, and methodology for, establishing national fee schedules for payment for clinical diagnostic laboratory tests under section 1395*l*(h) of this title, prior to repeal by Pub. L. 101–508, title IV, § 4154(e)(3), Nov. 5, 1990, 104 Stat. 1388–86, effective as if included in enactment of Pub. L. 99–509.

STATE STANDARDS FOR DIRECTORS OF CLINICAL LABORATORIES

Pub. L. 99–509, title IX, § 9339(d), Oct. 21, 1986, 100 Stat. 2037, provided that:

''(1) IN GENERAL.—If a State (as defined for purposes of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]) provides for the licensing or other standards with respect to the operation of clinical laboratories (including such laboratories in hospitals) in the State under which such a laboratory may be directed by an individual with certain qualifications, nothing in such title shall be construed as authorizing the Secretary of Health and Human Services to require such a laboratory, as a condition of payment or participation under such title, to be directed by an individual with other qualifications.

''(2) EFFECTIVE DATE.—Paragraph (1) shall take effect on January 1, 1987.''

TRANSITIONAL PROVISIONS FOR PAYMENT OF FEES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Pub. L. 99–272, title IX, § 9303(a)(3), Apr. 7, 1986, 100 Stat. 188, provided that: ''The Secretary of Health and Human Services shall provide that the annual adjustment under section 1833(h) of the Social Security Act [42 U.S.C. 1395*l*(h)] for 1986—

''(A) shall take effect on January 1, 1987,

''(B) shall apply for the 12-month period beginning on that date, and

''(C) shall take into account the percentage increase or decrease in the Consumer Price Index for all urban consumers (United States city average) occurring over an 18-month period, rather than over a 12-month period.''

EXTENSION OF MEDICARE PHYSICIAN PAYMENT PROVISIONS

Amount of payment under this part for physicians' services furnished between Oct. 1, 1985, and Mar. 14, 1986, to be determined on the same basis as the amount of such services furnished on Sept. 30, 1985, see section 5(b) of Pub. L. 99–107, as amended, set out as a note under section 1395ww of this title.

FEE SCHEDULES FOR DIAGNOSTIC LABORATORY TESTS AND FEASIBILITY OF DIRECT PAYMENTS TO PHYSICIANS; REPORT TO CONGRESS

Pub. L. 98–369, div. B, title III, § 2303(i), July 18, 1984, 98 Stat. 1066, provided that:

''(1) The Comptroller General shall report to the Congress on—

''(A) the appropriateness of the fee schedules under section 1833(h) of the Social Security Act [42 U.S.C. 1395*l*(h)] and their impact on the volume and quality of clinical diagnostic laboratory tests;

''(B) the potential impact of the adoption of a national fee schedule; and

''(C) the potential impact of applying a national fee schedule to clinical diagnostic laboratory tests provided by hospitals to their outpatients.

''(2) The Secretary of Health and Human Services shall report to the Congress with respect to the advisability and feasibility of a system of direct payment to any physician for all clinical diagnostic laboratory tests ordered by such physician.

''(3) The reports required by paragraphs (1) and (2) shall be submitted not later than January 1, 1987.''

PACEMAKER REIMBURSEMENT REVIEW AND REFORM

Pub. L. 98–369, div. B, title III, § 2304(a), July 18, 1984, 98 Stat. 1067, provided that:

''(1) The Secretary of Health and Human Services shall issue revisions to the current guidelines for the payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the transtelephonic monitoring of cardiac pacemakers. Such revised guidelines shall include provisions regarding the specifications for and frequency of transtelephonic monitoring procedures which will be found to be reasonable and necessary.

''(2)(A) Except as provided in subparagraph (B), if the guidelines required by paragraph (1) have not been issued and put into effect by October 1, 1984, and until such guidelines have been issued and put into effect, payment may not be made under part B of title XVIII of the Social Security Act for transtelephonic monitoring procedures, with respect to a single-chamber cardiac pacemaker powered by lithium batteries, conducted more frequently than—

''(i) weekly during the first month after implantation,

''(ii) once every two months during the period representing 80 percent of the estimated life of the implanted device, and

''(iii) monthly thereafter.

''(B) Subparagraph (A) shall not apply in cases where the Secretary determines that special medical factors (including possible evidence of pacemaker or lead malfunction) justify more frequent transtelephonic monitoring procedures.''

PAYMENT FOR PREADMISSION DIAGNOSTIC TESTING PERFORMED IN PHYSICIAN'S OFFICE

Pub. L. 98–369, div. B, title III, § 2305(f), July 18, 1984, 98 Stat. 1070, provided that: ''The amendments made by

this section [amending this section and enacting provisions set out above] shall not be construed as prohibiting payment, subject to the applicable copayments, under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for preadmission diagnostic testing performed in a physician's office to the extent such testing is otherwise reimbursable under regulations of the Secretary.''

PROVIDERS OF SERVICES TO CALCULATE AND REPORT LESSER-OF-COST-OR-CHARGES DETERMINATIONS SEPARATELY WITH RESPECT TO PAYMENTS UNDER PARTS A AND B OF THIS SUBCHAPTER; ISSUANCE OF REGULATIONS

For provision directing the Secretary to issue regulations requiring providers of services to calculate and report the lesser-of-cost-or-charges determinations separately with respect to payments for services under parts A and B of this subchapter other than diagnostic tests under subsec. (h) of this section, see section 2308(a) of Pub. L. 98–369, set out as a note under section 1395f of this title.

DETERMINATION OF NOMINAL CHARGES FOR APPLYING NOMINALITY TEST

For provision directing the Secretary to provide, in addition to other rules deemed appropriate, that charges representing 60 percent or less of costs be considered nominal for purposes of applying the nominality test under subsec. (a)(2)(B)(ii) of this section, see section 2308(b)(1) of Pub. L. 98–369, set out as a note under section 1395f of this title.

STUDY OF MEDICARE PART B PAYMENTS; COMPILATION OF CENTRALIZED CHARGE DATA BASE; REPORT TO CONGRESS

Pub. L. 98–369, div. B, title III, §2309, July 18, 1984, 98 Stat. 1074, directed Director of Office of Technology Assessment to conduct a study of physician reimbursement under the Medicare program and make a report not later than Dec. 31, 1985, covering findings and recommendations on methods by which payment amounts and other program policies under the program might be modified, and directed that Secretary of Health and Human Services compile a centralized Medicare part B charge data base to aid in the study.

MONITORING PROVISION OF HEPATITIS B VACCINE; REVIEW OF CHANGES IN MEDICAL TECHNOLOGY

Pub. L. 98–369, div. B, title III, §2323(e), July 18, 1984, 98 Stat. 1086, provided that: ''The Secretary shall monitor the provision of hepatitis B vaccine under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], and shall review any changes in medical technology which may have an effect on the amounts which should be paid for such service.''

REPORT ON PREADMISSION DIAGNOSTIC TESTING EXPENSES

Pub. L. 96–499, title IX, §932(b), Dec. 5, 1980, 94 Stat. 2635, required a report to Congress, no later than one year after Dec. 5, 1980, on the policy respecting expenses incurred for preadmission diagnostic testing furnished to an individual at a hospital within seven days of an individual's admission to another hospital.

STUDY OF FEASIBILITY AND DESIRABILITY OF IMPOSING COPAYMENT REQUIREMENT ON RURAL HEALTH CLINIC VISITS; REPORT NOT LATER THAN DECEMBER 13, 1978

Pub. L. 95–210, §1(c), Dec. 13, 1977, 91 Stat. 1485, directed Secretary of Health, Education, and Welfare to conduct a study of the feasibility and desirability of imposing a copayment for each visit to a rural health clinic for rural health clinic services under this part and that Secretary report to appropriate committee of Congress, not later than one year after Dec. 13, 1977, on such study.

PROHIBITION AGAINST PAYMENTS IN CASES OF NONENTITLEMENT TO MONTHLY BENEFITS UNDER SUBCHAPTER II OR SUSPENSION OF BENEFITS OF ALIENS OUTSIDE THE UNITED STATES

Pub. L. 89–97, title I, §104(b)(1), July 30, 1965, 79 Stat. 334, provided that: ''No payments shall be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to expenses incurred by an individual during any month for which such individual may not be paid monthly benefits under title II of such Act [42 U.S.C. 401 et seq.] (or for which such monthly benefits would be suspended if he were otherwise entitled thereto) by reason of section 202(t) of such Act [42 U.S.C. 402(t)] (relating to suspension of benefits of aliens who are outside the United States).''

§ 1395m. Special payment rules for particular items and services

(a) Payment for durable medical equipment

(1) General rule for payment

(A) In general

With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) Exclusive payment rule

Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for covered items under this part or under part A of this subchapter to a home health agency.

(D) Reduction in fee schedules for certain items

With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) Clinical conditions for coverage

(i) In general

The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements

The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1395x(r) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) and a prescription for the item.

(iii) Priority of establishment of standards

In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) Standards for power wheelchairs

Effective on December 8, 2003, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x(r)(1) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items

Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) Application of competitive acquisition; limitation of inherent reasonableness authority

In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1395w–3(a) of this title—

(i) 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;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1395w–3 of this title and in the case of such adjustment, paragraph (10)(B) shall not be applied; and

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1395w–3 of this title are recompeted in accordance with section 1395w–3(b)(3)(B) of this title.

(G) Use of information on competitive bid rates

The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.

(H) Diabetic supplies

(i) In general

On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1395w–3 of this title.

(ii) Date described

The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1395w–3 of this title.

(I) Treatment of vacuum erection systems

Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1395x(s)(8) of this title shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1395w–102(e)(2)(A) of this title.

(2) Payment for inexpensive and other routinely purchased durable medical equipment

(A) In general

Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or

(iv) in the case of devices furnished on or after October 1, 2015, and before October 1, 2018, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) Payment for items requiring frequent and substantial servicing

(A) In general

Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) Payment for certain customized items

Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this subchapter, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item.

(5) Payment for oxygen and oxygen equipment

(A) In general

Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) Add-on for portable oxygen equipment

When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) Volume adjustment

When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) Limit on adjustment

When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) Recertification for patients receiving home oxygen therapy

In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) Rental cap

(i) In general

Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) Payments and rules after rental cap

After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) Payment for other covered items (other than durable medical equipment)

Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) Payment for other items of durable medical equipment

(A) Payment

In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) Rental

(I) In general

Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) Payment amount

Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) Special rule for power-driven wheelchairs

For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting ''15 percent'' and ''6 percent'' for ''10 percent'' and ''7.5 percent'', respectively.

(ii) Ownership after rental

On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) Purchase agreement option for complex, rehabilitative power-driven wheelchairs

In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) Maintenance and servicing

After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) Range for rental amounts

(i) For 1989

For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) For 1990

For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) Replacement of items

(i) Establishment of reasonable useful lifetime

In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) Payment for replacement items

If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) Length of reasonable useful lifetime

The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, ex-

cept that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this subchapter, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) Purchase price recognized for miscellaneous devices and items

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price

Each carrier under section 1395u of this title shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; [1] or

(III) in 1992, 1993, and 1994, equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) Computation of national limited purchase price

With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) Purchase price recognized

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) Monthly payment amount recognized with respect to oxygen and oxygen equipment

For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an ''item'').

(A) Computation of local monthly payment rate

Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total

[1] So in original. The semicolon probably should be a comma.

reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this subchapter.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994, equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) Computation of national limited monthly payment rate

With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) Monthly payment amount recognized

For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(D) Authority to create classes

(i) In general

Subject to clause (ii), the Secretary may establish separate classes for any item of oxygen and oxygen equipment and separate national limited monthly payment rates for each of such classes.

(ii) Budget neutrality

The Secretary may take actions under clause (i) only to the extent such actions do not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken.

(10) Exceptions and adjustments

(A) Areas outside continental United States

Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) Adjustment for inherent reasonableness

The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1395u(b) of this title to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) Transcutaneous electrical nerve stimulator (TENS)

In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) Improper billing and requirement of physician order

(A) Improper billing for certain rental items

Notwithstanding any other provision of this subchapter, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1395u(j)(2) of this title in the same manner such sanctions may apply with respect to a physician.

(B) Requirement of physician order

(i) In general

The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1395cc(j) of this title or an eligible professional under section 1395w–4(k)(3)(B) of this title that is enrolled under section 1395cc(j) of this title has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) Requirement for face to face encounter

The Secretary shall require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) Regional carriers

The Secretary may designate, by regulation under section 1395u of this title, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) "Covered item" defined

In this subsection, the term ''covered item'' means durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title, but not including implantable items for which payment may be made under section 1395*l*(t) of this title.

(14) Covered item update

In this subsection, the term ''covered item update'' means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008—

(i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1395w–3(a)(1)(B)(i)(I) of this title before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, the percentage increase in the consumer price index for all urban consum-

ers (U.S. urban average) for the 12-month period ending with June of the previous year; and

(L) for 2011 and each subsequent year—

(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 (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) Advance determinations of coverage for certain items

(A) Development of lists of items by Secretary

The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) Development of lists of suppliers by Secretary

The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1395y(a)(1) of this title; or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) Determinations of coverage in advance

A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1395y(a)(1) of this title if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) Disclosure of information and surety bond

The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1320a–3(a)(3) of this title) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1320a–3(a)(2) of this title) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A of this subchapter or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1395u(b)(18)(C) of this title) who furnish items or services under this part.

(17) Prohibition against unsolicited telephone contacts by suppliers

(A) In general

A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) Prohibiting payment for items furnished subsequent to unsolicited contacts

If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) Exclusion from program for suppliers engaging in pattern of unsolicited contacts

If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this chapter, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1320a–7 of this title.

(18) Refund of amounts collected for certain disallowed items

(A) In general

If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) Sanctions

If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1395u(j)(2) of this title.

(C) Notice

Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) Timely basis defined

A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), 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 supplier receives notice of an adverse determination on reconsideration or appeal.

(19) Certain upgraded items

(A) Individual's right to choose upgraded item

Notwithstanding any other provision of this subchapter, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) Payments to supplier

In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) Consumer protection safeguards

Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) Identification of quality standards

(A) In general

Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this subchapter.

(B) Designation of independent accreditation organizations

Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1395bb(a) of this title, the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) Quality standards

The quality standards described in subparagraph (A) may not be less stringent than

the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) Items and services described

The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in subsection (h)(4) of this section.

(iii) Items and services described in section 1395u(s)(2) of this title.

(E) Implementation

The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) Application of accreditation requirement

In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1395w–4(k)(3)(B) of this title), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) Application of accreditation requirement to certain pharmacies

(i) In general

With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) Pharmacies described

A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this subchapter are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1395cc(j) of this title as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) Special payment rule for specified items and supplies

(A) In general

Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) fur-

nished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, as identified in the column entitled ''Median FEHP Price'' in the table entitled ''SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS'' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) Specified item or supply described

For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) Application of update to special payment amount

The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1395w–3 of this title.

(22) Special payment rule for diabetic supplies

Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after January 2, 2013, and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking ''but only if furnished through mail order''.

(b) Fee schedules for radiologist services

(1) Development

The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A) of this section, fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) Consultation

In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) Considerations

In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) Savings

(A) Budget neutral fee schedules

The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1395*l*(a)(1)(J) and 1395*l*(b) of this title) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) Initial savings

The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under the preliminary fee schedules developed under subparagraph (A).

(C) 1990 fee schedules

For radiologist services (other than portable X-ray services) furnished under this part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 fee schedules

For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) National weighted average conversion factor

The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) Reduced national weighted average

The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) Computation of 1990 locality index relative to national average

The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) Adjusted conversion factor

The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the locally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) Locally-adjusted amount

For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-adjusted amount

For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average 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 conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1395u(b)(14)(C)(iv) of this title for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) Limits on conversion factor

The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) Rule for certain scanning services

In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) Subsequent updating

For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year.

(G) Nonparticipating physicians and suppliers

Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1395u(b)(4)(A)(iv) of this title) of the payment rate recognized for participating physicians and suppliers.

(5) Limiting charges of nonparticipating physicians and suppliers

(A) In general

In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) "Limiting charge" defined

In subparagraph (A), the term ''limiting charge'' means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) Enforcement

If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1395u(j)(2) of this title in the same manner as such sanctions may apply to a physician.

(6) "Radiologist services" defined

For the purposes of this subsection and section 1395*l*(a)(1)(J) of this title, the term ''radiologist services'' only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) Payment and standards for screening mammography

(1) In general

With respect to expenses incurred for screening mammography (as defined in section 1395x(jj) of this title), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 263b of this title.

(2) Frequency covered

(A) In general

Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) Revision of frequency

(i) Review

The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) Revision of frequency

The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) Frequency limits and payment for colorectal cancer screening tests

(1) Screening fecal-occult blood tests

(A) Payment amount

The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1395*l*(h) of this title.

(B) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) Screening flexible sigmoidoscopies

(A) Fee schedule

With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1395w–4 of this title shall be consistent with payment under such section for similar or related services.

(B) Payment limit

In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395*l* of this title, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions

If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) Frequency limit

No payment may be made under this part for a colorectal cancer screening test con-

sisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) Screening colonoscopy

(A) Fee schedule

With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1395w–4 of this title shall be consistent with payment amounts under such section for similar or related services.

(B) Payment limit

In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395*l* of this title, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions

If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) Accreditation requirement for advanced diagnostic imaging services

(1) In general

(A) In general

Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1395w–4(b) of this title and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).[2]

(B) Advanced diagnostic imaging services defined

In this subsection, the term ''advanced diagnostic imaging services'' includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1395w–4(b)(4)(B) of this title (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) Supplier defined

In this subsection, the term ''supplier'' has the meaning given such term in section 1395x(d) of this title.

(2) Accreditation organizations

(A) Factors for designation of accreditation organizations

The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i)[2] and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppli-

[2] So in original. Subpar. (B) of par. (2) does not contain clauses.

ers located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) Designation

Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) Review and modification of list of accreditation organizations

(i) In general

The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations

In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) Criteria for accreditation

The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) Recognition in standards for the evaluation of medical directors and supervising physicians

The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) Rule for accreditations made prior to designation

In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) Reduction in payments for physician pathology services during 1991

(1) In general

For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) Limitation

The prevailing charge for the technical and professional components of an[3] physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

[3] So in original. Probably should be ''a''.

(g) Payment for outpatient critical access hospital services

(1) In general

The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) Election of cost-based hospital outpatient service payment plus fee schedule for professional services

A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1395cc(a)(2)(A) of this title:

(A) Facility fee

With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) Fee schedule for professional services

With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1395*l* of this title shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) Disregarding charges

The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) Treatment of clinical diagnostic laboratory services

No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this subchapter shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1395x(mm)(3) of this title, clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) Coverage of costs for certain emergency room on-call providers

In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this subchapter and are not on-call at any other provider or facility.

(h) Payment for prosthetic devices and orthotics and prosthetics

(1) General rule for payment

(A) In general

Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) Exception for certain public home health agencies

Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) Exclusive payment rule

Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A of this subchapter to a home health agency.

(E) Exception for certain items

Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of subsection (a)(2) of this section.

(F) Special payment rules for certain prosthetics and custom-fabricated orthotics

(i) In general

No payment shall be made under this subsection for an item of custom-fab-

ricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) Description of custom-fabricated item

(I) In general

An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) List of items

The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) Qualified practitioner defined

In this subparagraph, the term ''qualified practitioner'' means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) Qualified supplier defined

In this subparagraph, the term ''qualified supplier'' means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) Replacement of prosthetic devices and parts

(i) In general

Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) Confirmation may be required if device or part being replaced is less than 3 years old

If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1395y(a)(1)(A) of this title;

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) Application of competitive acquisition to orthotics; limitation of inherent reasonableness authority

In the case of orthotics described in paragraph (2)(C) of section 1395w–3(a) of this title furnished on or after January 1, 2011, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) 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 section 1395u(b) of this title shall not be applied.

(2) Purchase price recognized

For purposes of paragraph (1), the amount that is recognized under this paragraph as the

purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price

Each carrier under section 1395u of this title shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) Computation of regional purchase price

With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) Purchase price recognized

For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) Range on amount recognized

The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) Applicability of certain provisions relating to durable medical equipment

Paragraphs (12), (15), and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) of this section shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) Definitions

In this subsection—

(A) the term ''applicable percentage increase'' means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, 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;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, 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;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, 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;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for[4] each of 2007 through 2010, 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; and

(xi) for 2011 and each subsequent year—

(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 (A)(xi)(II) may result in the applicable percentage in-

[4] So in original.

crease under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(B) the term ''prosthetic devices'' has the meaning given such term in section 1395x(s)(8) of this title, except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1395*l*(t) of this title; and

(C) the term ''orthotics and prosthetics'' has the meaning given such term in section 1395x(s)(9) of this title (and includes shoes described in section 1395x(s)(12) of this title), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title.

(i) Payment for surgical dressings

(1) In general

Payment under this subsection for surgical dressings (described in section 1395x(s)(5) of this title) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) of this section (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) Exceptions

Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) Requirements for suppliers of medical equipment and supplies

(1) Issuance and renewal of supplier number

(A) Payment

Except as provided in subparagraph (C), no payment may be made under this part after October 31, 1994, for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number

A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after October 31, 1994, and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) Exception for items furnished as incident to a physician's service

Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) Prohibition against multiple supplier numbers

The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) Prohibition against delegation of supplier determinations

The Secretary may not delegate (other than by contract under section 1395u of this title) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity

(A) Limitation on information provided by suppliers on certificates of medical necessity

(i) In general

Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges

If a supplier distributes a certificate of medical necessity containing any of the

information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty

Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(B) "Certificate of medical necessity" defined

For purposes of this paragraph, the term ''certificate of medical necessity'' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria

The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability

If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15) of this section; or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1395y(a)(1) of this title;

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) of this section shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) "Medical equipment and supplies" defined

The term ''medical equipment and supplies'' means—

(A) durable medical equipment (as defined in section 1395x(n) of this title);

(B) prosthetic devices (as described in section 1395x(s)(8) of this title);

(C) orthotics and prosthetics (as described in section 1395x(s)(9) of this title);

(D) surgical dressings (as described in section 1395x(s)(5) of this title);

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1395x(s)(2)(F) of this title),

(ii) immunosuppressive drugs (as described in section 1395x(s)(2)(J) of this title),

(iii) therapeutic shoes for diabetics (as described in section 1395x(s)(12) of this title),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1395x(s)(2)(Q) of this title), and

(v) self-administered erythropoetin (as described in section 1395x(s)(2)(P) of this title).

(k) Payment for outpatient therapy services and comprehensive outpatient rehabilitation services

(1) In general

With respect to services described in section 1395*l*(a)(8) or 1395*l*(a)(9) of this title for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) Payment in 1998 based upon adjusted reasonable costs

The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) Applicable fee schedule amount

In this subsection, the term ''applicable fee schedule amount'' means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1395w–4 of this title for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) Adjusted reasonable costs

In paragraph (2), the term ''adjusted reasonable costs'' means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent

reduction shall not apply to services described in section 1395*l*(a)(8)(B) of this title (relating to services provided by hospitals).

(5) Uniform coding

For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) Restraint on billing

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(7) Adjustment in discount for certain multiple therapy services

In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

***(l)* Establishment of fee schedule for ambulance services**

(1) In general

The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5 and in accordance with the requirements of this subsection.

(2) Considerations

In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) Savings

In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title.

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) Consultation

In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) Restraint on billing

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(7) Coding system

The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) Services furnished by critical access hospitals

Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1395x(mm)(1) of this title), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) Transitional assistance for rural providers

In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) Phase-in providing floor using blend of fee schedule and regional fee schedules

In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1395ww(d)(2) of this title) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) Adjustment in payment for certain long trips

In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) Assistance for rural providers furnishing services in low population density areas

(A) In general

In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2018, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) Identification of qualified rural areas

(i) Determination of population density in area

Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) Ranking of areas

The Secretary shall rank each such area based on such population density.

(iii) Identification of qualified rural areas

The Secretary shall identify those areas (in subparagraph (A) referred to as ''qualified rural areas'') with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) Rural area

For purposes of this paragraph, the term ''rural area'' has the meaning given such

term in section 1395ww(d)(2)(D) of this title. If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, respecting the identification of an area under this subparagraph.

(13) Temporary increase for ground ambulance services

(A) In general

After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2018,,[4] for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018).

(B) Application of increased payments after applicable period

The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) Providing appropriate coverage of rural air ambulance services

(A) In general

The regulations described in section 1395x(s)(7) of this title shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) Satisfaction of requirement of medically necessary

The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) Rural air ambulance service defined

For purposes of this paragraph, the term ''rural air ambulance service'' means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) Limitation

(i) In general

Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) Exception

Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1395xx of this title) which are reimbursed under part A of this subchapter and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) Payment adjustment for non-emergency ambulance transports for ESRD beneficiaries

The fee schedule amount otherwise applicable under the preceding provisions of this sub-

section shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1395rr(b)(14)(B) of this title) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) Prior authorization for repetitive scheduled non-emergent ambulance transports

(A) In general

Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1315a(c) of this title, then the Secretary shall expand such model to all States.

(B) Funding

The Secretary shall use funds made available under section 1395ddd(h)(10) of this title to carry out this paragraph.

(C) Clarification regarding budget neutrality

Nothing in this paragraph may be construed to limit or modify the application of section 1315a(b)(3)(B) of this title to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(m) Payment for telehealth services

(1) In general

The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1395x(r) of this title) or a practitioner (described in section 1395u(b)(18)(C) of this title) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) Payment amount

(A) Distant site

The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this subchapter had such service been furnished without the use of a telecommunications system.

(B) Facility fee for originating site

With respect to a telehealth service, subject to section 1395*l*(a)(1)(U) of this title, there shall be paid to the originating site a facility fee equal to—

(i) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year.

(C) Telepresenter not required

Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) Limitation on beneficiary charges

(A) Physician and practitioner

The provisions of section 1395w–4(g) of this title and subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) Originating site

The provisions of section 1395u(b)(18) of this title shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) Definitions

For purposes of this subsection:

(A) Distant site

The term ''distant site'' means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) Eligible telehealth individual

The term ''eligible telehealth individual'' means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) Originating site

(i) In general

The term ''originating site'' means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 254e(a)(1)(A) of this title;

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) Sites described

The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1395x(mm)(1) of this title).

(III) A rural health clinic (as defined in section 1395x(aa)(2) of this title).

(IV) A Federally qualified health center (as defined in section 1395x(aa)(4) of this title).

(V) A hospital (as defined in section 1395x(e) of this title).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1395i–3(a) of this title).

(VIII) A community mental health center (as defined in section 1395x(ff)(3)(B) of this title).

(D) Physician

The term ''physician'' has the meaning given that term in section 1395x(r) of this title.

(E) Practitioner

The term ''practitioner'' has the meaning given that term in section 1395u(b)(18)(C) of this title.

(F) Telehealth service

(i) In general

The term ''telehealth service'' means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) Yearly update

The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(n) Authority to modify or eliminate coverage of certain preventive services

Notwithstanding any other provision of this subchapter, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1395x(ddd)(3) of this title to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this subchapter for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(*o*) Development and implementation of prospective payment system

(1) Development

(A) In general

The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this subchapter. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) Collection of data and evaluation

By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) Implementation

(A) In general

Notwithstanding section 1395*l*(a)(3)(A) of this title, the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this subchapter in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) Payments

(i) Initial payments

The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1395*l*(a)(1)(Z) of this title) under this subchapter for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1395cc(a)(2)(A)(ii) of this title) that would have occurred for such services under this subchapter in such year if the system had not been implemented.

(ii) Payments in subsequent years

Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage

increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved.

(C) Preparation for PPS implementation

Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(p) Quality incentives to promote patient safety and public health in computed tomography

(1) Quality incentives

In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) Applicable computed tomography services defined

In this subsection, the term ''applicable computed tomography service'' means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).[5]

(3) Applicable payment system defined

In this subsection, the term ''applicable payment system'' means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1395w–4(b) of this title.

(B) The prospective payment system for hospital outpatient department services under section 1395*l*(t) of this title.

(4) Consistency with CT equipment standard

In this subsection, the term ''not consistent with the CT equipment standard'' means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management''. Through rulemaking, the Secretary may apply successor standards.

(5) Applicable percentage defined

In this subsection, the term ''applicable percentage'' means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) Implementation

(A) Information

The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under subsection (e) and hospitals under section 1395bb(a) of this title.

(B) Administration

Chapter 35 of title 44 shall not apply to information described in subparagraph (A).

(q) Recognizing appropriate use criteria for certain imaging services

(1) Program established

(A) In general

The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) Appropriate use criteria defined

In this subsection, the term ''appropriate use criteria'' means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) Applicable imaging service defined

In this subsection, the term ''applicable imaging service'' means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) Applicable setting defined

In this subsection, the term ''applicable setting'' means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

[5] So in original. The period probably should be preceded by another closing parenthesis.

(E) Ordering professional defined

In this subsection, the term ''ordering professional'' means a physician (as defined in section 1395x(r) of this title) or a practitioner described in section 1395u(b)(18)(C) of this title who orders an applicable imaging service.

(F) Furnishing professional defined

In this subsection, the term ''furnishing professional'' means a physician (as defined in section 1395x(r) of this title) or a practitioner described in section 1395u(b)(18)(C) of this title who furnishes an applicable imaging service.

(2) Establishment of applicable appropriate use criteria

(A) In general

Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) Considerations

In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) Revisions

The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) Treatment of multiple applicable appropriate use criteria

In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) Mechanisms for consultation with applicable appropriate use criteria

(A) Identification of mechanisms to consult with applicable appropriate use criteria

(i) In general

The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) Consultation

The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) Inclusion of certain mechanisms

Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1395w–4(*o*)(4) of this title).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) Qualified clinical decision support mechanisms

(i) In general

For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) Requirements

The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) List of mechanisms for consultation with applicable appropriate use criteria

(i) Initial list

Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) Periodic updating of list

The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) Consultation with applicable appropriate use criteria

(A) Consultation by ordering professional

Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) Reporting by furnishing professional

Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) Exceptions

The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) Emergency services

An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1395dd(e)(1) of this title).

(ii) Inpatient services

An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) Significant hardship

An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) Applicable payment system defined

In this subsection, the term ''applicable payment system'' means the following:

(i) The physician fee schedule established under section 1395w–4(b) of this title.

(ii) The prospective payment system for hospital outpatient department services under section 1395*l*(t) of this title.

(iii) The ambulatory surgical center payment systems under section 1395*l*(i) of this title.

(5) Identification of outlier ordering professionals

(A) In general

With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) Outlier ordering professionals

The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) Use of two years of data

The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) Process

The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) Consultation with stakeholders

The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) Prior authorization for ordering professionals who are outliers

(A) In general

Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) Appropriate use criteria in prior authorization

In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) Funding

For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) Construction

Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) Payment for renal dialysis services for individuals with acute kidney injury

(1) Payment rate

In the case of renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) furnished under this part by a renal dialysis facility or provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) Individual with acute kidney injury defined

In this subsection, the term ''individual with acute kidney injury'' means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1395rr(b)(14) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1834, as added and amended Pub. L. 100–203, title IV, §§ 4049(a)(2), 4062(b), Dec. 22, 1987, 101 Stat. 1330–91, 1330–100; Pub. L. 100–360, title II, §§ 202(b)(4), 203(c)(1)(F), 204(b), title IV, § 411(a)(3)(A), (B)(ii), (C)(ii), (f)(8)(A), (B)(ii), (D), (g)(1)(A), (B), July 1, 1988, 102 Stat. 704, 722, 726, 768, 779, 781; Pub. L. 100–485, title VI, § 608(d)(21)(C), (22)(A), Oct. 13, 1988, 102 Stat. 2420; Pub. L. 101–234, title II, § 201(a), title III, § 301(b)(1), (c)(1), Dec. 13, 1989, 103 Stat. 1981, 1985; Pub. L. 101–239, title VI, §§ 6102(f)(1), 6105(a), 6112(a), (c), (d)(1), (e)(2), 6116(b)(2), 6140, Dec. 19, 1989, 103 Stat. 2188, 2210, 2214–2216, 2220, 2224; Pub. L. 101–508, title IV, §§ 4102(a), (d), (f), 4104(a), 4152(a)(1), (b), (c)(1)–(4)(B)(i), (e), (f)(1), (g)(1), 4153(a)(1), (2)(D), 4163(b), Nov. 5, 1990, 104 Stat. 1388–55, 1388–57, 1388–59, 1388–74, 1388–77 to 1388–81, 1388–83, 1388–97; Pub. L. 103–66, title XIII, §§ 13542(a), 13543(a), (b), 13544(a)(1), (2), (b)(1), 13545(a), 13546, Aug. 10, 1993, 107 Stat. 587, 589, 590; Pub. L. 103–432, title I, §§ 102(e), 126(b)(1), (2), (4), (5), (g)(1), (10)(B), 131(a), 132(a), (b), 133(a)(1), 134(a)(1), 135(a)(1), (b)(1), (3), (d)(1), (e)(2)–(5), 145(a), 156(a)(2)(C), Oct. 31, 1994, 108 Stat. 4403, 4414–4416, 4419, 4421, 4424, 4427, 4440; Pub. L. 105–33, title IV, §§ 4101(a), (c), 4104(b)(1), 4105(b)(2), 4201(c)(5), 4312(a), (c), 4316(b), 4531(b)(2), 4541(a)(2), 4551(a), (c)(1), 4552(a), (b), Aug. 5, 1997, 111 Stat. 360, 363, 367, 374, 386, 387, 392, 451, 455, 457–459; Pub. L. 106–113, div. B, § 1000(a)(6) [title II, § 201(e)(2), title III, § 321(k)(3), title IV, § 403(d)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A–340, 1501A–366, 1501A–371; Pub. L. 106–554, § 1(a)(6) [title I, §§ 103(b), 104(b), title II, §§ 201(a), 202(a), 204(a), 205(a), 221(a), 223(b), title IV, §§ 423(a)(1), (b)(1), 425(a), 426(a), 427(a), 428(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–468, 2763A–469, 2763A–481, 2763A–482, 2763A–486, 2763A–487, 2763A–518 to 2763A–520, 2763A–522; Pub. L. 108–173, title III, § 302(a), (c)(1)(A), (2), (3), (d)(1), (2), title IV, §§ 405(a)(1), (b)(1), (d)(1), 414(a)–(c)(1), (d), 415(a), title VI, § 627(b)(1), title VII, § 736(b)(4), (5), Dec. 8, 2003, 117 Stat. 2223, 2230–2232, 2266, 2267, 2278–2281, 2321, 2356; Pub. L. 109–171, title V, §§ 5101(a)(1), (b)(1), 5113(b), Feb. 8, 2006, 120 Stat. 37, 38, 44; Pub. L. 110–275, title I, §§ 125(b)(5), 135(a)(1), 144(b)(1), 146(a), (b)(2)(A), 148(a), 149(a), 154(a)(2)(A), (3), (4), (b)(1)(A), (d)(2), July 15, 2008, 122 Stat. 2519, 2532, 2547–2549, 2563, 2564, 2567; Pub. L. 111–72, § 1(a), Oct. 13, 2009, 123 Stat. 2059; Pub. L. 111–148, title III, §§ 3105(a), (c), 3109(a), 3128(a), 3136(a), (b), 3401(j), (m), (n), title IV, § 4105(a), title V, §§ 5501(a)(2), (b)(2), 5502(b), title VI, §§ 6402(g)(1), 6405(a), 6407(b), 6410(b), title X, §§ 10311(a), (c), 10501(i)(1), (3)(A), Mar. 23, 2010, 124 Stat. 417, 418, 426, 437, 438, 486, 487, 558, 653, 654, 759, 768, 770, 773, 942, 943, 997; Pub. L. 111–309, title I, § 106(a), (c), Dec. 15, 2010, 124 Stat. 3287; Pub. L. 112–78, title III, § 306(a), (c), Dec. 23, 2011, 125 Stat. 1285; Pub. L. 112–96, title III, § 3007(a), (c), Feb. 22, 2012, 126 Stat. 190; Pub. L. 112–240, title VI, §§ 604(a), (c), 633(b), 636, 637, Jan. 2, 2013, 126 Stat. 2347, 2348, 2355–2357; Pub. L. 113–67, div. B, title I, § 1104, Dec. 26, 2013, 127 Stat. 1196; Pub. L. 113–93, title I, § 104, title II, § 218(a)(1), (b)(1), Apr. 1, 2014, 128 Stat. 1042, 1063, 1065; Pub. L. 113–295, div. B, title II, § 203, Dec. 19, 2014, 128 Stat. 4065; Pub. L. 114–10, title II, § 203, title V, §§ 504(a), 515(b), Apr. 16, 2015, 129 Stat. 144, 165, 174; Pub. L. 114–27, title VIII, § 808(b), June 29, 2015, 129 Stat. 418; Pub. L. 114–40, § 3, July 30, 2015, 129 Stat. 441; Pub. L. 114–113, div. O, title V, § 504(a), Dec. 18, 2015, 129 Stat. 3021.)

AMENDMENT OF SECTION

Pub. L. 114–113, div. O, title V, § 504(a), (d), Dec. 18, 2015, 129 Stat. 3021, 3023, provided that, applicable to items furnished on or after Jan. 1, 2017, this section is amended by adding at the end the following new subsection:

(s) Payment for applicable disposable devices

(1) Separate payment

The Secretary shall make a payment (separate from the payments otherwise made under section 1395fff of this title) in the amount established under paragraph (3) to a home health agency for

an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1395fff(b) of this title.

(2) Applicable disposable device

In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) Payment amount

The separate payment amount established under this paragraph for an applicable disposable device for a year shall be equal to the amount of the payment that would be made under section 1395l(t) of this title (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

See 2015 Amendment note below.

REFERENCES IN TEXT

Section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (a)(14)(H)(i), is section 302(c)(1)(B) of Pub. L. 108–173, which is set out as a note under this section.

Section 4531(a) of the Balanced Budget Act of 1997, referred to in subsec. (*l*)(3)(A), is section 4531(a) of Pub. L. 105–33, which amended sections 1395u and 1395x of this title.

Section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015, referred to in subsec. (*l*)(16)(A), is section 515(a) of Pub. L. 114–10, title V, Apr. 16, 2015, 129 Stat. 174, which relates to the initial expansion of prior authorization model for repetitive scheduled nonemergent ambulance transports and is not classified to the Code.

CODIFICATION

Amendment of subsec. (a)(4) by Pub. L. 101–508, §4152(c)(4)(B)(i), did not become effective pursuant to Pub. L. 101–508, §4152(c)(4)(B)(ii), because of action of Secretary in developing specific criteria for the treatment of wheelchairs as customized items for purposes of subsec. (a)(4). See Effective Date of 1990 Amendment note below.

PRIOR PROVISIONS

A prior section 1395m, act Aug. 14, 1935, ch. 531, title XVIII, §1834, as added July 30, 1965, Pub. L. 89–97, title I, §102(a), 79 Stat. 303, prescribed limitations on payments for home health services, prior to repeal by Pub. L. 96–499, title IX, §930(i), Dec. 5, 1980, 94 Stat. 2631, effective with respect to services furnished on or after July 1, 1981.

AMENDMENTS

2015—Subsec. (a)(2)(A)(iv). Pub. L. 114–40 added cl. (iv).

Subsec. (a)(11)(B)(ii). Pub. L. 114–10, §504(a), struck out ''the physician documenting that'' after ''written pursuant to'' and substituted ''documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter'' for ''has had a face-to-face encounter''.

Subsec. (*l*)(12)(A). Pub. L. 114–10, §203(b), substituted ''January 1, 2018'' for ''April 1, 2015''.

Subsec. (*l*)(13)(A). Pub. L. 114–10, §203(a), substituted ''January 1, 2018'' for ''April 1, 2015'' wherever appearing.

Subsec. (*l*)(16). Pub. L. 114–10, §515(b), added par. (16).

Subsec. (r). Pub. L. 114–27 added subsec. (r).

Subsec. (s). Pub. L. 114–113 added subsec. (s).

2014—Subsec. (a)(1)(I). Pub. L. 113–295 added subpar. (I).

Subsec. (*l*)(12)(A). Pub. L. 113–93, §104(b), substituted ''April 1, 2015'' for ''April 1, 2014''.

Subsec. (*l*)(13)(A). Pub. L. 113–93, §104(a), substituted ''April 1, 2015'' for ''April 1, 2014'' wherever appearing.

Subsec. (p). Pub. L. 113–93, §218(a)(1), added subsec. (p).

Subsec. (q). Pub. L. 113–93, §218(b)(1), added subsec. (q).

2013—Subsec. (a)(1)(F). Pub. L. 112–240, §636(a)(1), substituted ''subparagraphs (G) and (H)'' for ''subparagraph (G)'' in introductory provisions.

Subsec. (a)(1)(H). Pub. L. 112–240, §636(a)(2), added subpar. (H).

Subsec. (a)(22). Pub. L. 112–240, §636(b), added par. (22).

Subsec. (k)(7). Pub. L. 112–240, §633(b), added par. (7).

Subsec. (*l*)(12)(A). Pub. L. 113–67, §1104(b), substituted ''April 1, 2014'' for ''January 1, 2014''.

Pub. L. 112–240, §604(c), substituted ''January 1, 2014'' for ''January 1, 2013''.

Subsec. (*l*)(13)(A). Pub. L. 113–67, §1104(a), substituted ''April 1, 2014'' for ''January 1, 2014'' wherever appearing.

Pub. L. 112–240, §604(a), substituted ''January 1, 2014'' for ''January 1, 2013'' wherever appearing.

Subsec. (*l*)(15). Pub. L. 112–240, §637, added par. (15).

2012—Subsec. (*l*)(12)(A). Pub. L. 112–96, §3007(c), substituted ''January 1, 2013'' for ''March 1, 2012''.

Subsec. (*l*)(13)(A). Pub. L. 112–96, §3007(a), substituted ''January 1, 2013'' for ''March 1, 2012'' wherever appearing.

2011—Subsec. (*l*)(12)(A). Pub. L. 112–78, §306(c), substituted ''March 1, 2012'' for ''January 1, 2012''.

Subsec. (*l*)(13)(A). Pub. L. 112–78, §306(a), substituted ''March 1, 2012'' for ''January 1, 2012'' wherever appearing.

2010—Subsec. (a)(1)(F)(ii). Pub. L. 111–148, §6410(b)(2)(A), inserted ''(and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall)'' after ''may''.

Subsec. (a)(1)(F)(iii). Pub. L. 111–148, §6410(b)(1), (2)(B), (3), added cl. (iii).

Subsec. (a)(7)(A)(i)(II). Pub. L. 111–148, §3136(a)(1)(A), inserted ''subclause (III) and'' after ''Subject to''.

Subsec. (a)(7)(A)(i)(III). Pub. L. 111–148, §3136(a)(1)(B), added subcl. (III).

Subsec. (a)(7)(A)(iii). Pub. L. 111–148, §3136(a)(2)(B), inserted ''complex, rehabilitative'' after ''case of a''.

Pub. L. 111–148, §3136(a)(2)(A), inserted ''complex, rehabilitative'' after ''option for'' in heading.

Subsec. (a)(7)(C)(ii)(II). Pub. L. 111–148, §3136(b), struck out ''(A)(ii) or'' after ''subparagraph''.

Subsec. (a)(11)(B). Pub. L. 111–148, §6407(b)(1), designated existing provisions as cl. (i) and inserted heading.

Pub. L. 111–148, §6405(a), substituted ''physician enrolled under section 1395cc(j) of this title or an eligible professional under section 1395w–4(k)(3)(B) of this title that is enrolled under section 1395cc(j) of this title'' for ''physician''.

Subsec. (a)(11)(B)(ii). Pub. L. 111–148, §6407(b)(2), added cl. (ii).

Subsec. (a)(14). Pub. L. 111–148, §3401(m)(3), inserted concluding provisions.

Subsec. (a)(14)(K). Pub. L. 111–148, §3401(m)(1), struck out ''2011, 2012, and 2013,'' after ''2010,'' and inserted ''and'' at the end.

Subsec. (a)(14)(L), (M). Pub. L. 111–148, § 3401(m)(2), added subpar. (L) and struck out former subpars. (L) and (M) which read as follows:

''(L) for 2014—

''(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, plus 2.0 percentage points; or

''(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013; and

''(M) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.''

Subsec. (a)(16)(B). Pub. L. 111–148, § 6402(g)(1), inserted ''that the Secretary determines is commensurate with the volume of the billing of the supplier'' after ''$50,000''.

Subsec. (a)(20)(F)(i). Pub. L. 111–148, § 3109(a)(1)(B), which directed amendment by inserting '', except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011'' before semicolon ''at the end'', was executed by making the insertion before ''; and'' to reflect the probable intent of Congress.

Pub. L. 111–148, § 3109(a)(1)(A), inserted ''and subparagraph (G)'' after ''clause (ii)''.

Subsec. (a)(20)(G). Pub. L. 111–148, § 3109(a)(2), added subpar. (G).

Subsec. (g)(2)(A). Pub. L. 111–148, § 3128(a), inserted ''101 percent of'' after ''subparagraph (B),''.

Subsec. (g)(2)(B). Pub. L. 111–148, § 5501(b)(2), substituted ''Subsections (x) and (y) of section 1395*l*'' for ''Section 1395*l*(x)''.

Pub. L. 111–148, § 5501(a)(2), inserted at end ''Section 1395*l*(x) of this title shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.''

Subsec. (h)(4)(A). Pub. L. 111–148, § 3401(n)(1)(D), inserted concluding provisions.

Subsec. (h)(4)(A)(x). Pub. L. 111–148, § 3401(n)(1)(B)(i), substituted ''for each of 2007 through 2010'' for ''a subsequent year''.

Subsec. (h)(4)(A)(xi). Pub. L. 111–148, § 3401(n)(1)(A), (B)(ii), (C), added cl. (xi).

Subsec. (*l*)(3). Pub. L. 111–148, § 3401(j)(4), inserted concluding provisions.

Subsec. (*l*)(3)(B). Pub. L. 111–148, § 3401(j)(2)(A), inserted '', subject to subparagraph (C) and the succeeding sentence of this paragraph,'' after ''increased''.

Subsec. (*l*)(3)(C). Pub. L. 111–148, § 3401(j)(1), (2)(B), (3), added subpar. (C).

Subsec. (*l*)(8). Pub. L. 111–148, § 3128(a), inserted ''101 percent of'' after ''pay'' in introductory provisions.

Subsec. (*l*)(12)(A). Pub. L. 111–309, § 106(c), substituted ''2012'' for ''2011''.

Pub. L. 111–148, § 10311(c), substituted ''2011'' for ''2010, and on or after April 1, 2010, and before January 1, 2011''.

Pub. L. 111–148, § 3105(c), substituted ''2010, and on or after April 1, 2010, and before January 1, 2011'' for ''2010''.

Subsec. (*l*)(13)(A). Pub. L. 111–309, § 106(a)(1), substituted ''2012,'' for ''2011'' in introductory provisions.

Pub. L. 111–148, § 10311(a)(1), in introductory provisions, substituted ''2007, and for'' for ''2007, for'' and ''2011'' for ''2010, and for such services furnished on or after April 1, 2010, and before January 1, 2011''.

Pub. L. 111–148, § 3105(a)(1), in introductory provisions, substituted ''2007, for'' for ''2007, and for'' and ''2010, and for such services furnished on or after April 1, 2010, and before January 1, 2011,'' for ''2010''.

Subsec. (*l*)(13)(A)(i), (ii). Pub. L. 111–309, § 106(a)(2), substituted ''January 1, 2012'' for ''January 1, 2011''.

Pub. L. 111–148, § 10311(a)(2)(B), substituted ''January 1, 2011'' for ''January 1, 2010''.

Pub. L. 111–148, § 10311(a)(2)(A), struck out '', and on or after April 1, 2010, and before January 1, 2011'' after ''January 1, 2010''.

Pub. L. 111–148, § 3105(a)(2), inserted '', and on or after April 1, 2010, and before January 1, 2011'' after ''January 1, 2010''.

Subsec. (n). Pub. L. 111–148, § 5502(b), which directed the addition of subsec. (n) relating to development and implementation of prospective payment system, was repealed by Pub. L. 111–148, § 10501(i)(1).

Pub. L. 111–148, § 4105(a), added subsec. (n) relating to authority to modify or eliminate coverage of certain preventive services.

Subsec. (*o*). Pub. L. 111–148, § 10501(i)(3)(A), added subsec. (*o*).

2009—Subsec. (a)(20)(F)(i). Pub. L. 111–72 inserted '', except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010'' before semicolon.

2008—Subsec. (a)(1)(E)(ii). Pub. L. 110–275, § 154(d)(2), substituted ''1395x(r)'' for ''1395x(r)(1)''.

Subsec. (a)(1)(F). Pub. L. 110–275, § 154(a)(3), (4)(A)(i), in introductory provisions, substituted ''January 1, 2011'' for ''January 1, 2009'' and inserted ''subject to subparagraph (G),'' before ''that are included''.

Subsec. (a)(1)(G). Pub. L. 110–275, § 154(a)(4)(A)(ii), added subpar. (G).

Subsec. (a)(5)(F). Pub. L. 110–275, § 144(b)(1), substituted ''Rental cap'' for ''Ownership of equipment'' in heading, added cl. (ii), and struck out former cl. (ii) which related to transfer of title to equipment and payments for oxygen and maintenance and servicing.

Subsec. (a)(14)(J) to (M). Pub. L. 110–275, § 154(a)(2)(A), added subpars. (J) to (L) and redesignated former subpar. (J) as (M).

Subsec. (a)(20)(B). Pub. L. 110–275, § 125(b)(5), substituted ''section 1395bb(a)'' for ''section 1395bb(b)''.

Subsec. (a)(20)(E). Pub. L. 110–275, § 154(b)(1)(A)(i), inserted ''including subparagraph (F),'' after ''under this paragraph,''.

Subsec. (a)(20)(F). Pub. L. 110–275, § 154(b)(1)(A)(ii), added subpar. (F).

Subsec. (e). Pub. L. 110–275, § 135(a)(1), added subsec. (e).

Subsec. (g)(4). Pub. L. 110–275, § 148(a), substituted ''Treatment of'' for ''No beneficiary cost-sharing for'' in heading and inserted at end ''For purposes of the preceding sentence and section 1395x(mm)(3) of this title, clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.''

Subsec. (h)(1)(H). Pub. L. 110–275, § 154(a)(3), (4)(B), in introductory provisions, substituted ''January 1, 2011'' for ''January 1, 2009'' and inserted ''subject to subsection (a)(1)(G),'' before ''that are included''.

Subsec. (*l*)(13)(A). Pub. L. 110–275, § 146(a)(1), inserted ''and for such services furnished on or after July 1, 2008, and before January 1, 2010'' after ''2007,'' in introductory provisions, ''(or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010)'' after ''2 percent'' in cl. (i), and ''(or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010)'' after ''1 percent'' in cl. (ii).

Subsec. (*l*)(13)(B). Pub. L. 110–275, § 146(a)(2), substituted ''applicable period'' for ''2006'' in heading and inserted ''applicable'' before ''period'' in text.

Subsec. (*l*)(14)(B)(i). Pub. L. 110–275, § 146(b)(2)(A), substituted ''certifies or reasonably determines'' for ''reasonably determines or certifies''.

Subsec. (m)(4)(C)(ii)(VI) to (VIII). Pub. L. 110–275, § 149(a), added subcls. (VI) to (VIII).

2006—Subsec. (a)(5)(A). Pub. L. 109–171, § 5101(b)(1)(A), substituted ''(E), and (F)'' for ''and (E)''.

Subsec. (a)(5)(F). Pub. L. 109–171, § 5101(b)(1)(B), added subpar. (F).

Subsec. (a)(7)(A). Pub. L. 109–171, §5101(a)(1), amended heading and text of subpar. (A) generally, revising and restating as cls. (i) to (iv) provisions of former cls. (i) to (vi).

Subsec. (d)(2)(C)(ii). Pub. L. 109–171, §5113(b), struck out ''deductible and'' before ''coinsurance'' in heading and struck out ''deductible or'' before ''copayment'' and before ''coinsurance'' in subcl. (I).

Subsec. (d)(3)(C)(ii). Pub. L. 109–171, §5113(b), struck out ''deductible and'' before ''coinsurance'' in heading and struck out ''deductible or'' before ''coinsurance'' in two places in subcl. (I).

2003—Subsec. (a)(1)(B). Pub. L. 108–173, §302(d)(1)(A), substituted ''Subject to subparagraph (F)(i), the payment basis'' for ''The payment basis'' in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 108–173, §302(d)(1)(B), substituted ''Subject to subparagraph (F)(ii), this subsection'' for ''This subsection''.

Subsec. (a)(1)(E). Pub. L. 108–173, §302(a)(2), added subpar. (E).

Subsec. (a)(1)(F). Pub. L. 108–173, §302(d)(1)(C), added subpar. (F).

Subsec. (a)(10)(B). Pub. L. 108–173, §302(d)(1)(D), inserted ''in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)'' after ''under this subsection''.

Subsec. (a)(14)(F). Pub. L. 108–173, §302(c)(1)(A)(ii), substituted ''2003'' for ''a subsequent year'' and ''2002;'' for ''the previous year.''

Subsec. (a)(14)(G) to (J). Pub. L. 108–173, §302(c)(1)(A)(i), (iii), added subpars (G) to (J).

Subsec. (a)(17), (19). Pub. L. 108–173, §302(a)(1)(A), redesignated par. (17), relating to certain upgraded items, as (19) and transferred it to the end of subsec. (a).

Subsec. (a)(20). Pub. L. 108–173, §302(a)(1)(B), added par. (20).

Subsec. (a)(21). Pub. L. 108–173, §302(c)(2), added par. (21).

Subsec. (b)(4)(D)(iv). Pub. L. 108–173, §736(b)(4), substituted ''clause (vi)'' for ''clauses (vi)''.

Subsec. (g)(1). Pub. L. 108–173, §405(a)(1), inserted ''equal to 101 percent of'' before ''the reasonable costs''.

Subsec. (g)(2). Pub. L. 108–173, §405(d)(1), inserted concluding provisions.

Subsec. (g)(5). Pub. L. 108–173, §405(b)(1), in heading, inserted ''certain'' before ''emergency'' and substituted ''providers'' for ''physicians'', and, in text, substituted ''physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services'' for ''emergency room physicians who are on-call (as defined by the Secretary)'' and ''services covered under this subchapter'' for ''physicians' services''.

Subsec. (h)(1)(B). Pub. L. 108–173, §302(d)(2)(A), substituted '', (E), and (H)(i)'' for ''and (E)'' in introductory provisions.

Subsec. (h)(1)(D). Pub. L. 108–173, §302(d)(2)(B), substituted ''Subject to subparagraph (H)(ii), this subsection'' for ''This subsection''.

Subsec. (h)(1)(H). Pub. L. 108–173, §302(d)(2)(C), added subpar. (H).

Subsec. (h)(4)(A)(viii). Pub. L. 108–173, §302(c)(3)(B), substituted ''2003'' for ''a subsequent year''.

Subsec. (h)(4)(A)(ix), (x). Pub. L. 108–173, §302(c)(3)(A), (C), added cls. (ix) and (x).

Subsec. (h)(4)(C). Pub. L. 108–173, §627(b)(1), inserted ''(and includes shoes described in section 1395x(s)(12) of this title)'' after ''in section 1395x(s)(9) of this title''.

Subsec. (*l*)(2)(E). Pub. L. 108–173, §414(a)(1), inserted ''consistent with paragraph (11)'' after ''in an efficient and fair manner''.

Subsec. (*l*)(8), (9). Pub. L. 108–173, §414(a)(2), redesignated par. (8), relating to transitional assistance for rural providers, as (9).

Subsec. (*l*)(10). Pub. L. 108–173, §414(a)(3), added par. (10).

Subsec. (*l*)(11). Pub. L. 108–173, §414(b), added par. (11).

Subsec. (*l*)(12). Pub. L. 108–173, §414(c)(1), added par. (12).

Subsec. (*l*)(13). Pub. L. 108–173, §414(d), added par. (13).

Subsec. (*l*)(14). Pub. L. 108–173, §415(a), added par. (14).

Subsec. (m)(4)(C)(ii)(III). Pub. L. 108–173, §736(b)(5), substituted ''1395x(aa)(2)'' for ''1395x(aa)(s)''.

2000—Subsec. (a)(14)(C). Pub. L. 106–554, §1(a)(6) [title IV, §425(a)(2)], substituted ''through 2000'' for ''through 2002'' and struck out ''and'' at end.

Subsec. (a)(14)(D) to (F). Pub. L. 106–554, §1(a)(6) [title IV, §425(a)(1), (3)], added subpars. (D) and (E) and redesignated former subpar. (D) as (F).

Subsec. (c). Pub. L. 106–554, §1(a)(6) [title I, §104(b)], amended heading and text generally, substituting present provisions for provisions which had set forth similar standards for screening mammography but had provided for payment limited to 80 percent of the least of the actual charge, a statutory fee schedule, if applicable, or the indexed dollar limit described, and which had set forth provisions relating to reduction of indexed dollar limit, application of limit in a hospital outpatient setting, and limitation of charges of nonparticipating physicians.

Subsec. (d)(2)(E)(ii). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(1)], inserted before period at end ''or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy''.

Subsec. (d)(3). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(A)], struck out ''for individuals at high risk for colorectal cancer'' after ''colonoscopy'' in heading.

Subsec. (d)(3)(A). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(B)], struck out ''for individuals at high risk for colorectal cancer (as defined in section 1395x(pp)(2) of this title)'' after ''screening colonoscopy''.

Subsec. (d)(3)(E). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(C)], inserted before period at end ''or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy''.

Subsec. (g)(2)(B). Pub. L. 106–554, §1(a)(6) [title II, §202(a)], inserted ''115 percent of'' before ''such amounts''.

Subsec. (g)(4). Pub. L. 106–554, §1(a)(6) [title II, §201(a)], added par. (4).

Subsec. (g)(5). Pub. L. 106–554, §1(a)(6) [title II, §204(a)], added par. (5).

Subsec. (h)(1)(F). Pub. L. 106–554, §1(a)(6) [title IV, §427(a)], added subpar. (F).

Subsec. (h)(1)(G). Pub. L. 106–554, §1(a)(6) [title IV, §428(a)], added subpar. (G).

Subsec. (h)(4)(A)(v). Pub. L. 106–554, §1(a)(6) [title IV, §426(a)(2)], substituted ''through 2000'' for ''through 2002'' and struck out ''and'' at end.

Subsec. (h)(4)(A)(vi) to (viii). Pub. L. 106–554, §1(a)(6) [title IV, §426(a)(1), (3)], added cls. (vi) and (vii) and redesignated former cl. (vi) as (viii).

Subsec. (*l*)(2)(E). Pub. L. 106–554, §1(a)(6) [title IV, §423(b)(1)], inserted before period at end '', except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported''.

Subsec. (*l*)(3)(A), (B). Pub. L. 106–554, §1(a)(6) [title IV, §423(a)(1)], substituted ''reduced in the case of 2002'' for ''reduced in the case of 2001 and 2002''.

Subsec. (*l*)(8). Pub. L. 106–554, §1(a)(6) [title II, §221(a)], added par. (8) relating to transitional assistance for rural providers.

Pub. L. 106–554, §1(a)(6) [title II, §205(a)], added par. (8) relating to services furnished by critical access hospitals.

Subsec. (m). Pub. L. 106–554, §1(a)(6) [title II, §223(b)], added subsec. (m).

1999—Subsec. (a)(13). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(2)(A)], substituted ''1395x(m)(5) of this title, but not including implantable items for which payment

may be made under section 1395*l*(t) of this title'' for ''1395x(m)(5) of this title)''.

Subsec. (g). Pub. L. 106–113, §1000(a)(6) [title IV, §403(d)(1)], amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: ''The amount of payment under this part for outpatient critical access hospital services is the reasonable costs of the critical access hospital in providing such services.''

Subsec. (h)(4)(A)(i). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(3)(A)], substituted semicolon for comma at end.

Subsec. (h)(4)(A)(v). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(3)(B)], substituted ''; and'' for '', and'' at end.

Subsec. (h)(4)(B). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(2)(B)], inserted ''and does not include an implantable item for which payment may be made under section 1395*l*(t) of this title'' before the semicolon.

1997—Subsec. (a)(2)(B)(iv). Pub. L. 105–33, §4105(b)(2), inserted before period at end ''(reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes)''.

Subsec. (a)(9)(B)(iv). Pub. L. 105–33, §4552(a)(2)(A), substituted ''1995, 1996, and 1997'' for ''each subsequent year''.

Subsec. (a)(9)(B)(v), (vi). Pub. L. 105–33, §4552(a)(1), (2)(B), (3), added cls. (v) and (vi).

Subsec. (a)(9)(D). Pub. L. 105–33, §4552(b), which directed amendment of section 1848(a)(9) (42 U.S.C. 1395m(a)(9)) by adding subpar. (D) at end, was executed by adding subpar. (D) at end of subsec. (a)(9) of this section, to reflect the probable intent of Congress.

Subsec. (a)(10)(B). Pub. L. 105–33, §4316(b), substituted ''The Secretary'' for ''For covered items furnished on or after January 1, 1991, the Secretary'' and struck out ''(other than subparagraph (D))'' before ''of section 1395u(b) of this title'' and ''as such provisions would otherwise apply to physicians' services and physicians and a reasonable charge under section 1395u(b) of this title but for the application of section 1395w–4(i)(3) of this title. In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable'' before period at end.

Subsec. (a)(14)(B). Pub. L. 105–33, §4551(a)(1)(B)(i), substituted ''1993, 1994, 1995, 1996, and 1997'' for ''a subsequent year''.

Subsec. (a)(14)(C), (D). Pub. L. 105–33, §4551(a)(1)(A), (B)(ii), (C), added subpars. (C) and (D).

Subsec. (a)(16). Pub. L. 105–33, §4312(c), inserted at end ''The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A of this subchapter or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1395u(b)(18)(C) of this title) who furnish items or services under this part.''

Pub. L. 105–33, §4312(a), added par. (16).

Subsec. (a)(17). Pub. L. 105–33, §4551(c)(1), added par. (17) relating to certain upgraded items.

Subsec. (c)(1)(C). Pub. L. 105–33, §4101(c), in introductory provisions, struck out '', subject to the deductible established under section 1395*l*(b) of this title,'' before ''be equal to 80''.

Subsec. (c)(2)(A)(iii). Pub. L. 105–33, §4101(a)(1), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: ''In the case of a woman over 39 years of age, but under 50 years of age, who—

''(I) is at a high risk of developing breast cancer (as determined pursuant to factors identified by the Secretary), payment may not be made under this part for a screening mammography performed within the 11 months following the month in which a previous screening mammography was performed, or

''(II) is not at a high risk of developing breast cancer, payment may not be made under this part for a screening mammography performed within the 23 months following the month in which a previous screening mammography was performed.''

Subsec. (c)(2)(A)(iv), (v). Pub. L. 105–33, §4101(a)(2), struck out cls. (iv) and (v), which read as follows:

''(iv) In the case of a woman over 49 years of age, but under 65 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

''(v) In the case of a woman over 64 years of age, payment may not be made for screening mammography performed within 23 months following the month in which a previous screening mammography was performed.''

Subsec. (d). Pub. L. 105–33, §4104(b)(1), added subsec. (d).

Subsec. (g). Pub. L. 105–33, §4201(c)(5), amended heading and text of subsec. (g) generally. Prior to amendment, text related to payment for outpatient rural primary care hospital services as determined, in par. (1), by either the cost-based facility fee plus professional charges method or the all-inclusive rate method and, in par. (2), by the prospective payment system.

Subsec. (h)(4)(A)(iv). Pub. L. 105–33, §4551(a)(2)(B), substituted ''1996 and 1997'' for ''a subsequent year''.

Subsec. (h)(4)(A)(v), (vi). Pub. L. 105–33, §4551(a)(2)(A), (C), added cls. (v) and (vi).

Subsec. (k). Pub. L. 105–33, §4541(a)(2), added subsec. (k).

Subsec. (*l*). Pub. L. 105–33, §4531(b)(2), added subsec. (*l*).

1994—Subsec. (a)(3)(D). Pub. L. 103–432, §135(e)(5), struck out heading and text of subpar. (D). Text read as follows: ''If the reasonable useful lifetime of such an item, as established under paragraph (7)(C), has been reached during a continuous period of medical need, or the Secretary determines on the basis of investigation by the carrier that the item is lost or irreparably damaged, payment for an item serving as a replacement for such item shall be made on a monthly basis for the rental of the replacement item in accordance with subparagraph (A).''

Subsec. (a)(5)(E). Pub. L. 103–432, §135(d)(1), substituted ''pressure of 56'' for ''pressure of 55''.

Subsec. (a)(7). Pub. L. 103–432, §135(e)(2), made technical amendment to directory language of Pub. L. 101–508, §4152(c)(2). See 1990 Amendment note below.

Subsec. (a)(7)(A)(iii)(II). Pub. L. 103–432, §135(e)(3), substituted ''clause (vi)'' for ''clause (v)''.

Subsec. (a)(7)(C)(i). Pub. L. 103–432, §135(e)(4), substituted ''this paragraph'' for ''this paragraph or paragraph (3)''.

Subsec. (a)(10)(B). Pub. L. 103–432, §134(a)(1), inserted at end ''In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable.''

Pub. L. 103–432, §126(g)(10)(B), substituted ''would otherwise apply to physicians' services'' for ''apply to physicians' services'' and inserted before period at end ''but for the application of section 1395w–4(i)(3) of this title''.

Subsec. (a)(14)(A). Pub. L. 103–432, §135(a)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''for 1991 and 1992, reduction of 1 percentage point; and''.

Subsec. (a)(15). Pub. L. 103–432, §135(b)(1), amended heading and text of par. (15) generally. Prior to amendment, text read as follows:

''(A) DEVELOPMENT OF LIST OF ITEMS BY SECRETARY.—The Secretary shall develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization, and shall include in

such list seat-lift mechanisms, transcutaneous electrical nerve stimulators, and motorized scooters.

''(B) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance whether payment for an item included on the list developed by the Secretary under subparagraph (A) may not be made because of the application of section 1395y(a)(1) of this title.''

Subsec. (a)(16). Pub. L. 103–432, §131(a)(2), struck out heading and text of par. (16). Text read as follows:

''(A) IN GENERAL.—A supplier of a covered item under this subsection may not distribute to physicians or to individuals entitled to benefits under this part for commercial purposes any completed or partially completed forms or other documents required by the Secretary to be submitted to show that a covered item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

''(B) PENALTY.—Any supplier of a covered item who knowingly and willfully distributes a form or other document in violation of subparagraph (A) is subject to a civil money penalty in an amount not to exceed $1,000 for each such form or document so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.''

Subsec. (a)(17), (18). Pub. L. 103–432, §132(a)(1), (2), added pars. (17) and (18).

Subsec. (b)(4)(D). Pub. L. 103–432, §126(b)(2)(A), in introductory provisions substituted ''shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:'' for ''shall be determined as follows:''.

Subsec. (b)(4)(D)(iv). Pub. L. 103–432, §126(b)(2)(B), substituted ''Adjusted conversion factor'' for ''Local adjustment'' in heading and ''The adjusted conversion factor for'' for ''Subject to clause (vii), the conversion factor to be applied to'' in text.

Subsec. (b)(4)(D)(vii). Pub. L. 103–432, §126(b)(2)(C), (D), struck out ''under this subparagraph'' after ''applied to a locality'' and inserted ''reduced under this subparagraph by'' before ''more than 9.5 percent''.

Subsec. (b)(4)(E). Pub. L. 103–432, §126(b)(5), inserted heading ''Rule for certain scanning services''.

Pub. L. 103–432, §126(b)(4), made technical amendment to directory language of Pub. L. 101–508, §4102(d). See 1990 Amendment note below.

Pub. L. 103–432, §126(b)(1), redesignated subpar. (E), relating to subsequent updating, as (F).

Subsec. (b)(4)(F), (G). Pub. L. 103–432, §126(b)(1), redesignated subpars. (E), relating to subsequent updating, and (F) as (F) and (G), respectively.

Subsec. (c)(1)(B). Pub. L. 103–432, §145(a)(1), substituted ''is conducted by a facility that has a certificate (or provisional certificate) issued under section 263b of this title'' for ''meets the quality standards established under paragraph (3)''.

Subsec. (c)(1)(C)(iii). Pub. L. 103–432, §145(a)(2), substituted ''paragraph (3)'' for ''paragraph (4)''.

Subsec. (c)(3) to (5). Pub. L. 103–432, §145(a)(3), (4), redesignated pars. (4) and (5) as (3) and (4), respectively, and struck out former par. (3) which directed Secretary to establish standards to assure the safety and accuracy of screening mammography performed under this part.

Subsec. (f). Pub. L. 103–432, §126(g)(1), substituted ''during 1991'' for ''during fiscal year 1991'' in heading.

Subsec. (g)(1). Pub. L. 103–432, §102(e)(1)(A), (2), substituted in introductory provisions ''during a year before the prospective payment system described in paragraph (2) is in effect'' for ''during a year before 1993'' and inserted at end ''The amount of payment shall be determined under either method without regard to the amount of the customary or other charge.''

Subsec. (g)(1)(B). Pub. L. 103–432, §156(a)(2)(C), struck out ''and for items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title, or a third opinion, if the second opinion was in disagreement with the first opinion'' after ''section 1395x(s)(10)(A) of this title''.

Subsec. (g)(2). Pub. L. 103–432, §102(e)(1)(B), substituted ''January 1, 1996'' for ''January 1, 1993''.

Subsec. (h)(3). Pub. L. 103–432, §135(b)(3), substituted ''Paragraphs (12), (15), and (17)'' for ''Paragraphs (12) and (17)''.

Pub. L. 103–432, §132(b), substituted ''Paragraphs (12) and (17)'' for ''Paragraph (12)''.

Subsec. (j). Pub. L. 103–432, §131(a)(1), added subsec. (j).

Subsec. (j)(4), (5). Pub. L. 103–432, §133(a)(1), added par. (4) and redesignated former par. (4) as (5).

1993—Subsec. (a)(1)(D). Pub. L. 103–66, §13545(a), substituted ''45 percent'' for ''15 percent'' after ''(as previously reduced) by''.

Subsec. (a)(2)(A)(iii). Pub. L. 103–66, §13543(b), added cl. (iii).

Subsec. (a)(2)(C). Pub. L. 103–66, §13542(a)(1), in cl. (i)(II), substituted ''for 1992, 1993, and 1994'' for ''for 1992'' and ''update for the year'' for ''update for 1992'', and in cl. (ii), struck out ''and'' at end of subcl. (I), added subcls. (II) and (III), and redesignated former subcl. (II) as (IV).

Subsec. (a)(3)(A). Pub. L. 103–66, §13543(a), substituted ''IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices'' for ''ventilators, aspirators, IPPB machines, and nebulizers''.

Subsec. (a)(3)(C). Pub. L. 103–66, §13542(a)(1), in cl. (i)(II), substituted ''for 1992, 1993, and 1994'' for ''for 1992'' and ''update for the year'' for ''update for 1992'', and in cl. (ii), struck out ''and'' at end of subcl. (I), added subcls. (II) and (III), and redesignated former subcl. (II) as (IV).

Subsec. (a)(8)(A)(ii)(III). Pub. L. 103–66, §13542(a)(2)(A), substituted ''1992, 1993, and 1994'' for ''1992''.

Subsec. (a)(8)(B)(ii) to (iv). Pub. L. 103–66, §13542(a)(2)(B), added cls. (ii) and (iii) and redesignated former cl. (ii) as (iv).

Subsec. (a)(9)(A)(ii)(II). Pub. L. 103–66, §13542(a)(3)(A), substituted ''1991, 1992, 1993, and 1994'' for ''1991 and 1992''.

Subsec. (a)(9)(B)(ii) to (iv). Pub. L. 103–66, §13542(a)(3)(B), added cls. (ii) and (iii) and redesignated former cl. (ii) as (iv).

Subsec. (h)(1)(B). Pub. L. 103–66, §13544(a)(2), substituted ''subparagraphs (C) and (E)'' for ''subparagraph (C)'' in introductory provisions.

Subsec. (h)(1)(E). Pub. L. 103–66, §13544(a)(1), added subpar. (E).

Subsec. (h)(4)(A). Pub. L. 103–66, §13546, struck out ''and'' at end of cl. (i), substituted ''1992 and 1993'' for ''a subsequent year'' in cl. (ii), and added cls. (iii) and (iv).

Subsec. (i). Pub. L. 103–66, §13544(b)(1), added subsec. (i).

1990—Subsec. (a). Pub. L. 101–508, §4153(a)(2)(D)(i), struck out '', prosthetic devices, orthotics, and prosthetics'' after ''medical equipment'' in heading.

Subsec. (a)(1)(D). Pub. L. 101–508, §4152(a)(1), inserted before period at end '', and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 15 percent''.

Subsec. (a)(2)(A). Pub. L. 101–508, §4153(a)(2)(D)(ii), substituted ''(13)'' for ''(13)(A)''.

Pub. L. 101–508, §4152(c)(4)(A), inserted ''or'' after ''$150,'' in cl. (i), struck out ''or'' after ''purchase,'' in cl. (ii), and struck out cl. (iii) which read as follows: ''which is a power-driven wheelchair (other than a customized wheelchair that is classified as a customized item under paragraph (4) pursuant to criteria specified by the Secretary),''.

Subsec. (a)(2)(B). Pub. L. 101–508, §4152(b)(1)(A), (B), struck out ''or'' after ''1987;'' in cl. (i), added cls. (ii) to

(iv), and struck out former cl. (ii) which read as follows: ''in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of that preceding year.''

Subsec. (a)(2)(C). Pub. L. 101–508, § 4152(b)(1)(C), added subpar. (C).

Subsec. (a)(3)(B). Pub. L. 101–508, § 4152(b)(1)(A), (B), struck out ''or'' after ''1987;'' in cl. (i), added cls. (ii) to (iv), and struck out former cl. (ii) which read as follows: ''in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of that preceding year.''

Subsec. (a)(3)(C). Pub. L. 101–508, § 4152(b)(1)(C), added subpar. (C).

Subsec. (a)(3)(D). Pub. L. 101–508, § 4152(c)(3), added subpar. (D).

Subsec. (a)(4). Pub. L. 101–508, § 4152(c)(4)(B)(i), directed amendment of par. (4) by inserting at end ''In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.'' The amendment did not become effective pursuant to Pub. L. 101–508, § 4152(c)(4)(B)(ii). See Effective Date of 1990 Amendment note below.

Subsec. (a)(5)(A). Pub. L. 101–508, § 4152(g)(1)(A), substituted ''(B), (C), and (E)'' for ''(B) and (C)''.

Subsec. (a)(5)(E). Pub. L. 101–508, § 4152(g)(1)(B), added subpar. (E).

Subsec. (a)(7)(A)(i). Pub. L. 101–508, § 4152(c)(2)(A), as amended by Pub. L. 103–432, § 135(e)(2), substituted ''15 months, or, in the case of an item for which a purchase agreement has been entered into under clause (iii), a period of continuous use of longer than 13 months'' for ''15 months''.

Pub. L. 101–508, § 4152(c)(1), substituted ''for each of the first 3 months of such period'' for ''for each such month'' and '', and for each of the remaining months of such period is 7.5 percent of such purchase price;'' for semicolon at end.

Subsec. (a)(7)(A)(ii), (iii). Pub. L. 101–508, § 4152(c)(2)(D), as amended by Pub. L. 103–432, § 135(e)(2), added cls. (ii) and (iii). Former cls. (ii) and (iii) redesignated (iv) and (v), respectively.

Subsec. (a)(7)(A)(iv). Pub. L. 101–508, § 4152(c)(2)(B), as amended by Pub. L. 103–432, § 135(e)(2), redesignated cl. (ii) as (iv), substituted ''in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii), during the first 6-month period of medical need that follows the period of medical need during which payment is made under clause (i),'' for ''during the succeeding 6-month period of medical need,'' and struck out ''and'' at end.

Subsec. (a)(7)(A)(v). Pub. L. 101–508, § 4152(c)(2)(C), as amended by Pub. L. 103–432, § 135(e)(2), redesignated cl. (iii) as (v), inserted at beginning ''in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii),'', and substituted ''; and'' for period at end.

Subsec. (a)(7)(A)(vi). Pub. L. 101–508, § 4152(c)(2)(E), as amended by Pub. L. 103–432, § 135(e)(2), added cl. (vi).

Subsec. (a)(7)(C). Pub. L. 101–508, § 4152(c)(2)(F), as amended by Pub. L. 103–432, § 135(e)(2), added subpar. (C).

Subsec. (a)(8)(A)(ii). Pub. L. 101–508, § 4152(b)(2)(A), added subcl. (II), redesignated former subcl. (II) as (III), struck out ''1991 or'' before ''1992'', and substituted ''the covered item update for the year'' for ''the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year''.

Subsec. (a)(8)(B). Pub. L. 101–508, § 4152(b)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

''(i) for 1991 and for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

''(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year.''

Subsec. (a)(8)(C). Pub. L. 101–508, § 4152(b)(2)(C)(ii), struck out ''and subject to subparagraph (D)'' after ''and (7)'' in introductory provisions.

Subsec. (a)(8)(C)(ii). Pub. L. 101–508, § 4152(b)(2)(C)(i), (iii), in subcl. (I) substituted ''67 percent'' for ''75 percent'' and in subcl. (II) substituted ''33 percent'' for ''25 percent'' and ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(C)(iii). Pub. L. 101–508, § 4152(b)(2)(C)(i), (iv), in subcl. (I) substituted ''33 percent'' for ''50 percent'' and ''subparagraph (A)(ii)(III)'' for ''subparagraph (A)(ii)(II)'' and in subcl. (II) substituted ''67 percent'' for ''50 percent'' and ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(C)(iv). Pub. L. 101–508, § 4152(b)(2)(C)(i), substituted ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(D). Pub. L. 101–508, § 4152(b)(2)(D), struck out subpar. (D) which read as follows: ''The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

''(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

''(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.''

Subsec. (a)(9)(A)(ii)(II). Pub. L. 101–508, § 4152(b)(3)(A), substituted ''the covered item increase for the year'' for ''the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year''.

Subsec. (a)(9)(B). Pub. L. 101–508, § 4152(b)(3)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''With respect to the furnishing of an item in each region (as defined by the Secretary), the Secretary shall compute a regional monthly payment rate—

''(i) for 1991 and 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local monthly payment rates for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

''(ii) for each subsequent year, equal to the regional monthly payment rates computed under this subparagraph for the previous year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year.''

Subsec. (a)(9)(C)(ii). Pub. L. 101–508, § 4152(b)(3)(C)(i), (ii), in subcl. (I) substituted ''67 percent'' for ''75 percent'' and in subcl. (II) substituted ''33 percent'' for ''25 percent'' and ''national limited monthly payment rate'' for ''regional monthly payment rate''.

Subsec. (a)(9)(C)(iii). Pub. L. 101–508, § 4152(b)(3)(C)(i), (iii), in subcl. (I) substituted ''33 percent'' for ''50 per-

cent'' and in subcl. (II) substituted ''67 percent'' for ''50 percent'', ''national limited monthly payment rate'' for ''regional monthly payment rate'', and ''subparagraph (B)(ii)'' for ''subparagraph (B)(i)''.

Subsec. (a)(9)(C)(iv). Pub. L. 101–508, §4152(b)(3)(C)(i), substituted ''national limited monthly payment rate'' for ''regional monthly payment rate''.

Subsec. (a)(9)(D). Pub. L. 101–508, §4152(b)(3)(D), struck out subpar. (D) which read as follows: ''The amount that is recognized under subparagraph (C) as the base monthly payment amount for an item furnished—

''(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year; and

''(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year.''

Subsec. (a)(12). Pub. L. 101–508, §4152(b)(5), struck out ''defined for purposes of paragraphs (8)(B) and (9)(B)'' after ''one or more entire regions''.

Subsec. (a)(13). Pub. L. 101–508, §4153(a)(2)(D)(iii), substituted ''means durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title).'' for ''means—

''(A) durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title;

''(B) prosthetic devices (described in section 1395x(s)(8) of this title), but not including parenteral and enteral nutrition nutrients, supplies, and equipment; and

''(C) orthotics and prosthetics (described in section 1395x(s)(9) of this title);

but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title.''

Subsec. (a)(14). Pub. L. 101–508, §4152(b)(4), added par. (14).

Subsec. (a)(15). Pub. L. 101–508, §4152(e), added par. (15).

Subsec. (a)(16). Pub. L. 101–508, §4152(f)(1), added par. (16).

Subsec. (b)(1)(B). Pub. L. 101–508, §4163(b)(1), inserted ''and subject to subsection (c)(1)(A) of this section'' after ''conversion factors''.

Pub. L. 101–508, §4102(f), inserted ''locality,'' after ''statewide,''.

Subsec. (b)(4)(D). Pub. L. 101–508, §4102(a)(2), added subpar. (D). Former subpar. (D) redesignated (E) relating to subsequent updating.

Subsec. (b)(4)(E). Pub. L. 101–508, §4102(d), as amended by Pub. L. 103–432, §126(b)(4), added subpar. (E) relating to rule for certain scanning services.

Pub. L. 101–508, §4102(a)(1), redesignated subpar. (D), relating to subsequent updating, as (E). Former subpar. (E) redesignated (F).

Subsec. (b)(4)(F). Pub. L. 101–508, §4102(a)(1), redesignated subpar. (E) as (F).

Subsec. (c). Pub. L. 101–508, §4163(b)(2), added subsec. (c).

Subsec. (f). Pub. L. 101–508, §4104(a), amended subsec. (f) generally, substituting provisions relating to reduction in payments for physician pathology services during 1991 for provisions directing Secretary to provide for application of a fee schedule with respect to such services.

Subsec. (h). Pub. L. 101–508, §4153(a)(1), added subsec. (h).

1989—Subsec. (a)(1)(D). Pub. L. 101–239, §6112(c), added subpar. (D).

Subsec. (a)(2)(A)(iii). Pub. L. 101–239, §6112(d)(1), added cl. (iii).

Subsec. (a)(2)(B)(i), (3)(B)(i). Pub. L. 101–239, §6112(a)(1), inserted ''and in 1990'' after ''1989''.

Subsec. (a)(7)(A)(i). Pub. L. 101–239, §6112(a)(4)(A), substituted ''this clause'' for ''this subparagraph''.

Subsec. (a)(7)(B)(i). Pub. L. 101–239, §6112(a)(4)(B), inserted ''in'' after ''rental of the item''.

Subsec. (a)(7)(B)(ii). Pub. L. 101–239, §6112(a)(4)(C), substituted ''clause (i) shall apply in the same manner as it applies to items furnished during 1989'' for ''the payment amount recognized under subparagraph (A)(i) shall not be more than the maximum amount established under clause (i), and shall not be less than the minimum amount established under such clause, for 1989, each such amount increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 1989''.

Subsec. (a)(8)(A)(ii)(I). Pub. L. 101–239, §6112(a)(2)(A), inserted ''and 1990'' after ''1989''.

Subsec. (a)(8)(A)(ii)(II). Pub. L. 101–239, §6112(a)(2)(B), substituted ''1991 or 1992'' for ''1990, 1991, or 1992''.

Subsec. (a)(8)(D)(i). Pub. L. 101–239, §6140(1), substituted ''1991, may not exceed 125 percent, and may not be lower than 85 percent'' for ''1991, may not exceed 130 percent, and may not be lower than 80 percent''.

Subsec. (a)(8)(D)(ii). Pub. L. 101–239, §6140(2), substituted ''120 percent, and may not be lower than 90 percent'' for ''125 percent, and may not be lower than 85 percent''.

Subsec. (a)(9)(A)(ii)(I). Pub. L. 101–239, §6112(a)(3)(A), inserted ''and 1990'' after ''1989''.

Subsec. (a)(9)(A)(ii)(II). Pub. L. 101–239, §6112(a)(3)(B), substituted ''1991 and 1992'' for ''1990, 1991, and 1992''.

Subsec. (a)(9)(D)(i). Pub. L. 101–239, §6140(1), substituted ''1991, may not exceed 125 percent, and may not be lower than 85 percent'' for ''1991, may not exceed 130 percent, and may not be lower than 80 percent''.

Subsec. (a)(9)(D)(ii). Pub. L. 101–239, §6140(2), substituted ''120 percent, and may not be lower than 90 percent'' for ''125 percent, and may not be lower than 85 percent''.

Subsec. (a)(13). Pub. L. 101–239, §6112(e)(2), inserted before period at end ''or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title''.

Subsec. (b)(1)(B). Pub. L. 101–234, §201(a), repealed Pub. L. 100–360, §204(b)(1), 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)(4)(A). Pub. L. 101–234, §301(b)(1), (c)(1), amended subpar. (A) identically, substituting ''coinsurance and deductibles under sections 1395*l*(a)(1)(J)'' for ''insurance and deductibles under section 1395n(a)(1)(I)''.

Subsec. (b)(4)(C) to (E). Pub. L. 101–239, §6105(a), added subpar. (C) and redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsecs. (c) to (e). Pub. L. 101–234, §201(a), repealed Pub. L. 100–360, §§202(b)(4), 203(c)(1)(F), 204(b)(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. (f). Pub. L. 101–239, §6102(f)(1), added subsec. (f).

Subsec. (g). Pub. L. 101–239, §6116(b)(2), added subsec. (g).

1988—Pub. L. 100–360, §411(g)(1)(A), inserted ''items and'' in section catchline.

Subsec. (a)(1)(C). Pub. L. 100–360, §411(g)(1)(B)(i), inserted ''or under part A of this subchapter to a home health agency'' before period at end.

Subsec. (a)(2)(A). Pub. L. 100–360, §411(g)(1)(B)(iii), struck out ''rental'' before ''payments'' in concluding provisions.

Subsec. (a)(2)(B)(i). Pub. L. 100–360, §411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowed''.

Subsec. (a)(3)(A). Pub. L. 100–360, §411(g)(1)(B)(iv), struck out the extra space appearing in text of original act after ''ventilators''.

Subsec. (a)(3)(B)(i). Pub. L. 100–360, § 411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowable''.

Subsec. (a)(4). Pub. L. 100–360, § 411(g)(1) (B)(v)–(vii), inserted '', and for that reason cannot be grouped with similar items for purposes of payment under this subchapter,'' after ''individual patient'', inserted cl. (A) and (B) designations, and in cl. (B), substituted ''servicing'' for ''service'' in two places.

Subsec. (a)(7)(A)(ii). Pub. L. 100–360, § 411(g)(1) (B)(vii), inserted ''maintenance and'' before ''servicing''.

Subsec. (a)(7)(A)(iii). Pub. L. 100–360, § 411(g)(1) (B)(vii), (viii), substituted ''maintenance and servicing'' for ''service and maintenance'', and in subcl. (I) substituted ''fee or fees established by the Secretary'' for ''fee established by the carrier''.

Subsec. (a)(7)(B)(i). Pub. L. 100–360, § 411(a)(3)(A), (C)(ii), provided that subsec. (a)(7)(B)(i) of this section, as inserted by section 4062(b) of Pub. L. 100–203, is deemed to have a reference to ''1987'' immediately after ''December''.

Subsec. (a)(8)(A)(i)(I). Pub. L. 100–360, § 411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowable''.

Subsec. (a)(8)(B). Pub. L. 100–360, § 411(g)(1)(B)(xi), as amended Pub. L. 100–485, § 608(d)(22)(A)(i), substituted ''(as defined by the Secretary)'' for ''(as defined in section 1395ww(d)(2)(D) of this title)'', and in cl. (i) struck out the comma after ''1991''.

Subsec. (a)(9)(A)(ii)(I). Pub. L. 100–360, § 411(g)(1) (B)(ix), substituted ''6-month'' for ''12-month''.

Subsec. (a)(9)(A)(ii)(II). Pub. L. 100–360, § 411(g)(1) (B)(x), substituted '', 1991, and 1992'' for ''and to 1991''.

Subsec. (a)(9)(B). Pub. L. 100–360, § 411(g)(1)(B)(xi), as amended by Pub. L. 100–485, § 608(d)(22)(A)(i), substituted ''(as defined by the Secretary)'' for ''(as defined in section 1395ww(d)(2)(D) of this title)'', and in cl. (i) struck out the comma after ''1991''.

Subsec. (a)(9)(C)(i). Pub. L. 100–360, § 411(g)(1) (B)(xii), substituted ''subparagraph (A)(ii)'' for ''subparagraph (A)(ii)(I)''.

Subsec. (a)(10)(B). Pub. L. 100–360, § 411(g)(1) (B)(xiii), inserted before period at end ''and payments under this subsection as such provisions apply to physicians' services and physicians and a reasonable charge under section 1395u(b) of this title''.

Subsec. (a)(11)(A). Pub. L. 100–360, § 411(g)(1) (B)(vii), (xiv), inserted ''maintenance and'' before ''servicing'' and substituted ''section 1395u(j)(2) of this title'' for ''subsection (j)(2) of this section''.

Subsec. (a)(12). Pub. L. 100–360, § 411(g)(1)(B)(xv), as amended by Pub. L. 100–485, § 608(d)(22)(A)(ii), substituted ''one or more entire regions defined for purposes of paragraphs (8)(B) and (9)(B)'' for ''each region (as defined in section 1395ww(d)(2)(D) of this title)''.

Subsec. (a)(14). Pub. L. 100–360, § 411(g)(1)(B)(xvi), struck out par. (14) which read as follows: ''In this subsection, any reference to the term 'carrier' includes a reference, with respect to durable medical equipment furnished by a home health agency as part of home health services, to a fiscal intermediary.''

Subsec. (b). Pub. L. 100–360, § 411(a)(3)(A), (B)(ii), (f)(8)(B)(ii), amended Pub. L. 100–203, § 4049(a)(2), see 1987 Amendment note below.

Subsec. (b)(1)(B). Pub. L. 100–360, § 204(b)(1), inserted ''and subject to subsection (e)(1)(A) of this section'' after ''conversion factors''.

Subsec. (b)(4)(C). Pub. L. 100–360, § 411(f)(8)(D)(ii), as added by Pub. L. 100–485, § 608(d)(21)(C), substituted ''For radiologist'' for ''Radiologist'' and ''1395u(i)(3) of this title'' for ''1395u(b)(4)(E)(ii) of this title''.

Subsec. (b)(4)(D), (5). Pub. L. 100–360, § 411(f)(8)(D)(i), inserted ''and suppliers'' after ''physicians'' in heading.

Subsec. (b)(5)(C). Pub. L. 100–360, § 411(f)(8)(D)(iii), (iv), formerly (ii), (iii), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''bills'' for ''imposes a charge'' and inserted ''in the same manner as such sanctions may apply to a physician'' before period at end.

Subsec. (b)(6). Pub. L. 100–360, § 411(f)(8)(D)(v), formerly (iv), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''and section 1395*l*(a)(1)(J) of this title'' for '', section 1395*l*(a)(1)(I) of this title, and section 1395u(h)(1)(B) of this title''.

Pub. L. 100–360, § 411(f)(8)(A), substituted ''radiology'' for ''radiologic''.

Subsec. (b)(6)(B). Pub. L. 100–360, § 411(f)(8)(D)(vi), formerly (v), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''the total amount of charges'' for ''billings''.

Pub. L. 100–360, § 411(f)(8)(A), substituted ''radiology'' for ''radiologic''.

Subsec. (c). Pub. L. 100–360, § 202(b)(4), added subsec. (c) relating to payment for covered outpatient drugs.

Subsec. (d). Pub. L. 100–360, § 203(c)(1)(F), added subsec. (d) relating to home intravenous drug therapy services.

Subsec. (e). Pub. L. 100–360, § 204(b)(2), added subsec. (e) relating to payments and standards for screening mammography.

1987—Subsec. (b). Pub. L. 100–203, § 4049(a)(2), as amended by Pub. L. 100–360, § 411(a)(3)(A), (B)(ii), (f)(8)(B)(ii), added subsec. (b).

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–113 applicable to items furnished on or after Jan. 1, 2017, see section 504(d) of Pub. L. 114–113, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3128(b), Mar. 23, 2010, 124 Stat. 426, provided that: ''The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 405(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2266).''

Pub. L. 111–148, title III, § 3136(c), Mar. 23, 2010, 124 Stat. 438, provided that:

''(1) IN GENERAL.—Subject to paragraph (2), the amendments made by subsection (a) [amending this section] shall take effect on January 1, 2011, and shall apply to power-driven wheelchairs furnished on or after such date.

''(2) APPLICATION TO COMPETITIVE BIDDING.—The amendments made by subsection (a) shall not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) prior to January 1, 2011, pursuant to the implementation of subsection (a)(1)(B)(i)(I) of such section 1847.''

Amendment by section 6405(a) of Pub. L. 111–148 applicable to written orders and certifications made on or after July 1, 2010, see section 6405(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 125(b)(5) of Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110–275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1395bb of this title.

Pub. L. 110–275, title I, § 144(b)(2), July 15, 2008, 122 Stat. 2547, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 2009.''

Pub. L. 110–275, title I, § 146(b)(2)(B), July 15, 2008, 122 Stat. 2548, provided that: ''The amendment made by subparagraph (A) [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [July 15, 2008].''

Pub. L. 110–275, title I, § 148(b), July 15, 2008, 122 Stat. 2549, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2009.''

Pub. L. 110–275, title I, § 149(c), July 15, 2008, 122 Stat. 2549, provided that: ''The amendments made by this section [amending this section and section 1395yy of

this title] shall apply to services furnished on or after January 1, 2009.''

Pub. L. 110–275, title I, §154(e), July 15, 2008, 122 Stat. 2568, provided that: ''The amendments made by this section [amending this section, sections 1395u and 1395w–3 of this title, and provisions set out as notes under section 1395w–3 of this title] shall take effect as of June 30, 2008.''

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–171, title V, §5101(a)(2), Feb. 8, 2006, 120 Stat. 38, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to items furnished for which the first rental month occurs on or after January 1, 2006.''

Pub. L. 109–171, title V, §5101(b)(2), Feb. 8, 2006, 120 Stat. 39, provided that:

''(A) IN GENERAL.—The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 2006.

''(B) APPLICATION TO CERTAIN INDIVIDUALS.—In the case of an individual receiving oxygen equipment on December 31, 2005, for which payment is made under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)), the 36-month period described in paragraph (5)(F)(i) of such section, as added by paragraph (1), shall begin on January 1, 2006.''

Amendment by section 5113(b) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2007, see section 5113(c) of Pub. L. 109–171, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 405(a)(1) of Pub. L. 108–173 applicable to payments for services furnished during cost reporting periods beginning on or after Jan. 1, 2004, see section 405(a)(2) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Pub. L. 108–173, title IV, §405(b)(2), Dec. 8, 2003, 117 Stat. 2266, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply with respect to costs incurred for services furnished on or after January 1, 2005.''

Pub. L. 108–173, title IV, §405(d)(2), Dec. 8, 2003, 117 Stat. 2267, provided that:

''(A) IN GENERAL.—Except as provided in subparagraph (B), the amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 2004.

''(B) RULE OF APPLICATION.—In the case of a critical access hospital that made an election under section 1834(g)(2) of the Social Security Act (42 U.S.C. 1395m(g)(2)) before November 1, 2003, the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2001.''

Pub. L. 108–173, title IV, §415(c), Dec. 8, 2003, 117 Stat. 2282, provided that: ''The amendments made by this subsection [probably should be ''this section'', amending this section and section 1395x of this title] shall apply to services furnished on or after January 1, 2005.''

Amendment by section 627(b)(1) 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*l* of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, §1(a)(6) [title I, §103(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–469, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] shall apply to colorectal cancer screening services provided on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title I, §104(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–470, provided that: ''The amendments made by subsections (a) and (b) [amending this section and section 1395w–4 of this title] shall apply with respect to screening mammographies furnished on or after January 1, 2002.''

Amendment by section 1(a)(6) [title II, §201(a)] of Pub. L. 106–554 applicable to services furnished on or after Nov. 29, 1999, see section 1(a)(6) [title II, §201(c)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title II, §202(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: ''The amendment made by subsection (a) [amending this section] shall apply with respect to items and services furnished on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title II, §204(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–482, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 2001.''

Amendment by section 1(a)(6) [title II, §205(a)] of Pub. L. 106–554 applicable to services furnished on or after Dec. 21, 2000, see section 1(a)(6) [title II, §205(c)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title II, §221(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2001. In applying such amendment to services furnished on or after such date and before January 1, 2002, the amount of the rate increase provided under such amendment shall be equal to $1.25 per mile.''

Amendment by section 1(a)(6) [title II, §223(b)] of Pub. L. 106–554 effective for services furnished on or after Oct. 1, 2001, see section 1(a)(6) [title II, §223(e)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title IV, §423(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title IV, §428(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to items replaced on or after April 1, 2001.''

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(6) [title II, §201(e)(2)] of Pub. L. 106–113 effective as if included in enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see §1000(a)(6) [title II, §201(m)] of Pub. L. 106–113, set out as a note under section 1395*l* of this title.

Amendment by section 1000(a)(6) [title III, §321(k)(3)] 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.

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §403(d)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–371, as amended by Pub. L. 106–554, §1(a)(6) [title II, §201(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: ''Paragraphs (1) through (3) of section 1834(g) of the Social Security Act [42 U.S.C. 1395m(g)(1)–(3)] (as amended by paragraph (1)) apply for cost reporting periods beginning on or after October 1, 2000.''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4101(a), (c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4101(d) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4104(b)(1) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Pub. L. 105–33, title IV, §4105(d), Aug. 5, 1997, 111 Stat. 367, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 1395w–4 and 1395x of this title] shall apply to items and services furnished on or after July 1, 1998.

''(2) TESTING STRIPS.—The amendment made by subsection (b)(2) [amending this section] shall apply with respect to blood glucose testing strips furnished on or after January 1, 1998.''

Amendment by section 4201(c)(5) 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.

Pub. L. 105–33, title IV, §4312(f)(1), Aug. 5, 1997, 111 Stat. 387, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to suppliers of durable medical equipment with respect to such equipment furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4312(f)(3), Aug. 5, 1997, 111 Stat. 388, provided that: ''The amendments made by subsections (c) through (e) [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and may be applied with respect to items and services furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4316(c), Aug. 5, 1997, 111 Stat. 392, provided that: ''The amendments made by this section [amending this section and section 1395u of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997].''

Amendment by section 4531(b)(2) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 2000, see section 4531(b)(3) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4541(a)(2) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, including portions of cost reporting periods occurring on or after such date, except that subsec. (k) of this section inapplicable to services described in section 1395*l*(a)(8)(B) of this title that are furnished during 1998, see section 4541(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Pub. L. 105–33, title IV, §4551(c)(2), Aug. 5, 1997, 111 Stat. 459, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to purchases or rentals after the effective date of any regulations issued pursuant to such amendment.''

Pub. L. 105–33, title IV, §4552(e), Aug. 5, 1997, 111 Stat. 459, provided that:

''(1) OXYGEN.—The amendments made by subsection (a) [amending this section] shall apply to items furnished on and after January 1, 1998.

''(2) OTHER PROVISIONS.—The amendments made by this section other than subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Aug. 5, 1997].''

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, §126(i), Oct. 31, 1994, 108 Stat. 4416, provided that: ''Except as provided in subsection (h) [amending section 1395u of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as a note under section 1395w–4 of this title], the amendments made by this section and the provisions of this section [amending this section and sections 1395u, 1395w–1, and 1395w–4 of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as notes under this section and sections 1395u and 1395w–4 of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].''

Pub. L. 103–432, title I, §131(a)(2), Oct. 31, 1994, 108 Stat. 4419, provided that the amendment made by that section is effective 60 days after Oct. 31, 1994.

Pub. L. 103–432, title I, §132(c), Oct. 31, 1994, 108 Stat. 4421, provided that: ''The amendments made by subsections (a) and (b) [amending this section] shall apply to items furnished after the expiration of the 60-day period that begins on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §133(c), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendments made by this section [amending this section and sections 1395m and 1395pp of this title] shall apply to items or services furnished on or after January 1, 1995.''

Pub. L. 103–432, title I, §134(a)(2), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(a)(2), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(b)(1), Oct. 31, 1994, 108 Stat. 4422, provided that the amendment made by that section is effective Oct. 31, 1994.

Pub. L. 103–432, title I, §135(b)(3), Oct. 31, 1994, 108 Stat. 4423, provided that the amendment made by that section is effective Oct. 31, 1994.

Pub. L. 103–432, title I, §135(d)(2), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(e)(8), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendments made by this subsection [amending this section and provisions set out as notes under this section and section 1395cc of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].''

Pub. L. 103–432, title I, §145(d), Oct. 31, 1994, 108 Stat. 4428, provided that: ''The amendments made by this section [amending this section and sections 1395x to 1395bb of this title] shall apply to mammography furnished by a facility on and after the first date that the certificate requirements of section 354(b) of the Public Health Service Act [section 263b(b) of this title] apply to such mammography conducted by such facility.''

Amendment by section 156(a)(2)(C) of Pub. L. 103–432 applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103–432, set out as a note under section 1320c–3 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, §13542(b), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this section [amending this section] shall apply to items furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, §13543(c), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this section [amending this section] shall apply to items furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, §13544(a)(3), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this subsection [amending this section] shall apply to items furnished on or after January 1, 1994.''

Amendment by section 13544(b)(1) of Pub. L. 103–66 applicable to items furnished on or after Jan. 1, 1994, see section 13544(b)(3) of Pub. L. 103–66, set out as a note under section 1395*l* of this title.

Pub. L. 103–66, title XIII, §13545(b), Aug. 10, 1993, 107 Stat. 590, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to items furnished on or after January 1, 1994.''

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, §4102(i), Nov. 5, 1990, 104 Stat. 1388–58, provided that:

''(1) Except as otherwise provided, the amendments made by this section [amending this section, section 1395w–4 of this title, and provisions set out as a note below] shall apply to services furnished on or after January 1, 1991.

''(2) The amendment made by subsection (f) [amending this section] shall be effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].''

Amendment by section 4104(a) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4104(d) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

Pub. L. 101–508, title IV, §4152(a)(3), Nov. 5, 1990, 104 Stat. 1388–74, as amended by Pub. L. 103–432, title I, §135(e)(1), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendments made by this subsection [amending

this section and section 1395x of this title] shall apply to items furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4152(c)(4)(B)(ii), Nov. 5, 1990, 104 Stat. 1388–79, provided that: ''The amendment made by clause (i) [amending this section] shall apply to items furnished on or after January 1, 1992, unless the Secretary develops specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1834(a)(4) of the Social Security Act [subsec. (a)(4) of this section] (in which case the amendment made by such clause shall not become effective).'' [Criteria established by Secretary Nov. 1, 1991, see 56 F.R. 65995, Dec. 20, 1991, 42 CFR §414.224.]

Pub. L. 101–508, title IV, §4152(f)(2), Nov. 5, 1990, 104 Stat. 1388–80, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to forms and documents distributed on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4152(g)(2), Nov. 5, 1990, 104 Stat. 1388–80, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to patients who first receive home oxygen therapy services on or after January 1, 1991.''

Pub. L. 101–508, title IV, §4152(i), Nov. 5, 1990, 104 Stat. 1388–81, provided that: ''Except as otherwise provided, the amendments made by this section [amending this section, section 1395x of this title, and provisions set out as a note under section 1395f of this title] shall apply to items furnished on or after January 1, 1991.''

Amendment by section 4153(a)(1), (2)(D) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(a)(3) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4163(b) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6102(f)(1) of Pub. L. 101–239 applicable to services furnished on or after Jan. 1, 1991, see section 6102(f)(3) of Pub. L. 101–239, set out as a note under section 1395*l* of this title.

Pub. L. 101–239, title VI, §6112(e)(4), Dec. 19, 1989, 103 Stat. 2216, provided that: ''The amendments made by this subsection [amending this section and sections 1395x and 1395cc of this title] shall apply with respect to items furnished on or after January 1, 1990.''

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(b)(1), (c)(1), Dec. 13, 1989, 103 Stat. 1985, provided that the amendments made by that section are effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.

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.

Amendment by section 202(b)(4) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100–360, set out as a note under section 1395u of this title.

Amendment by section 203(c)(1)(F) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Pub. L. 100–360, title II, §204(e), July 1, 1988, 102 Stat. 729, which provided that the amendments made by section 204 of Pub. L. 100–360 [amending this section and sections 1395*l*, 1395x to 1395z, 1395aa, 1395bb, 1396a, and 1396n of this title] applied to screening mammography performed on or after January 1, 1990, and that subsec. (e)(5) of this section only applied until such time as the Secretary of Health and Human Services implemented the physician fee schedules based on relative value scale developed under section 1395w–1(e) of this title, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(a)(3)(A), (B)(ii), (C)(ii), (f)(8)(A), (B)(ii), (D), (g)(1)(A) and (B) 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

Pub. L. 100–203, title IV, §4049(b)(2), Dec. 22, 1987, 101 Stat. 1330–92, as amended by Pub. L. 101–239, title VI, §6102(e)(6)(B), Dec. 19, 1989, 103 Stat. 2188; Pub. L. 101–508, title IV, §4118(h)(2), Nov. 5, 1990, 104 Stat. 1388–70, provided that: ''The amendments made by this section [amending this section and section 1395*l* of this title] shall apply to services performed on or after April 1, 1989.''

[Pub. L. 101–508, title IV, §4118(h), Nov. 5, 1990, 104 Stat. 1388–70, provided that the amendment by that section to section 4049(b)(2) 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.]

EFFECTIVE DATE

Subsection (a) of this section applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, set out as an Effective Date of 1987 Amendment note under section 1395f of this title.

REGULATIONS

Pub. L. 106–554, §1(a)(6) [title IV, §427(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–521, provided that: ''Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall promulgate revised regulations to carry out the amendment made by subsection (a) [amending this section] using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.''

CONSTRUCTION OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3109(c), Mar. 23, 2010, 124 Stat. 420, provided that: ''Nothing in the provisions of or amendments made by this section [amending this section and enacting provisions set out as a note under this section] shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).''

Pub. L. 111–148, title IV, §4105(b), Mar. 23, 2010, 124 Stat. 559, provided that: ''Nothing in the amendment made by paragraph (1) [probably means subsec. (a), amending this section] shall be construed to affect the coverage of diagnostic or treatment services under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].''

CONSTRUCTION OF 2009 AMENDMENT

Pub. L. 111–72, §1(b), Oct. 13, 2009, 123 Stat. 2059, provided that: ''Nothing in subsection (a) [amending this section] shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).''

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–275, title I, §154(b)(1)(B), July 15, 2008, 122 Stat. 2565, provided that: ''Section 1834(a)(20)(F)(ii) of

the Social Security Act [42 U.S.C. 1395m(a)(20)(F)(ii)], as added by subparagraph (A), shall not be construed as preventing the Secretary of Health and Human Services from implementing the first round of competition under section 1847 of such Act [42 U.S.C. 1395w–3] on a timely basis.''

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.

IMPLEMENTATION OF 2015 AMENDMENT

Pub. L. 114–10, title V, § 504(b), Apr. 16, 2015, 129 Stat. 166, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.''

IMPLEMENTATION OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3109(b), Mar. 23, 2010, 124 Stat. 419, provided that: ''Notwithstanding any other provision of law, the Secretary may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.''

DEMONSTRATION PROJECT TO ASSESS THE APPROPRIATE USE OF IMAGING SERVICES

Pub. L. 110–275, title I, § 135(b), July 15, 2008, 122 Stat. 2535, provided that:

''(1) CONDUCT OF DEMONSTRATION PROJECT.—

''(A) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a demonstration project using the models described in paragraph (2)(E) to collect data regarding physician compliance with appropriateness criteria selected under paragraph (2)(D) in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries.

''(B) ADVANCED DIAGNOSTIC IMAGING SERVICES.—In this subsection, the term 'advanced diagnostic imaging services' has the meaning given such term in section 1834(e)(1)(B) of the Social Security Act [42 U.S.C. 1395m(e)(1)(B)], as added by subsection (a).

''(C) AUTHORITY TO FOCUS DEMONSTRATION PROJECT.—The Secretary may focus the demonstration project with respect to certain advanced diagnostic imaging services, such as services that account for a large amount of expenditures under the Medicare program, services that have recently experienced a high rate of growth, or services for which appropriateness criteria exists.

''(2) IMPLEMENTATION AND DESIGN OF DEMONSTRATION PROJECT.—

''(A) IMPLEMENTATION AND DURATION.—

''(i) IMPLEMENTATION.—The Secretary shall implement the demonstration project under this subsection not later than January 1, 2010.

''(ii) DURATION.—The Secretary shall conduct the demonstration project under this subsection for a 2-year period.

''(B) APPLICATION AND SELECTION OF PARTICIPATING PHYSICIANS.—

''(i) APPLICATION.—Each physician that desires to participate in the demonstration project under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

''(ii) SELECTION.—The Secretary shall select physicians to participate in the demonstration project under this subsection from among physicians submitting applications under clause (i). The Secretary shall ensure that the physicians selected—

''(I) represent a wide range of geographic areas, demographic characteristics (such as urban, rural, and suburban), and practice settings (such as private and academic practices); and

''(II) have the capability to submit data to the Secretary (or an entity under a subcontract with the Secretary) in an electronic format in accordance with standards established by the Secretary.

''(C) ADMINISTRATIVE COSTS AND INCENTIVES.—The Secretary shall—

''(i) reimburse physicians for reasonable administrative costs incurred in participating in the demonstration project under this subsection; and

''(ii) provide reasonable incentives to physicians to encourage participation in the demonstration project under this subsection.

''(D) USE OF APPROPRIATENESS CRITERIA.—

''(i) IN GENERAL.—The Secretary, in consultation with medical specialty societies and other stakeholders, shall select criteria with respect to the clinical appropriateness of advanced diagnostic imaging services for use in the demonstration project under this subsection.

''(ii) CRITERIA SELECTED.—Any criteria selected under clause (i) shall—

''(I) be developed or endorsed by a medical specialty society; and

''(II) be developed in adherence to appropriateness principles developed by a consensus organization, such as the AQA alliance.

''(E) MODELS FOR COLLECTING DATA REGARDING PHYSICIAN COMPLIANCE WITH SELECTED CRITERIA.—Subject to subparagraph (H), in carrying out the demonstration project under this subsection, the Secretary shall use each of the following models for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D):

''(i) A model described in subparagraph (F).

''(ii) A model described in subparagraph (G).

''(iii) Any other model that the Secretary determines to be useful in evaluating the use of appropriateness criteria for advanced diagnostic imaging services.

''(F) POINT OF SERVICE MODEL DESCRIBED.—A model described in this subparagraph is a model that—

''(i) uses an electronic or paper intake form that—

''(I) contains a certification by the physician furnishing the imaging service that the data on the intake form was confirmed with the Medicare beneficiary before the service was furnished;

''(II) contains standardized data elements for diagnosis, service ordered, service furnished, and such other information determined by the Secretary, in consultation with medical specialty societies and other stakeholders, to be germane to evaluating the effectiveness of the use of appropriateness criteria selected under subparagraph (D); and

''(III) is accessible to physicians participating in the demonstration project under this subsection in a format that allows for the electronic submission of such form; and

''(ii) provides for feedback reports in accordance with paragraph (3)(B).

''(G) POINT OF ORDER MODEL DESCRIBED.—A model described in this subparagraph is a model that—

''(i) uses a computerized order-entry system that requires the transmittal of relevant supporting information at the time of referral for advanced diagnostic imaging services and provides automated decision-support feedback to the referring physician regarding the appropriateness of furnishing such imaging services; and

''(ii) provides for feedback reports in accordance with paragraph (3)(B).

''(H) LIMITATION.—In no case may the Secretary use prior authorization—

''(i) as a model for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D) under the demonstration project under this subsection; or

''(ii) under any model used for collecting such data under the demonstration project.

''(I) REQUIRED CONTRACTS AND PERFORMANCE STANDARDS FOR CERTAIN ENTITIES.—

''(i) IN GENERAL.—The Secretary shall enter into contracts with entities to carry out the model described in subparagraph (G).

''(ii) PERFORMANCE STANDARDS.—The Secretary shall establish and enforce performance standards for such entities under the contracts entered into under clause (i), including performance standards with respect to—

''(I) the satisfaction of Medicare beneficiaries who are furnished advanced diagnostic imaging services by a physician participating in the demonstration project;

''(II) the satisfaction of physicians participating in the demonstration project;

''(III) if applicable, timelines for the provision of feedback reports under paragraph (3)(B); and

''(IV) any other areas determined appropriate by the Secretary.

''(3) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC IMAGING SERVICES AND FEEDBACK REPORTS.—

''(A) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC IMAGING SERVICES.—The Secretary shall consult with medical specialty societies and other stakeholders to develop mechanisms for comparing the utilization of advanced diagnostic imaging services by physicians participating in the demonstration project under this subsection against—

''(i) the appropriateness criteria selected under paragraph (2)(D); and

''(ii) to the extent feasible, the utilization of such services by physicians not participating in the demonstration project.

''(B) FEEDBACK REPORTS.—The Secretary shall, in consultation with medical specialty societies and other stakeholders, develop mechanisms to provide feedback reports to physicians participating in the demonstration project under this subsection. Such feedback reports shall include—

''(i) a profile of the rate of compliance by the physician with appropriateness criteria selected under paragraph (2)(D), including a comparison of—

''(I) the rate of compliance by the physician with such criteria; and

''(II) the rate of compliance by the physician's peers (as defined by the Secretary) with such criteria; and

''(ii) to the extent feasible, a comparison of—

''(I) the rate of utilization of advanced diagnostic imaging services by the physician; and

''(II) the rate of utilization of such services by the physician's peers (as defined by the Secretary) who are not participating in the demonstration project.

''(4) CONDUCT OF DEMONSTRATION PROJECT AND WAIVER.—

''(A) CONDUCT OF DEMONSTRATION PROJECT.—Chapter 35 of title 44, United States Code, shall not apply to the conduct of the demonstration project under this subsection.

''(B) WAIVER.—The Secretary may waive such provisions of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary to carry out the demonstration project under this subsection.

''(5) EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall evaluate the demonstration project under this subsection to—

''(i) assess the timeliness and efficacy of the demonstration project;

''(ii) assess the performance of entities under a contract entered into under paragraph (2)(I)(i);

''(iii) analyze data—

''(I) on the rates of appropriate, uncertain, and inappropriate advanced diagnostic imaging services furnished by physicians participating in the demonstration project;

''(II) on patterns and trends in the appropriateness and inappropriateness of such services furnished by such physicians;

''(III) on patterns and trends in national and regional variations of care with respect to the furnishing of such services; and

''(IV) on the correlation between the appropriateness of the services furnished and image results; and

''(iv) address—

''(I) the thresholds used under the demonstration project to identify acceptable and outlier levels of performance with respect to the appropriateness of advanced diagnostic imaging services furnished;

''(II) whether prospective use of appropriateness criteria could have an effect on the volume of such services furnished;

''(III) whether expansion of the use of appropriateness criteria with respect to such services to a broader population of Medicare beneficiaries would be advisable;

''(IV) whether, under such an expansion, physicians who demonstrate consistent compliance with such appropriateness criteria should be exempted from certain requirements;

''(V) the use of incident-specific versus practice-specific outlier information in formulating future recommendations with respect to the use of appropriateness criteria for such services under the Medicare program; and

''(VI) the potential for using methods (including financial incentives), in addition to those used under the models under the demonstration project, to ensure compliance with such criteria.

''(B) REPORT.—Not later than 1 year after the completion of the demonstration project under this subsection, the Secretary shall submit to Congress a report containing the results of the evaluation of the demonstration project conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

''(6) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of $10,000,000, for carrying out the demonstration project under this subsection (including costs associated with administering the demonstration project, reimbursing physicians for administrative costs and providing incentives to encourage participation under paragraph (2)(C), entering into contracts under paragraph (2)(I), and evaluating the demonstration project under paragraph (5)).''

AIR AMBULANCE PAYMENT IMPROVEMENTS

Pub. L. 110–275, title I, §146(b)(1), July 15, 2008, 122 Stat. 2548, as amended by Pub. L. 111–148, title III, §3105(b), title X, §10311(b), Mar. 23, 2010, 124 Stat. 417, 943; Pub. L. 111–309, title I, §106(b), Dec. 15, 2010, 124 Stat. 3287; Pub. L. 112–78, title III, §306(b), Dec. 23, 2011, 125 Stat. 1285; Pub. L. 112–96, title III, §3007(b), Feb. 22, 2012, 126 Stat. 190; Pub. L. 112–240, title VI, §604(b), Jan. 2, 2013, 126 Stat. 2348, provided that: ''Notwithstanding any other provision of law, for purposes of making payments under section 1834(*l*) of the Social Security Act (42 U.S.C. 1395m(*l*)) for air ambulance services furnished during the period beginning on July 1, 2008, and ending on June 30, 2013, any area that was designated as a rural area for purposes of making payments under such section for air ambulance services furnished on December 31, 2006, shall be treated as a rural area for purposes of making payments under such section for air ambulance services furnished during such period.''

EVALUATION OF CERTAIN CODE

Pub. L. 110–275, title I, §154(c)(3), July 15, 2008, 122 Stat. 2566, provided that: ''The Secretary of Health and

Human Services shall evaluate the existing Health Care Common Procedure Coding System (HCPCS) codes for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such codes. In carrying out such evaluation, the Secretary shall use an existing process, administered by the Durable Medical Equipment Medicare Administrative Contractors, for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.''

GAO REPORT ON CLASS III MEDICAL DEVICES

Pub. L. 108–173, title III, § 302(c)(1)(B), Dec. 8, 2003, 117 Stat. 2231, provided that: ''Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary [of Health and Human Services], a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C) [360c(a)(1)(C)]) furnished to medicare beneficiaries during 2007 and 2008.''

USE OF DATA

Pub. L. 108–173, title IV, § 414(c)(2), Dec. 8, 2003, 117 Stat. 2280, provided that: ''In order to promptly implement section 1834(*l*)(12) of the Social Security Act [42 U.S.C. 1395m(*l*)(12)], as added by paragraph (1), the Secretary [of Health and Human Services] may use data furnished by the Comptroller General of the United States.''

IMPLEMENTATION OF 2003 AMENDMENT

Pub. L. 108–173, title IV, § 414(e), Dec. 8, 2003, 117 Stat. 2280, provided that: ''The Secretary [of Health and Human Services] may implement the amendments made by this section [amending this section, section 1395x of this title, and provisions set out as a note under this section], and revise the conversion factor applicable under section 1834(*l*) of the Social Security Act (42 U.S.C. 1395m(*l*)) for purposes of implementing such amendments, on an interim final basis, or by program instruction.''

GAO REPORT ON COSTS AND ACCESS

Pub. L. 108–173, title IV, § 414(f), Dec. 8, 2003, 117 Stat. 2280, which required the Comptroller General of the United States to submit to Congress initial and final reports on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule under section 1395m(*l*) of this title, was repealed by Pub. L. 111–68, div. A, title I, § 1501(e)(1), Oct. 1, 2009, 123 Stat. 2041.

REPORT ON DEMONSTRATION PROJECT PERMITTING SKILLED NURSING FACILITIES TO BE ORIGINATING TELEHEALTH SITES; AUTHORITY TO IMPLEMENT

Pub. L. 108–173, title IV, § 418, Dec. 8, 2003, 117 Stat. 2283, provided that:

''(a) EVALUATION.—The Secretary [of Health and Human Services], acting through the Administrator of the Health Resources and Services Administration in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a))[)] are treated as originating sites for telehealth services.

''(b) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall include recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, as is otherwise required by the Secretary.

''(c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar as the Secretary concludes in the report required under subsection (b) that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and that the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, the Secretary may deem a skilled nursing facility to be an originating site under paragraph (4)(C)(ii) of such section beginning on January 1, 2006.''

PAYMENT FOR NEW TECHNOLOGIES

Pub. L. 106–554, § 1(a)(6) [title I, § 104(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–470, as amended by Pub. L. 108–173, title IX, § 900(e)(6)(H), Dec. 8, 2003, 117 Stat. 2374, provided that:

''(1) TESTS FURNISHED IN 2001.—

''(A) SCREENING.—For a screening mammography (as defined in section 1861(jj) of the Social Security Act (42 U.S.C. 1395x(jj))) furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology, payment for such screening mammography shall be made as follows:

''(i) In the case of a technology which directly takes a digital image (without involving film), in an amount equal to 150 percent of the amount of payment under section 1848 of such Act (42 U.S.C. 1395w–4) for a bilateral diagnostic mammography (under HCPCS code 76091) for such year.

''(ii) In the case of a technology which allows conversion of a standard film mammogram into a digital image and subsequently analyzes such resulting image with software to identify possible problem areas, in an amount equal to the limit that would otherwise be applied under section 1834(c)(3) of such Act (42 U.S.C. 1395m(c)(3)) for 2001, increased by $15.

''(B) BILATERAL DIAGNOSTIC MAMMOGRAPHY.—For a bilateral diagnostic mammography furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology described in subparagraph (A), payment for such mammography shall be the amount of payment provided for under such subparagraph.

''(C) ALLOCATION OF AMOUNTS.—The Secretary shall provide for an appropriate allocation of the amounts under subparagraphs (A) and (B) between the professional and technical components.

''(D) IMPLEMENTATION OF PROVISION.—The Secretary of Health and Human Services may implement the provisions of this paragraph by program memorandum or otherwise.

''(2) CONSIDERATION OF NEW HCPCS CODE FOR NEW TECHNOLOGIES AFTER 2001.—The Secretary shall determine, for such mammographies performed after 2001, whether the assignment of a new HCPCS code is appropriate for mammography that uses a new technology. If the Secretary determines that a new code is appropriate for such mammography, the Secretary shall provide for such new code for such tests furnished after 2001.

''(3) NEW TECHNOLOGY DESCRIBED.—For purposes of this subsection, a new technology with respect to a mammography is an advance in technology with respect to the test or equipment that results in the following:

''(A) A significant increase or decrease in the resources used in the test or in the manufacture of the equipment.

''(B) A significant improvement in the performance of the test or equipment.

''(C) A significant advance in medical technology that is expected to significantly improve the treatment of medicare beneficiaries.

''(4) HCPCS CODE DEFINED.—The term 'HCPCS code' means a code under the Health Care Common Procedure Coding System (HCPCS).''

MEDPAC STUDY AND REPORT ON MEDICARE COVERAGE OF CARDIAC AND PULMONARY REHABILITATION THERAPY SERVICES

Pub. L. 106–554, §1(a)(6) [title I, §127], Dec. 21, 2000, 114 Stat. 2763, 2763A–479, provided that:

''(a) STUDY.—

''(1) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study on coverage of cardiac and pulmonary rehabilitation therapy services under the medicare program under title XVIII of the Social Security Act [this subchapter].

''(2) FOCUS.—In conducting the study under paragraph (1), the Commission shall focus on the appropriate—

''(A) qualifying diagnoses required for coverage of cardiac and pulmonary rehabilitation therapy services;

''(B) level of physician direct involvement and supervision in furnishing such services; and

''(C) level of reimbursement for such services.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a) together with such recommendations for legislation and administrative action as the Commission determines appropriate.''

GAO STUDIES ON COSTS OF AMBULANCE SERVICES FURNISHED IN RURAL AREAS

Pub. L. 106–554, §1(a)(6) [title II, §221(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–486, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study on each of the matters described in paragraph (2).

''(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are the following:

''(A) The cost of efficiently providing ambulance services for trips originating in rural areas, with special emphasis on collection of cost data from rural providers.

''(B) The means by which rural areas with low population densities can be identified for the purpose of designating areas in which the cost of providing ambulance services would be expected to be higher than similar services provided in more heavily populated areas because of low usage. Such study shall also include an analysis of the additional costs of providing ambulance services in areas designated under the previous sentence.

''(3) REPORT.—Not later than June 30, 2002, the Comptroller General shall submit to Congress a report on the results of the studies conducted under paragraph (1) and shall include recommendations on steps that should be taken to assure access to ambulance services in rural areas.''

ADJUSTMENT IN RURAL RATES

Pub. L. 106–554, §1(a)(6) [title II, §221(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, as amended by Pub. L. 108–173, title IV, §414(f)(1), formerly §414(g)(1), Dec. 8, 2003, 117 Stat. 2281, as renumbered by Pub. L. 111–68, div. A, title I, §1501(e)(2), Oct. 1, 2009, 123 Stat. 2041, provided that: ''In providing for adjustments under subparagraph (D) of section 1834(*l*)(2) of the Social Security Act (42 U.S.C. 1395m(*l*)(2)) for years beginning with 2004, the Secretary of Health and Human Services shall take into consideration the recommendations contained in the report under subsection (b)(3) [set out above] and shall adjust the fee schedule payment rates under such section for ambulance services provided in low density rural areas based on the increased cost (if any) of providing such services in such areas.''

STUDY AND REPORT ON ADDITIONAL COVERAGE FOR TELEHEALTH SERVICES

Pub. L. 106–554, §1(a)(6) [title II, §223(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–489, provided that:

''(1) STUDY.—The Secretary of Health and Human Services shall conduct a study to identify—

''(A) settings and sites for the provision of telehealth services that are in addition to those permitted under section 1834(m) of the Social Security Act [42 U.S.C. 1395m(m)], as added by subsection (b);

''(B) practitioners that may be reimbursed under such section for furnishing telehealth services that are in addition to the practitioners that may be reimbursed for such services under such section; and

''(C) geographic areas in which telehealth services may be reimbursed that are in addition to the geographic areas where such services may be reimbursed under such section.

''(2) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation that the Secretary determines are appropriate.''

SPECIAL RULES FOR PAYMENTS FOR 2001

Pub. L. 106–554, §1(a)(6) [title IV, §423(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: ''Notwithstanding the amendment made by paragraph (1) [amending this section], for purposes of making payments for ambulance services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], for services furnished during 2001, the 'percentage increase in the consumer price index' specified in section 1834(*l*)(3)(B) of such Act (42 U.S.C. 1395m(*l*)(3)(B))—

''(A) for services furnished on or after January 1, 2001, and before July 1, 2001, shall be the percentage increase for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

''(B) for services furnished on or after July 1, 2001, and before January 1, 2002, shall be equal to 4.7 percent.''

Pub. L. 106–554, §1(a)(6) [title IV, §425(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–519, provided that: ''Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for durable medical equipment under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)), other than for oxygen and oxygen equipment specified in paragraph (9) of such section, the payment basis recognized for 2001 under such section—

''(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000] (including the application of section 228(a)(1) of BBRA [Pub. L. 106–113, §1000(a)(6) [title II, §228(a)(1)], set out as a note below]); and

''(2) for items furnished on or after July 1, 2001, and before January 1, 2002, shall be the payment basis that is determined under such section 1834(a) if such section 228(a)(1) did not apply and taking into account the amendment made by subsection (a), increased by a transitional percentage allowance equal to 3.28 percent (to account for the timing of implementation of the CPI update).''

Pub. L. 106–554, §1(a)(6) [title IV, §426(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–520, provided that: ''Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for prosthetic devices and orthotics and prosthetics (as defined in subparagraphs (B) and (C) of paragraph (4) of section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) under such section, the payment basis recognized for 2001 under paragraph (2) of such section—

''(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for

2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

''(2) for items furnished on or after July 1, 2001, and before January 1, 2002, shall be the payment basis that is determined under such section taking into account the amendments made by subsection (a), increased by a transitional percentage allowance equal to 2.6 percent (to account for the timing of implementation of the CPI update).''

PREEMPTION OF RULE

Pub. L. 106–554, §1(a)(6) [title IV, §428(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: ''The provisions of section 1834(h)(1)(G) [42 U.S.C. 1395m(h)(1)(G)] as added by subsection (a) shall supersede any rule that as of the date of the enactment of this Act [Dec. 21, 2000] may have applied a 5-year replacement rule with regard to prosthetic devices.''

GAO STUDY AND REPORT ON COSTS OF EMERGENCY AND MEDICAL TRANSPORTATION SERVICES

Pub. L. 106–554, §1(a)(6) [title IV, §436], Dec. 21, 2000, 114 Stat. 2763, 2763A–527, provided that:

''(a) STUDY.—The Comptroller General of the United States shall conduct a study on the costs of providing emergency and medical transportation services across the range of acuity levels of conditions for which such transportation services are provided.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Comptroller General shall submit to Congress a report on the study conducted under subsection (a), together with recommendations for any changes in methodology or payment level necessary to fairly compensate suppliers of emergency and medical transportation services and to ensure the access of beneficiaries under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].''

TREATMENT OF TEMPORARY PAYMENT INCREASES AFTER CALENDAR YEAR 2001

Pub. L. 106–554, §1(a)(6) [title V, §547(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–553, provided that: ''The payment increase provided under the following sections shall not apply after calendar year 2001 and shall not be taken into account in calculating the payment amounts applicable for items and services furnished after such year:

''(1) Section 401(c)(2) [set out as a note under section 1395*l* of this title] (relating to covered OPD services).

''(2) Section 422(e)(2) [set out as a note under section 1395rr of this title] (relating to renal dialysis services paid for on a composite rate basis).

''(3) Section 423(a)(2)(B) [set out above] (relating to ambulance services).

''(4) Section 425(b)(2) [set out above] (relating to durable medical equipment).

''(5) Section 426(b)(2) [set out above] (relating to prosthetic devices and orthotics and prosthetics).''

STUDY OF DELIVERY OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) OUTSIDE HOSPITALS AND PHYSICIANS' OFFICES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(n)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, required the Secretary of Health and Human Services to conduct a study of the extent to which intravenous immune globulin could be delivered and reimbursed under the medicare program outside of a hospital or physician's office and to submit a report on such study to Congress within 18 months after Nov. 29, 1999.

TEMPORARY INCREASE IN PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT AND OXYGEN

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §228], Nov. 29, 1999, 113 Stat. 1536, 1501A–356, provided that:

''(a) IN GENERAL.—For purposes of payments under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) for covered items (as defined in paragraph (13) of that section) furnished during 2001 and 2002, the Secretary of Health and Human Services shall increase the payment amount in effect (but for this section) for such items for—

''(1) 2001 by 0.3 percent, and

''(2) 2002 by 0.6 percent.

''(b) LIMITING APPLICATION TO SPECIFIED YEARS.—The payment amount increase—

''(1) under subsection (a)(1) shall not apply after 2001 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year; and

''(2) under subsection (a)(2) shall not apply after 2002 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year.''

DEMONSTRATION OF COVERAGE OF AMBULANCE SERVICES UNDER MEDICARE THROUGH CONTRACTS WITH UNITS OF LOCAL GOVERNMENT

Pub. L. 105–33, title IV, §4532, Aug. 5, 1997, 111 Stat. 453, as amended by Pub. L. 106–113, div. B, §1000(a)(6) [title II, §225], Nov. 29, 1999, 113 Stat. 1536, 1501A–353, provided that:

''(a) DEMONSTRATION PROJECT CONTRACTS WITH LOCAL GOVERNMENTS.—The Secretary of Health and Human Services shall establish up to 3 demonstration projects under which, at the request of a unit of local government, the Secretary enters into a contract with the unit of local government under which—

''(1) the unit of local government furnishes (or arranges for the furnishing of) ambulance services for which payment may be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for individuals residing in the unit of local government who are enrolled under such part, except that the unit of local government may not enter into the contract unless the contract covers at least 80 percent of the individuals residing in the unit of local government who are enrolled under such part but not in a Medicare+Choice plan;

''(2) any individual or entity furnishing ambulance services under the contract meets the requirements otherwise applicable to individuals and entities furnishing such services under such part; and

''(3) for each month during which the contract is in effect, the Secretary makes a capitated payment to the unit of local government in accordance with subsection (b).

The projects may extend over a period of not to exceed 3 years each. Not later than July 1, 2000, the Secretary shall publish a request for proposals for such projects.

''(b) AMOUNT OF PAYMENT.—

''(1) IN GENERAL.—The amount of the monthly payment made for months occurring during a calendar year to a unit of local government under a demonstration project contract under subsection (a) shall be equal to the product of—

''(A) the Secretary's estimate of the number of individuals covered under the contract for the month; and

''(B) 1/12 of the capitated payment rate for the year established under paragraph (2).

''(2) CAPITATED PAYMENT RATE DEFINED.—In this subsection, the term 'capitated payment rate' means, with respect to a demonstration project—

''(A) in its first year, a rate established for the project by the Secretary, using the most current available data, in a manner that ensures that aggregate payments under the project will not exceed the aggregate payment that would have been made for ambulance services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in the local area of government's jurisdiction; and

''(B) in a subsequent year, the capitated payment rate established for the previous year increased by an appropriate inflation adjustment factor.

''(c) OTHER TERMS OF CONTRACT.—The Secretary and the unit of local government may include in a contract

under this section such other terms as the parties consider appropriate, including—

''(1) covering individuals residing in additional units of local government (under arrangements entered into between such units and the unit of local government involved);

''(2) permitting the unit of local government to transport individuals to non-hospital providers if such providers are able to furnish quality services at a lower cost than hospital providers; or

''(3) implementing such other innovations as the unit of local government may propose to improve the quality of ambulance services and control the costs of such services.

''(d) CONTRACT PAYMENTS IN LIEU OF OTHER BENEFITS.—Payments under a contract to a unit of local government under this section shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the services covered under the contract which are furnished to individuals who reside in the unit of local government.

''(e) REPORT ON EFFECTS OF CAPITATED CONTRACTS.—

''(1) STUDY.—The Secretary shall evaluate the demonstration projects conducted under this section. Such evaluation shall include an analysis of the quality and cost-effectiveness of ambulance services furnished under the projects.

''(2) REPORT.—Not later than January 1, 2000, the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary considers appropriate, including recommendations regarding modifications to the methodology used to determine the amount of payments made under such contracts and extending or expanding such projects.''

[References to Medicare+Choice deemed to refer to Medicare Advantage, see section 201(b) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.]

[Pub. L. 106–113, div. B, §1000(a)(6) [title II, §225], Nov. 29, 1999, 113 Stat. 1536, 1501A–353, provided that the amendment made by that section to section 4532 of Pub. L. 105–33, set out above, is effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33.]

PAYMENT FREEZE FOR PARENTERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND EQUIPMENT

Pub. L. 105–33, title IV, §4551(b), Aug. 5, 1997, 111 Stat. 458, provided that: ''In determining the amount of payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to parenteral and enteral nutrients, supplies, and equipment during each of the years 1998 through 2002, 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 1995.''

SERVICE STANDARDS FOR PROVIDERS OF OXYGEN AND OXYGEN EQUIPMENT

Pub. L. 105–33, title IV, §4552(c), Aug. 5, 1997, 111 Stat. 459, provided that: ''The Secretary shall as soon as practicable establish service standards for persons seeking payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the providing of oxygen and oxygen equipment to beneficiaries within their homes.''

ACCESS TO HOME OXYGEN EQUIPMENT

Pub. L. 105–33, title IV, §4552(d), Aug. 5, 1997, 111 Stat. 459, provided that:

''(1) STUDY.—The Comptroller General of the United States shall study issues relating to access to home oxygen equipment and shall, within 18 months after the date of the enactment of this Act [Aug. 5, 1997], report to the Committees on Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate the results of the study, including recommendations (if any) for legislation.

''(2) PEER REVIEW EVALUATION.—The Secretary of Health and Human Services shall arrange for peer review [now ''quality improvement''] organizations established under section 1154 of the Social Security Act [42 U.S.C. 1320c–3] to evaluate access to, and quality of, home oxygen equipment.''

USE OF COVERED ITEMS BY DISABLED BENEFICIARIES

Pub. L. 103–432, title I, §131(b), Oct. 31, 1994, 108 Stat. 4419, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with representatives of suppliers of durable medical equipment under part B of the medicare program [42 U.S.C. 1395j et seq.] and individuals entitled to benefits under such program on the basis of disability, shall conduct a study of the effects of the methodology for determining payments for items of such equipment under such part on the ability of such individuals to obtain items of such equipment, including customized items.

''(2) REPORT.—Not later than one year after the date of the enactment of this Act [Oct. 31, 1994], the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary considers appropriate to assure that disabled medicare beneficiaries have access to items of durable medical equipment.''

CRITERIA FOR TREATMENT OF ITEMS AS PROSTHETIC DEVICES OR ORTHOTICS AND PROSTHETICS

Pub. L. 103–432, title I, §131(c), Oct. 31, 1994, 108 Stat. 4419, provided that not later than one year after Oct. 31, 1994, Secretary of Health and Human Services was to submit to Congress a report describing prosthetic devices or orthotics and prosthetics covered under this part that do not require individualized or custom fitting and adjustment to be used by a patient, including recommendations for appropriate methodology for determining amount of payment for such items.

ADJUSTMENT REQUIRED FOR CERTAIN ITEMS

Pub. L. 103–432, title I, §134(b), Oct. 31, 1994, 108 Stat. 4422, provided that:

''(1) IN GENERAL.—In accordance with section 1834(a)(10)(B) of the Social Security Act [42 U.S.C. 1395m(a)(10)(B)] (as amended by subsection (a)), the Secretary of Health and Human Services shall determine whether the payment amounts for the items described in paragraph (2) are not inherently reasonable, and shall adjust such amounts in accordance with such section if the amounts are not inherently reasonable.

''(2) ITEMS DESCRIBED.—The items referred to in paragraph (1) are decubitus care equipment, transcutaneous electrical nerve stimulators, and any other items considered appropriate by the Secretary.''

LIMITATION ON PREVAILING CHARGE FOR PHYSICIANS' RADIOLOGY SERVICES FURNISHED DURING 1991; EXCEPTIONS

Pub. L. 101–508, title IV, §4102(c), Nov. 5, 1990, 104 Stat. 1388–57, as amended by Pub. L. 103–432, title I, §126(b)(3), Oct. 31, 1994, 108 Stat. 4415, provided that:

''(1) IN GENERAL.—In applying part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], the prevailing charge for physicians' services, furnished during 1991, which are radiology services may not exceed the fee schedule amount established under section 1834(b) of such Act [42 U.S.C. 1395m(b)] with respect to such services.

''(2) EXCEPTION.—Paragraph (1) shall not apply to nuclear medicine services.''

LIMITATION ON CARRIER ADJUSTMENTS FOR RADIOLOGIST SERVICES FURNISHED DURING 1991

Pub. L. 101–508, title IV, §4102(e), Nov. 5, 1990, 104 Stat. 1388–57, provided that: ''For radiologist services

furnished during 1991 for which payment is made under section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)]—

''(1) a carrier may not make any adjustment, under section 1842(b)(3)(B) of such Act [42 U.S.C. 1395u(b)(3)(B)], in the payment amount for the service under section 1834(b) on the basis that the payment amount is higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier,

''(2) no payment adjustment may be made under section 1842(b)(8) of such Act, and

''(3) section 1842(b)(9) of such Act shall not apply.''

STUDY OF PAYMENTS FOR PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS

Pub. L. 101–508, title IV, § 4153(c), Nov. 9, 1990, 104 Stat. 1388–84, as amended by Pub. L. 103–432, title I, § 135(e)(6), Oct. 31, 1994, 108 Stat. 4424, directed Comptroller General to conduct a study of feasibility and desirability of establishing a separate fee schedule for use in determining the amount of payments for covered items under subsec. (h) of this section with respect to suppliers of prosthetic devices, orthotics, and prosthetics who provide professional services that would take into account the costs to such providers of providing such services and, not later than 1 year after Nov. 5, 1990, submit a report on the study to Committees on Energy and Commerce and Ways and Means of House of Representatives and Committee on Finance of Senate, including any recommendations regarding payments for prosthetic devices, orthotics, and prosthetics under the medicare program.

SPECIAL RULE FOR NUCLEAR MEDICINE PHYSICIANS

Pub. L. 101–239, title VI, § 6105(b), Dec. 19, 1989, 103 Stat. 2210, as amended by Pub. L. 101–508, title IV, § 4102(g)(1), Nov. 5, 1990, 104 Stat. 1388–57, provided that: ''In applying section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)] with respect to nuclear medicine services furnished by a physician for whom nuclear medicine services account for at least 80 percent of the total amount of charges made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] beginning April 1, 1990, and ending December 31, 1991, there shall be substituted for the fee schedule otherwise applicable a fee schedule based ⅓ on the fee schedule computed under such section (without regard to this subsection) and ⅔ on 101 percent of the 1988 prevailing charge for such services.''

SPECIAL RULE FOR INTERVENTIONAL RADIOLOGISTS; ''SPLIT BILLING''

Pub. L. 101–239, title VI, § 6105(c), Dec. 19, 1989, 103 Stat. 2210, as amended by Pub. L. 101–508, title IV, § 4102(h), Nov. 5, 1990, 104 Stat. 1388–58, provided that: ''In applying section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)] to radiologist services furnished in 1990 or 1991, the exception for 'split billing' set forth at section 5262J of the Medicare Carriers Manual shall apply to services furnished in 1990 or 1991 in the same manner and to the same extent as the exception applied to services furnished in 1989.''

RENTAL PAYMENTS FOR ENTERAL AND PARENTERAL PUMPS

Pub. L. 101–239, title VI, § 6112(b), Dec. 19, 1989, 103 Stat. 2215, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amount of any monthly rental payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for an enteral or parenteral pump furnished on or after April 1, 1990, shall be determined in accordance with the methodology under which monthly rental payments for such pumps were determined during 1989.

''(2) CAP ON RENTAL PAYMENTS, SERVICING, AND REPAIRS.—In the case of an enteral or parenteral pump described in paragraph (1) that is furnished on a rental basis during a period of medical need—

''(A) monthly rental payments shall not be made under part B of title XVIII of the Social Security Act for more than 15 months during such period, and

''(B) after monthly rental payments have been made for 15 months during such period, payment under such part shall be made for maintenance and servicing of the pump in such amounts as the Secretary of Health and Human Services determines to be reasonable and necessary to ensure the proper operation of the pump.''

TREATMENT OF POWER-DRIVEN WHEELCHAIRS AS CUSTOMIZED ITEMS

Pub. L. 101–239, title VI, § 6112(d)(2), Dec. 19, 1989, 103 Stat. 2215, provided that: ''The Secretary of Health and Human Services shall by regulation specify criteria to be used by carriers in making determinations on a case-by-case basis as whether to classify power-driven wheelchairs as a customized item (as described in section 1834(a)(4) of the Social Security Act [42 U.S.C. 1395m(a)(4)]) for purposes of reimbursement under title XVIII of such Act [42 U.S.C. 1395 et seq.].''

STUDY OF PAYMENT FOR PORTABLE X-RAY SERVICES

Pub. L. 101–239, title VI, § 6134, Dec. 19, 1989, 103 Stat. 2222, directed Secretary of Health and Human Services to conduct a study of costs of furnishing, and payments for, portable x-ray services under part B and, not later than 1 year after Dec. 19, 1989, report to Congress on results of such study including a recommendation respecting whether payment for such services should be made in the same manner as for radiologists' services or on the basis of a separate fee schedule.

GAO STUDY OF STANDARDS FOR USE OF AND PAYMENT FOR ITEMS OF DURABLE MEDICAL EQUIPMENT

Pub. L. 101–239, title VI, § 6139, Dec. 19, 1989, 103 Stat. 2224, directed Comptroller General to conduct a study of appropriate uses of items of durable medical equipment and of appropriate criteria for making determinations of medical necessity under this subchapter for such items, with particular emphasis on items (including seat-lift chairs) that may be subject to abusive billing practices, such study to include an analysis of appropriate use of forms in making medical necessity determinations for items of durable medical equipment under such title, and procedures for identifying items of durable medical equipment that should no longer be covered under this subchapter, and to be conducted with a panel convened by the Comptroller General consisting of specialists in the disciplines of orthopedic medicine, rehabilitation, arthritis, and geriatric medicine, representatives of consumer organizations, and representatives of carriers under the medicare program, with the Comptroller General to submit not later than Apr. 1, 1991, a report to Committees on Ways and Means and Energy and Commerce of House of Representatives and Committee on Finance of Senate on the study including recommendations.

REPORTS ON MEDICARE BENEFICIARY DRUG EXPENSES

Pub. L. 100–360, title II, § 202(i), July 1, 1988, 102 Stat. 718, directed Secretary of Health and Human Services, by not later than Apr. 1, 1989, to report to Congress on expenses incurred by medicare beneficiaries for outpatient prescription drugs, and to provide Director of Congressional Budget Office with such data from that Survey as Director might request to make required estimates, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

ADDITIONAL STUDIES BY SECRETARY OR COMPTROLLER GENERAL

Pub. L. 100–360, title II, § 202(k), July 1, 1988, 102 Stat. 719, directed Secretary of Health and Human Services to conduct a study, and make a report to Congress by Jan. 1, 1990, on possibility of including drugs which

have not yet been approved under section 355 or 357 of Title 21, Food and Drugs, and biological products which have not been licensed under section 262 of this title but which are commonly used in the treatment of cancer or in immunosuppressive therapy and other experimental drugs and biological products as covered outpatient drugs under medicare program, to conduct a study, and report to Congress by Jan. 1, 1990, evaluating potential to use mail service pharmacies to reduce costs to medicare program and to medicare beneficiaries, to conduct a study, and report to Congress by Jan. 1, 1993, on methods to improve utilization review of covered outpatient drugs, and to conduct a longitudinal study, and report to Congress by Jan. 1, 1993, on use of outpatient prescription drugs by medicare beneficiaries with respect to medical necessity, potential for adverse drug interactions, cost (including whether lower cost drugs could have been used), and patient stockpiling or wastage, and which further directed Comptroller General to conduct studies, and report to Congress by not later than May 1, 1991, on comparing average wholesale prices with actual pharmacy acquisition costs by type of pharmacy, on determining the overhead costs of retail pharmacies, and on discounts given by pharmacies to other third-party insurers, prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

DEVELOPMENT OF STANDARD MEDICARE CLAIMS FORMS

Pub. L. 100–360, title II, §202(*l*), July 1, 1988, 102 Stat. 720, directed Secretary of Health and Human Services to develop, in consultation with representatives of pharmacies and other interested individuals, a standard claims form (and a standard electronic claims format) to be used in requests for payment for covered outpatient drugs under medicare program and other third-party payors, prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

STUDIES AND REPORTS ON SCREENING MAMMOGRAPHY

Pub. L. 100–360, title II, §204(f), July 1, 1988, 102 Stat. 729, directed Physician Payment Review Commission to study and report, by July 1, 1989, to Committees on Ways and Means and Energy and Commerce of the House of Representatives and Committee on Finance of the Senate concerning the cost of providing screening mammography in a variety of settings and at different volume levels, prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

DEADLINE FOR ESTABLISHMENT OF FEE SCHEDULES FOR RADIOLOGIST SERVICES; REPORT TO CONGRESS

Pub. L. 100–203, title IV, §4049(b)(1), Dec. 22, 1987, 101 Stat. 1330–92, as amended by Pub. L. 100–360, title IV, §411(f)(8)(E), July 1, 1988, 102 Stat. 780; Pub. L. 101–508, title IV, §4118(g)(3), Nov. 5, 1990, 104 Stat. 1388–70, directed Secretary of Health and Human Services to propose the relative value scale and fee schedules for radiologist services (under subsec. (b) of this section) by not later than Aug. 1, 1988.

STUDY AND EVALUATION

Pub. L. 100–203, title IV, §4062(c), Dec. 22, 1987, 101 Stat. 1330–107, as amended by Pub. L. 100–360, title IV, §411(g)(1)(C), July 1, 1988, 102 Stat. 782, provided that:

''(1) The Secretary of Health and Human Services shall monitor the impact of the amendments made by this section [enacting this section, amending sections 1395f, 1395k, 1395*l*, and 1395cc of this title, and repealing section 1395zz of this title] on the availability of covered items and shall evaluate the appropriateness of the volume adjustment for oxygen and oxygen equipment under section 1834(a)(5)(C) of the Social Security Act [42 U.S.C. 1395m(a)(5)(C)] (as amended by subsection (b) of this section). The Secretary shall report to Congress, by not later than January 1, 1991, on such impact and on the evaluation and shall include in such report recommendations for changes in payment methodology for covered items under section 1834(a) of such Act.

''(2) Before January 1, 1991, the Secretary may not conduct any demonstration project respecting alternative methods of payment for covered items under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

''(3) In this subsection, the term 'covered item' has the meaning given such term in section 1834(a)(13) of the Social Security Act [42 U.S.C. 1395m(a)(13)] (as amended by subsection (b) of this section).

''(4) The Secretary shall, upon written request and payment of a reasonable copying fee which the Secretary may establish, provide the data and information used in determining the payment amounts for covered items under section 1834(a) of the Social Security Act [42 U.S.C. 1395m(a)], but only in a form which does not permit identification of individual suppliers.

''(5) The Comptroller General shall conduct a study on the appropriateness of the level of payments allowed for covered items under the medicare program, and shall report to Congress on the results of such study (including recommendations on the transition to regional or national rates) by not later than January 1, 1991. Entities furnishing such items which fail to provide the Comptroller General with reasonable access to necessary records to carry out the study under this paragraph are subject to exclusion from the medicare program under section 1128(a) of the Social Security Act [42 U.S.C. 1320a–7(a)].''

§ 1395m–1. Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

Beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(2) Definition of applicable laboratory

In this section, the term ''applicable laboratory'' means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w–4 of this title. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

In this section, subject to subparagraph (B), the term ''applicable information'' means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

In this section, the term ''data collection period'' means a period of time, such as a previous 12 month period, specified by the Secretary.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1395w–3a(c)(3) of this title.

(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term ''private payor'' means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined in section 300gg–91 of this title).

(B) A Medicare Advantage plan under part C of this subchapter.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).

(9) Civil money penalty

(A) In general

If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

(B) Application

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

(10) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except—

(A) as the Secretary determines to be necessary to carry out this section;

(B) to permit the Comptroller General to review the information provided;

(C) to permit the Director of the Congressional Budget Office to review the information provided; and

(D) to permit the Medicare Payment Advisory Commission to review the information provided.

(11) Protection from public disclosure

A payor shall not be identified on information reported under this subsection. The name of an applicable laboratory under this subsection shall be exempt from disclosure under section 552(b)(3) of title 5.

(12) Regulations

Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection.

(b) Payment for clinical diagnostic laboratory tests

(1) Use of private payor rate information to determine medicare payment rates

(A) In general

Subject to paragraph (3) and subsections (c) and (d), in the case of a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period.

(B) Application of payment amounts to hospital laboratories

The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1395*l*(t) of this title.

(2) Calculation of weighted median

For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.

(3) Phase-in of reductions from private payor rate implementation

(A) In general

Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2022 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent

(as defined in subparagraph (B)) of the amount of payment for the test for the preceding year.

(B) Applicable percent defined

In this paragraph, the term ''applicable percent'' means—

(i) for each of 2017 through 2019, 10 percent; and

(ii) for each of 2020 through 2022, 15 percent.

(C) No application to new tests

This paragraph shall not apply to payment amounts determined under this section for either of the following.

(i) A new test under subsection (c).

(ii) A new advanced diagnostic test[1] (as defined in subsection (d)(5)) under subsection (d).

(4) Application of market rates

(A) In general

Subject to paragraph (3), once established for a year following a data collection period, the payment amounts under this subsection shall continue to apply until the year following the next data collection period.

(B) Other adjustments not applicable

The payment amounts under this section shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

(5) Sample collection fee

In the case of a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, the nominal fee that would otherwise apply under section 1395*l*(h)(3)(A) of this title shall be increased by $2.

(c) Payment for new tests that are not advanced diagnostic laboratory tests

(1) Payment during initial period

In the case of a clinical diagnostic laboratory test that is assigned a new or substantially revised HCPCS code on or after April 1, 2014, and which is not an advanced diagnostic laboratory test (as defined in subsection (d)(5)), during an initial period until payment rates under subsection (b) are established for the test, payment for the test shall be determined—

(A) using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period; or

(B) if no existing test is comparable to the new test, according to the gapfilling process described in paragraph (2).

(2) Gapfilling process described

The gapfilling process described in this paragraph shall take into account the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges.

(B) Resources required to perform the test.

(C) Payment amounts determined by other payors.

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

(E) Other criteria the Secretary determines appropriate.

(3) Additional consideration

In determining the payment amount under crosswalking or gapfilling processes under this subsection, the Secretary shall consider recommendations from the panel established under subsection (f)(1).

(4) Explanation of payment rates

In the case of a clinical diagnostic laboratory test for which payment is made under this subsection, the Secretary shall make available to the public an explanation of the payment rate for the test, including an explanation of how the criteria described in paragraph (2) and paragraph (3) are applied.

(d) Payment for new advanced diagnostic laboratory tests

(1) Payment during initial period

(A) In general

In the case of an advanced diagnostic laboratory test for which payment has not been made under the fee schedule under section 1395*l*(h) of this title prior to April 1, 2014, during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test.

(B) Actual list charge

For purposes of subparagraph (A), the term ''actual list charge'', with respect to a laboratory test furnished during such period, means the publicly available rate on the first day at which the test is available for purchase by a private payor.

(2) Special rule for timing of initial reporting

With respect to an advanced diagnostic laboratory test described in paragraph (1)(A), an applicable laboratory shall initially be required to report under subsection (a) not later than the last day of the second quarter of the initial period under such paragraph.

(3) Application of market rates after initial period

Subject to paragraph (4), data reported under paragraph (2) shall be used to establish the payment amount for an advanced diagnostic laboratory test after the initial period under paragraph (1)(A) using the methodology described in subsection (b). Such payment amount shall continue to apply until the year following the next data collection period.

(4) Recoupment if actual list charge exceeds market rate

With respect to the initial period described in paragraph (1)(A), if, after such period, the Secretary determines that the payment amount for an advanced diagnostic laboratory

[1] So in original. Probably should be preceded by ''laboratory''.

test under paragraph (1)(A) that was applicable during the period was greater than 130 percent of the payment amount for the test established using the methodology described in subsection (b) that is applicable after such period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

(5) Advanced diagnostic laboratory test defined

In this subsection, the term ''advanced diagnostic laboratory test'' means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

(B) The test is cleared or approved by the Food and Drug Administration.

(C) The test meets other similar criteria established by the Secretary.

(e) Coding

(1) Temporary codes for certain new tests

(A) In general

The Secretary shall adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests (as defined in subsection (d)(5)) and new laboratory tests that are cleared or approved by the Food and Drug Administration.

(B) Duration

(i) In general

Subject to clause (ii), the temporary code shall be effective until a permanent HCPCS code is established (but not to exceed 2 years).

(ii) Exception

The Secretary may extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

(2) Existing tests

Not later than January 1, 2016, for each existing advanced diagnostic laboratory test (as so defined) and each existing clinical diagnostic laboratory test that is cleared or approved by the Food and Drug Administration for which payment is made under this part as of April 1, 2014, if such test has not already been assigned a unique HCPCS code, the Secretary shall—

(A) assign a unique HCPCS code for the test; and

(B) publicly report the payment rate for the test.

(3) Establishment of unique identifier for certain tests

For purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an advanced diagnostic laboratory test (as so defined) or a laboratory test that is cleared or approved by the Food and Drug Administration, the Secretary shall utilize a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

(f) Input from clinicians and technical experts

(1) In general

The Secretary shall consult with an expert outside advisory panel, established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests, to provide—

(A) input on—

(i) the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and

(ii) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and

(B) recommendations to the Secretary under this section.

(2) Compliance with FACA

The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(3) Continuation of annual meeting

The Secretary shall continue to convene the annual meeting described in section 1395*l*(h)(8)(B)(iii) of this title after the implementation of this section for purposes of receiving comments and recommendations (and data on which the recommendations are based) as described in such section on the establishment of payment amounts under this section.

(g) Coverage

(1) Issuance of coverage policies

(A) In general

A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1395ff(f)(2)(B) of this title), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).

(B) No effect on national coverage determination process

This paragraph shall not apply to the national coverage determination process (as defined in section 1395ff(f)(1)(B) of this title).

(C) Effective date

This paragraph shall apply to coverage policies issued on or after January 1, 2015.

(2) Designation of one or more medicare administrative contractors for clinical diagnostic laboratory tests

The Secretary may designate one or more (not to exceed 4) medicare administrative con-

tractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary.

(h) Implementation

(1) Implementation

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of the establishment of payment amounts under this section.

(2) Administration

Chapter 35 of title 44 shall not apply to information collected under this section.

(3) Funding

For purposes of implementing this section, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to the Centers for Medicare & Medicaid Services Program Management Account, for each of fiscal years 2014 through 2018, $4,000,000, and for each of fiscal years 2019 through 2023, $3,000,000. Amounts transferred under the preceding sentence shall remain available until expended.

(i) Transitional rule

During the period beginning on April 1, 2014, and ending on December 31, 2016, with respect to advanced diagnostic laboratory tests under this part, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before April 1, 2014, which may include cross-walking or gapfilling methods.

(Aug. 14, 1935, ch. 531, title XVIII, § 1834A, as added Pub. L. 113–93, title II, § 216(a), Apr. 1, 2014, 128 Stat. 1053.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (f)(2), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS

Pub. L. 113–93, title II, § 216(c)(2), Apr. 1, 2014, 128 Stat. 1061, provided that: ''The Inspector General of the Department of Health and Human Services shall—

''(A) publicly release an annual analysis of the top 25 laboratory tests by expenditures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

''(B) conduct analyses the Inspector General determines appropriate with respect to the implementation and effect of the new payment system for laboratory tests under section 1834A of the Social Security Act [42 U.S.C. 1395m–1], as added by subsection (a).''

§ 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e) of this section, payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service; and

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1395x(s)(2) of this title, such services are or were medically required;

(C) in the case of outpatient physical therapy services or outpatient occupational therapy services, (i) such services are or were required because the individual needed physical therapy services or occupational therapy services, respectively, (ii) a plan for furnishing such services has been established by a physician or by the qualified physical therapist or qualified occupational thera-

pist, respectively, providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(D) in the case of outpatient speech pathology services, (i) such services are or were required because the individual needed speech pathology services, (ii) a plan for furnishing such services has been established by a physician or by the speech pathologist providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(E) in the case of comprehensive outpatient rehabilitation facility services, (i) such services are or were required because the individual needed skilled rehabilitation services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician; and

(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

For purposes of this section, the term ''provider of services'' shall include a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) of this title (or meets the requirements of such section through the operation of subsection (g) or (*ll*)(2) of section 1395x of this title), or if, in the case of a public health agency, such agency meets the requirements of section 1395x(p)(4)(B) of this title (or meets the requirements of such section through the operation of subsection (g) or (*ll*)(2) of section 1395x of this title), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of subsection (g) or (*ll*)(2) of section 1395x of this title) with respect to the furnishing of outpatient occupational therapy services or outpatient speech-language pathology services, respectively.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be ''confined to his home'' if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered ''confined to his home'', the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be ''confined to his home''. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

(b) Conditions for payment for services described in section 1395x(s) of this title

(1) Payment may also be made to any hospital for services described in section 1395x(s) of this title furnished as an outpatient service by a hospital or by others under arrangements made by it to an individual entitled to benefits under this part even though such hospital does not have an agreement in effect under this subchapter if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has made an election pursuant to section 1395f(d)(1)(C) of this title with respect to the calendar year in which such emergency services are provided. Such payments shall be made only in the amounts provided under section 1395*l*(a)(2) of this title and then only if such hospital agrees

to comply, with respect to the emergency services provided, with the provisions of section 1395cc(a) of this title.

(2) Payment may also be made on the basis of an itemized bill to an individual for services described in paragraph (1) of this subsection if (A) payment cannot be made under such paragraph (1) solely because the hospital does not elect, in accordance with section 1395f(d)(1)(C) of this title, to claim such payments and (B) such individual files application (submitted within such time and in such form and manner, and containing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amounts payable under this paragraph shall, subject to the provisions of section 1395*l* of this title, be equal to 80 percent of the hospital's reasonable charges for such services.

(c) Collection of charges from individuals for services specified in section 1395x(s) of this title

Notwithstanding the provisions of this section and sections 1395k, 1395*l*, and 1395cc(a)(1)(A) of this title, a hospital or a critical access hospital may, subject to such limitations as may be prescribed by regulations, collect from an individual the customary charges for services specified in section 1395x(s) of this title and furnished to him by such hospital as an outpatient, but only if such charges for such services do not exceed the applicable supplementary medical insurance deductible, and such customary charges shall be regarded as expenses incurred by such individual with respect to which benefits are payable in accordance with section 1395*l*(a)(1) of this title. Payments under this subchapter to hospitals which have elected to make collections from individuals in accordance with the preceding sentence shall be adjusted periodically to place the hospital in the same position it would have been had it instead been reimbursed in accordance with section 1395*l*(a)(2) of this title (or, in the case of a critical access hospital, in accordance with section 1395*l*(a)(6) of this title).

(d) Payment to Federal provider of services or other Federal agencies prohibited

Subject to section 1395qq of this title, no payment may be made under this part to any Federal provider of services or other Federal agency, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any provider of services or other person for any item or service which such provider or person is obligated by a law of, or a contract with, the United States to render at public expense.

(e) Payment to fund designated by medical staff or faculty of medical school

For purposes of services (1) which are inpatient hospital services by reason of paragraph (7) of section 1395x(b) of this title or for which entitlement exists by reason of clause (II) of section 1395k(a)(2)(B)(i) of this title, and (2) for which the reasonable cost thereof is determined under section 1395x(v)(1)(D) of this title (or would be if section 1395ww of this title did not apply), payment under this part shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school, to such fund as may be designated by such faculty, but only if—

(A) such hospital has an agreement with the Secretary under section 1395cc of this title, and

(B) the Secretary has received written assurances that (i) such payment will be used by such fund solely for the improvement of care to patients in such hospital or for educational or charitable purposes and (ii) the individuals who were furnished such services or any other persons will not be charged for such services (or if charged provision will be made for return of any moneys incorrectly collected).

(Aug. 14, 1935, ch. 531, title XVIII, § 1835, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 303; amended Pub. L. 90–248, title I, §§ 126(b), 129(c)(9)(A), (B), 130(a), (b), 133(e), Jan. 2, 1968, 81 Stat. 846, 848, 849, 851; Pub. L. 92–603, title II, §§ 204(b), 227(e)(2), 251(b)(2), 281(f), 283(b), Oct. 30, 1972, 86 Stat. 1377, 1406, 1445, 1456; Pub. L. 94–437, title IV, § 401(a), Sept. 30, 1976, 90 Stat. 1408; Pub. L. 96–499, title IX, §§ 930(e), (j), 933(b), 944(a), Dec. 5, 1980, 94 Stat. 2631, 2632, 2635, 2642; Pub. L. 97–35, title XXI, §§ 2106(b)(1), 2122(a)(1), Aug. 13, 1981, 95 Stat. 792, 796; Pub. L. 98–21, title VI, § 602(b), Apr. 20, 1983, 97 Stat. 163; Pub. L. 98–369, div. B, title III, §§ 2336(a), (b), 2342(b), 2354(b)(1), (8), (9), July 18, 1984, 98 Stat. 1091, 1094, 1100; Pub. L. 98–617, § 3(a)(3), Nov. 8, 1984, 98 Stat. 3295; Pub. L. 99–509, title IX, § 9337(c), Oct. 21, 1986, 100 Stat. 2034; Pub. L. 100–203, title IV, §§ 4024(b), 4070(b)(3), 4085(i)(4), Dec. 22, 1987, 101 Stat. 1330–74, 1330–115, 1330–132; Pub. L. 100–360, title II, §§ 203(d)(1), 205(d), July 1, 1988, 102 Stat. 724, 731; Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101–239, title VI, § 6003(g)(3)(D)(viii), Dec. 19, 1989, 103 Stat. 2153; Pub. L. 101–508, title IV, § 4008(m)(2)(D), Nov. 5, 1990, 104 Stat. 1388–53; Pub. L. 105–33, title IV, §§ 4201(c)(1), 4615(a), Aug. 5, 1997, 111 Stat. 373, 475; Pub. L. 106–554, § 1(a)(6) [title V, § 507(a)(1)], Dec. 21, 2000, 114 Stat. 2763, 2763A–532; Pub. L. 108–173, title VII, § 736(c)(2)(B), Dec. 8, 2003, 117 Stat. 2356; Pub. L. 110–275, title I, § 143(b)(4), July 15, 2008, 122 Stat. 2543; Pub. L. 111–148, title VI, §§ 6404(a)(2)(B), 6405(b)(2), 6407(a)(2), title X, §§ 10604, 10605(b), Mar. 23, 2010, 124 Stat. 768, 770, 1006.)

AMENDMENTS

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

Subsec. (a)(1). Pub. L. 111–148, § 6404(a)(2)(B)(i), substituted ''period ending 1 calendar year after the date of service;'' for ''period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;''.

Subsec. (a)(2). Pub. L. 111–148, § 6405(b)(2), as amended by Pub. L. 111–148, § 10604, inserted '', or, in the case of services described in subparagraph (A), a physician en-

rolled under section 1395cc(j) of this title,'' after ''a physician'' in introductory provisions.

Subsec. (a)(2)(A)(iv). Pub. L. 111–148, §10605(b), inserted '', or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician,'' after ''must document that the physician''.

Pub. L. 111–148, §6407(a)(2), added cl. (iv).

2008—Subsec. (a). Pub. L. 110–275, in second sentence, substituted ''subsection (g) or (*ll*)(2) of section 1395x of this title'' for ''section 1395x(g) of this title'' wherever appearing and inserted ''or outpatient speech-language pathology services, respectively'' before period at end.

2003—Subsec. (a). Pub. L. 108–173 substituted ''leave home and'' for ''leave home,'' in fifth sentence of concluding provisions.

2000—Subsec. (a). Pub. L. 106–554, in concluding provisions, struck out '', and that absences of the individual from home are infrequent or of relatively short duration, or are attributable to the need to receive medical treatment'' after ''taxing effort by the individual'' and inserted at end ''Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be 'confined to his home'. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.''

1997—Subsec. (a)(2)(A). Pub. L. 105–33, §4615(a), inserted ''(other than solely venipuncture for the purpose of obtaining a blood sample)'' after ''skilled nursing care''.

Subsec. (c). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care'' in two places.

1990—Subsec. (c). Pub. L. 101–508 substituted ''a hospital or a rural primary care hospital may'' for ''a hospital may'' in first sentence, substituted ''section 1395*l*(a)(2) of this title (or, in the case of a rural primary care hospital, in accordance with section 1395*l*(a)(6) of this title)'' for ''section 1395*l*(a)(2) of this title'' in second sentence, and struck out at end ''A rural primary care hospital shall be considered a hospital for purposes of this subsection.''

1989—Subsec. (a)(2)(G), (H). Pub. L. 101–234 repealed Pub. L. 100–360, §§203(d)(1), 205(d), 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. (c). Pub. L. 101–239 inserted at end ''A rural primary care hospital shall be considered a hospital for purposes of this subsection.''

1988—Subsec. (a)(2)(G). Pub. L. 100–360, §203(d)(1), added subpar. (G) relating to home intravenous drug therapy services.

Subsec. (a)(2)(H). Pub. L. 100–360, §205(d), added subpar. (H) relating to in-home care provided to chronically dependent individuals.

1987—Subsec. (a). Pub. L. 100–203, §4024(b), inserted two sentences at end clarifying ''confined to his home'' for purposes of par. (2)(A).

Subsec. (a)(2)(C)(i). Pub. L. 100–203, §4085(i)(4), struck out second comma at end.

Subsec. (a)(2)(F). Pub. L. 100–203, §4070(b)(3), added subpar. (F).

1986—Subsec. (a). Pub. L. 99–509, §9337(c)(2), inserted in second sentence ''(or meets the requirements of such section through the operation of section 1395x(g) of this title)'' in two places, and ''or (through the operation of section 1395x(g) of this title) with respect to the furnishing of outpatient occupational therapy services''.

Subsec. (a)(2)(C). Pub. L. 99–509, §9337(c)(1), inserted ''or outpatient occupational therapy services'' in introductory provisions, ''or occupational therapy services, respectively,'' in cl. (i), and ''or qualified occupational therapist, respectively,'' in cl. (ii).

1984—Subsec. (a). Pub. L. 98–369, §2354(b)(1), as amended by Pub. L. 98–617, §3(a)(3), in concluding provisions, substituted ''contractual'' for ''contractural''.

Pub. L. 98–369, §2336(b), inserted before period at end of fourth sentence '', except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary)''.

Pub. L. 98–369, §2336(a), inserted sentence at end that for purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency.

Subsec. (a)(2)(B), (C). Pub. L. 98–369, §2354(b)(8)(A), struck out ''and'' at end.

Subsec. (a)(2)(C)(ii). Pub. L. 98–369, §2342(b), substituted ''by a physician or by the qualified physical therapist providing such services and is periodically reviewed by a physician'' for '', and is periodically reviewed, by a physician''.

Subsec. (a)(2)(D). Pub. L. 98–369, §2354(b)(8)(B), realigned margin of subpar. (D).

Subsec. (e)(2). Pub. L. 98–369, §2354(b)(9), designated concluding pars. (1) and (2) as (A) and (B), respectively, and in par. (B) inserted ''(i)'' after ''written assurances that'' and substituted ''(ii) the individuals who'' for ''(B) the individuals who'' and ''return of'' for ''return for''.

1983—Subsec. (e). Pub. L. 98–21 inserted ''(or would be if section 1395ww of this title did not apply)'' after ''section 1395(v)(1)(D) of this title''.

1981—Subsec. (a)(2)(A). Pub. L. 97–35, §2122(a)(1), substituted ''needs or needed skilled nursing care on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy'' for ''needed skilled nursing care on an intermittent basis, or physical, occupational, or speech therapy''.

Subsec. (a)(2)(D). Pub. L. 97–35, §2106(b)(1), inserted ''and'' after ''physician;''.

Subsec. (a)(2)(E). Pub. L. 97–35, §2106(b)(1), substituted a period for ''; and'' at the end.

1980—Subsec. (a). Pub. L. 96–499, §930(e), inserted sentence at end authorizing Secretary to prescribe regulations to prohibit significantly interested physicians from performing physician certification required by par. (2) for home health services.

Subsec. (a)(2)(A). Pub. L. 96–499, §930(j), substituted ''physical, occupational, or speech'' for ''physical or speech''.

Subsec. (a)(2)(D)(ii). Pub. L. 96–499, §944(a), inserted ''by a physician or by the speech pathologist providing such services'', after ''has been established''.

Subsec. (a)(2)(E). Pub. L. 96–499, §933(b), added subpar. (E).

1976—Subsec. (d). Pub. L. 94–437 substituted ''Subject to section 1395qq of this title, no payment'' for ''No payment''.

1972—Subsec. (a). Pub. L. 92–603, §227(e)(2)(A), inserted reference to subsec. (e) of this section in introductory provisions.

Subsec. (a)(1). Pub. L. 92–603, §281(f), placed a 3-year time limitation on time within which a written request for payment is filed, with provision for reduction of limit to 1 year.

Subsec. (a)(2)(C). Pub. L. 92–603, §251(b)(2), substituted ''because the individual needed physical therapy services'' for ''because the individual needed physical therapy services on an outpatient basis''.

Subsec. (a)(2)(D). Pub. L. 92–603, § 283(b), added subpar. (D).

Subsec. (c). Pub. L. 92–603, § 204(b), substituted ''the applicable supplementary medical insurance deductible'' for ''$50''.

Subsec. (e). Pub. L. 92–603, § 227(e)(2)(B), added subsec. (e).

1968—Subsec. (a). Pub. L. 90–248, §§ 129(c)(9)(A), 130(a), inserted introductory exception phrase and included reference to subsec. (c).

Subsec. (a)(2). Pub. L. 90–248, § 133(e)(5), inserted sentence at end defining ''provider of services''.

Subsec. (a)(2)(B). Pub. L. 90–248, §§ 126(b), 133(e)(4), inserted ''except services described in subparagraphs (B) and (C) of section 1395x(s)(2) of this title,'' after ''health services,'' and inserted reference to subpar. (d).

Subsec. (a)(2)(C). Pub. L. 90–248, § 133(e)(1)–(3), added subpar. (C).

Subsec. (b). Pub. L. 90–248, § 129(c)(9)(B), added subsec. (b). Former subsec. (b) redesignated (c), in turn redesignated (d).

Subsec. (c). Pub. L. 90–248, § 130(b), added subsec. (c). Former subsec. (c), previously designated (b), redesignated (d).

Subsec. (d). Pub. L. 90–248, §§ 129(c)(9)(B), 130(b), redesignated former subsec. (b) as (c), in turn as (d), respectively.

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 6404(a)(2)(B) 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. 1395n(a) 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 6405(b)(2) of Pub. L. 111–148 applicable to written orders and certifications made on or after July 1, 2010, see section 6405(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106–554 applicable to home health services furnished on or after Dec. 21, 2000, see section 1(a)(6) [title V, § 507(a)(2)] of Pub. L. 106–554, set out as a note under section 1395f 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 4615(a) of Pub. L. 105–33 applicable to home health services furnished after 6-month period beginning after Aug. 5, 1997, see section 4615(b) of Pub. L. 105–33, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 203(d)(1) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Amendment by section 205(d) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100–360, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by section 4024(b) of Pub. L. 100–203 applicable to items and services provided on or after Jan. 1, 1988, see section 4024(c) of Pub. L. 100–203, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–509 applicable to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987, see section 9337(e) of Pub. L. 99–509, set out as a note under section 1395k 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 2336(a) of Pub. L. 98–369 applicable to certifications and plans of care made or established on or after July 18, 1984, see section 2336(c)(1) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Pub. L. 98–369, div. B, title III, § 2342(c), July 18, 1984, 98 Stat. 1094, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] apply to plans of care established on or after the date of the enactment of this Act [July 18, 1984].''

Amendment by section 2354(b)(1), (8), (9) 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.

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by Pub. L. 98–21 applicable to items and services furnished by or under arrangement with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, see section 604(a)(1) of Pub. L. 98–21, set out as a note under section 1395ww of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by section 2122(a)(1) of Pub. L. 97–35 applicable to services furnished pursuant to plans of treatment implemented after the third month beginning after Aug. 13, 1981, see section 2122(b) of Pub. L. 97–35, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by section 930(e), (j) of Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(s)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Amendment by section 933(b) of Pub. L. 96–499 effective with respect to a comprehensive outpatient rehabilitation facility's first accounting period beginning on or after July 1, 1981, see section 933(h) of Pub. L. 96–499, set out as a note under section 1395k of this title.

Pub. L. 96–499, title IX, § 944(b), Dec. 5, 1980, 94 Stat. 2642, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to plans for furnishing services established on or after January 1, 1981.''

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 204(b) of Pub. L. 92–603 effective with respect to calendar years after 1972, see section 204(c) of Pub. L. 92–603, set out as a note under section 1395*l* of this title.

Amendment by section 227(e)(2) 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.

Amendment by section 251(b)(2) of Pub. L. 92–603 applicable with respect to services furnished on or after Oct. 30, 1972, see section 251(d)(2) of Pub. L. 92–603, set out as a note under section 1395x of this title.

Amendment by section 281(f) of Pub. L. 92–603 applicable in the case of services furnished (or deemed to have been furnished) after 1970, see section 281(g) of Pub. L. 92–603, set out as a note under section 1395gg of this title.

Pub. L. 92–603, title II, § 283(c), Oct. 30, 1972, 86 Stat. 1456, provided that: ''The provisions of this section [amending this section and section 1395x of this title] shall apply with respect to services rendered after December 31, 1972.''

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 126(b) of Pub. L. 90–248 applicable with respect to services furnished after Jan. 2, 1968, see section 126(c) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Amendment by section 129(c)(9)(A), (B) of Pub. L. 90–248 applicable with respect to services furnished after March 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395d of this title.

Pub. L. 90–248, title I, § 130(c), Jan. 2, 1968, 81 Stat. 849, provided that: ''The amendments made by this section [amending this section] shall apply with respect to services furnished after March 31, 1968.''

Amendment by section 133(e) of Pub. L. 90–248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90–248, set out as a note under section 1395k of this title.

REGULATIONS

Secretary of Health and Human Services required to provide, not later than 90 days after July 18, 1984, for revision of regulations as may be required to reflect amendment to subsec. (a) by section 2336(b) of Pub. L. 98–369, see section 2336(c)(2) of Pub. L. 98–369, set out as a note under section 1395f of this title.

MEDPAC STUDY ON DIRECT ACCESS TO PHYSICAL THERAPY SERVICES

Pub. L. 108–173, title VI, § 647, Dec. 8, 2003, 117 Stat. 2326, provided that:

''(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the 'Commission') shall conduct a study on the feasibility and advisability of allowing medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as comprehensive rehabilitation facility services.

''(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

''(c) DIRECT ACCESS DEFINED.—The term 'direct access' means, with respect to outpatient physical therapy services and physical therapy services furnished as comprehensive outpatient rehabilitation facility services, coverage of and payment for such services in accordance with the provisions of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], except that sections 1835(a)(2), 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2), 1395x(p), and 1395x(cc), respectively) shall be applied—

''(1) without regard to any requirement that—

''(A) an individual be under the care of (or referred by) a physician; or

''(B) services be provided under the supervision of a physician; and

''(2) by allowing a physician or a qualified physical therapist to satisfy any requirement for—

''(A) certification and recertification; and

''(B) establishment and periodic review of a plan of care.''

HOME HEALTH PROSPECTIVE PAYMENT DEMONSTRATION PROJECT

Pub. L. 100–203, title IV, § 4027, Dec. 22, 1987, 101 Stat. 1330–75, as amended by Pub. L. 100–360, title IV, § 411(d)(6), July 1, 1988, 102 Stat. 775, directed Secretary of Health and Human Services to provide for a demonstration project to develop and test alternative methods of paying home health agencies on a prospective basis for services furnished under the medicare and medicaid programs, directed that the project be designed in a manner to enable the Secretary to evaluate the effects of various methods of prospective payment (including payments on a per-visit, per-case, and per-episode basis) on program expenditures, access to, and quality of, home health care, and home health agency operations, directed Secretary to assure that services are first furnished under the project not later than Apr. 1, 1989, and, for this purpose, authorized Secretary to reinstate a previously awarded contract, or award a sole source contract, to carry out the project, provided for funding, and directed Secretary to submit to Congress, not later than one year after Dec. 22, 1987, an interim report on the demonstration project and, not later than four years after Dec. 22, 1987, a final report on results of the project.

§ 1395*o*. Eligible individuals

Every individual who—

(1) is entitled to hospital insurance benefits under part A of this subchapter, or

(2) has attained age 65 and is a resident of the United States, and is either (A) a citizen or (B) an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under this part,

is eligible to enroll in the insurance program established by this part.

(Aug. 14, 1935, ch. 531, title XVIII, § 1836, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 304; amended Pub. L. 92–603, title II, § 201(c)(1), Oct. 30, 1972, 86 Stat. 1372.)

AMENDMENTS

1972—Pub. L. 92–603 designed former par. (2)(B) as par. (1), former par. (1) as introductory clause in par. (2), and former pars. (2)(A)(i) and (ii) as pars. (2)(A) and (B), and struck out ''(A)'' after ''(2)''.

PERSONS CONVICTED OF SUBVERSIVE ACTIVITIES

Pub. L. 89–97, title I, § 104(b)(2), July 30, 1965, 79 Stat. 334, provided that: ''An individual who has been convicted of any offense under (A) chapter 37 [section 792 et seq. of Title 18, Crimes and Criminal Procedure] (relating to espionage and censorship), chapter 105 [section 2151 et seq. of Title 18] (relating to sabotage), or chapter 115 [section 2381 et seq. of Title 18] (relating to treason, sedition, and subversive activities) of title 18 of the United States Code, or (B) section 4, 112, or 113 of the Internal Security Act of 1950, as amended [section 783, 822, or 823 of Title 50, War and National Defense], may not enroll under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.].''

§ 1395p. Enrollment periods

(a) Generally; regulations

An individual may enroll in the insurance program established by this part only in such manner and form as may be prescribed by regulations, and only during an enrollment period prescribed in or under this section.

(b) Repealed. Pub. L. 96–499, title IX, § 945(a), Dec. 5, 1980, 94 Stat. 2642

(c) Initial general enrollment period; eligible individuals before March 1, 1966

In the case of individuals who first satisfy paragraph (1) or (2) of section 1395*o* of this title before March 1, 1966, the initial general enrollment period shall begin on the first day of the second month which begins after July 30, 1965, and shall end on May 31, 1966. For purposes of this subsection and subsection (d) of this section, an individual who has attained age 65 and who satisfies paragraph (1) of section 1395*o* of this title but not paragraph (2) of such section shall be treated as satisfying such paragraph (1) on the first day on which he is (or on filing application would have been) entitled to hospital insurance benefits under part A.

(d) Eligible individuals on or after March 1, 1966

In the case of an individual who first satisfies paragraph (1) or (2) of section 1395*o* of this title on or after March 1, 1966, his initial enrollment period shall begin on the first day of the third month before the month in which he first satisfies such paragraphs and shall end seven months later. Where the Secretary finds that an individual who has attained age 65 failed to enroll under this part during his initial enrollment period (based on a determination by the Secretary of the month in which such individual attained age 65), because such individual (relying on documentary evidence) was mistaken as to his correct date of birth, the Secretary shall establish for such individual an initial enrollment period based on his attaining age 65 at the time shown in such documentary evidence (with a coverage period determined under section 1395q of this title as though he had attained such age at that time).

(e) General enrollment period

There shall be a general enrollment period during the period beginning on January 1 and ending on March 31 of each year.

(f) Individuals deemed enrolled in medical insurance program

Any individual—

(1) who is eligible under section 1395*o* of this title to enroll in the medical insurance program by reason of entitlement to hospital insurance benefits as described in paragraph (1) of such section, and

(2) whose initial enrollment period under subsection (d) of this section begins after March 31, 1973, and

(3) who is residing in the United States, exclusive of Puerto Rico,

shall be deemed to have enrolled in the medical insurance program established by this part.

(g) Commencement of enrollment period

All of the provisions of this section shall apply to individuals satisfying subsection (f) of this section, except that—

(1) in the case of an individual who satisfies subsection (f) of this section by reason of entitlement to disability insurance benefits described in section 426(b) of this title, his initial enrollment period shall begin on the first day of the later of (A) April 1973 or (B) the third month before the 25th month of such entitlement, and shall reoccur with each continuous period of eligibility (as defined in section 1395r(d) of this title) and upon attainment of age 65;

(2)(A) in the case of an individual who is entitled to monthly benefits under section 402 or 423 of this title on the first day of his initial enrollment period or becomes entitled to monthly benefits under section 402 of this title during the first 3 months of such period, his enrollment shall be deemed to have occurred in the third month of his initial enrollment period, and

(B) in the case of an individual who is not entitled to benefits under section 402 of this title on the first day of his initial enrollment period and does not become so entitled during the first 3 months of such period, his enrollment shall be deemed to have occurred in the month in which he files the application establishing his entitlement to hospital insurance benefits provided such filing occurs during the last 4 months of his initial enrollment period; and

(3) in the case of an individual who would otherwise satisfy subsection (f) of this section but does not establish his entitlement to hospital insurance benefits until after the last day of his initial enrollment period (as defined in subsection (d) of this section), his enrollment shall be deemed to have occurred on the first day of the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section).

(h) Waiver of enrollment period requirements where individual's rights were prejudiced by administrative error or inaction

In any case where the Secretary finds that an individual's enrollment or nonenrollment in the insurance program established by this part or part A pursuant to section 1395i–2 of this title is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Federal Government, or its instrumentalities, the Secretary may take such action (including the designation for such individual of a special initial or subsequent enrollment period, with a coverage period determined on the basis thereof and with appropriate adjustments of premiums) as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

(i) Special enrollment periods

(1) In the case of an individual who—

(A) at the time the individual first satisfies paragraph (1) or (2) of section 1395*o* of this title, is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual's (or the individual's spouse's) current employment status, and

(B) has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period,

there shall be a special enrollment period described in paragraph (3). In the case of an indi-

vidual not described in the previous sentence who has not attained the age of 65, at the time the individual first satisfies paragraph (1) of section 1395*o* of this title, is enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual), and has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period, there shall be a special enrollment period described in paragraph (3)(B).

(2) In the case of an individual who—

(A)(i) has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part during the individual's initial enrollment period, or (ii) is an individual described in paragraph (1)(A);

(B) has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual's (or individual's spouse's) current employment status; and

(C) has not terminated enrollment under this section at any time at which the individual is not enrolled in such a group health plan by reason of the individual's (or individual's spouse's) current employment status,

there shall be a special enrollment period described in paragraph (3). In the case of an individual not described in the previous sentence who has not attained the age of 65, has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part during the individual's initial enrollment period, or is an individual described in the second sentence of paragraph (1), has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual), and has not terminated enrollment under this section at any time at which the individual is not enrolled in such a large group health plan by reason of the individual's current employment status (or the current employment status of a family member of the individual), there shall be a special enrollment period described in paragraph (3)(B).

(3)(A) The special enrollment period referred to in the first sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of current employment status ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(B) The special enrollment period referred to in the second sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual) ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(4)(A) In the case of an individual who is entitled to benefits under part A pursuant to section 426(b) of this title and—

(i) who at the time the individual first satisfies paragraph (1) of section 1395*o* of this title—

(I) is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual's current or former employment or by reason of the current or former employment status of a member of the individual's family, and

(II) has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period; and

(ii) whose continuous enrollment under such group health plan is involuntarily terminated at a time when the enrollment under the plan is not by reason of the individual's current employment or by reason of the current employment of a member of the individual's family,

there shall be a special enrollment period described in subparagraph (B).

(B) The special enrollment period referred to in subparagraph (A) is the 6-month period beginning on the first day of the month which includes the date of the enrollment termination described in subparagraph (A)(ii).

(j) Special rules for individuals with ALS

In applying this section in the case of an individual who is entitled to benefits under part A pursuant to the operation of section 426(h) of this title, the following special rules apply:

(1) The initial enrollment period under subsection (d) of this section shall begin on the first day of the first month in which the individual satisfies the requirement of section 1395*o*(1) of this title.

(2) In applying subsection (g)(1) of this section, the initial enrollment period shall begin on the first day of the first month of entitlement to disability insurance benefits referred to in such subsection.

(k) Special enrollment period for certain volunteers serving outside United States

(1) In the case of an individual who—

(A) at the time the individual first satisfies paragraph (1) or (2) of section 1395*o* of this title, is described in paragraph (3), and has elected not to enroll (or to be deemed enrolled) under this section during the individual's initial enrollment period; or

(B) has terminated enrollment under this section during a month in which the individual is described in paragraph (3),

there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph is the 6-month period beginning on the first day of the month which includes the date that the individual is no longer described in paragraph (3).

(3) For purposes of paragraph (1), an individual described in this paragraph is an individual who—

(A) is serving as a volunteer outside of the United States through a program—

(i) that covers at least a 12-month period; and

(ii) that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code; and

(B) demonstrates health insurance coverage while serving in the program.

(*l*) Special enrollment period for disabled TRICARE beneficiaries

(1) In the case of any individual who is a covered beneficiary (as defined in section 1072(5) of title 10) at the time the individual is entitled to part A under section 426(b) of this title or section 426–1 of this title and who is eligible to enroll but who has elected not to enroll (or to be deemed enrolled) during the individual's initial enrollment period, there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph, with respect to an individual, is the 12-month period beginning on the day after the last day of the initial enrollment period of the individual or, if later, the 12-month period beginning with the month the individual is notified of enrollment under this section.

(3) In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under this part shall begin on the first day of the month in which the individual enrolls, or, at the option of the individual, the first month after the end of the individual's initial enrollment period.

(4) An individual may only enroll during the special enrollment period provided under paragraph (1) one time during the individual's lifetime.

(5) The Secretary shall ensure that the materials relating to coverage under this part that are provided to an individual described in paragraph (1) prior to the individual's initial enrollment period contain information concerning the impact of not enrolling under this part, including the impact on health care benefits under the TRICARE program under chapter 55 of title 10.

(6) The Secretary of Defense shall collaborate with the Secretary of Health and Human Services and the Commissioner of Social Security to provide for the accurate identification of individuals described in paragraph (1). The Secretary of Defense shall provide such individuals with notification with respect to this subsection. The Secretary of Defense shall collaborate with the Secretary of Health and Human Services and the Commissioner of Social Security to ensure appropriate follow up pursuant to any notification provided under the preceding sentence.

(Aug. 14, 1935, ch. 531, title XVIII, §1837, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 304; amended Pub. L. 89–384, §3(a), (b), Apr. 8, 1966, 80 Stat. 105; Pub. L. 90–248, title I, §§136(a), 145(a), (b), Jan. 2, 1968, 81 Stat. 853, 859; Pub. L. 92–603, title II, §§201(c)(2), 206(a), 259(a), 260, Oct. 30, 1972, 86 Stat. 1372, 1378, 1448; Pub. L. 96–265, title I, §103(a)(3), June 9, 1980, 94 Stat. 444; Pub. L. 96–499, title IX, §945(a), (b), Dec. 5, 1980, 94 Stat. 2642; Pub. L. 97–35, title XXI, §2151(a)(1), (2), Aug. 13, 1981, 95 Stat. 801; Pub. L. 98–369, div. B, title III, §§2338(b), 2354(b)(10), July 18, 1984, 98 Stat. 1092, 1101; Pub. L. 99–272, title IX, §§9201(c)(1), 9219(a)(2), Apr. 7, 1986, 100 Stat. 171, 182; Pub. L. 99–509, title IX, §9319(c)(1)–(3), Oct. 21, 1986, 100 Stat. 2011; Pub. L. 99–514, title XVIII, §1895(b)(12), Oct. 22, 1986, 100 Stat. 2934; Pub. L. 101–239, title VI, §6202(b)(4)(C), (c)(1), Dec. 19, 1989, 103 Stat. 2233; Pub. L. 103–432, title I, §§147(f)(1)(A), 151(c)(2), Oct. 31, 1994, 108 Stat. 4430, 4435; Pub. L. 105–33, title IV, §§4581(b)(1), 4631(a)(2), Aug. 5, 1997, 111 Stat. 465, 486; Pub. L. 106–554, §1(a)(6) [title I, §115(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–474; Pub. L. 109–171, title V, §5115(a)(2)(A), Feb. 8, 2006, 120 Stat. 45; Pub. L. 111–148, title III, §3110(a)(1), Mar. 23, 2010, 124 Stat. 420.)

REFERENCES IN TEXT

Section 501 of the Internal Revenue Code of 1986, referred to in subsec. (k)(3)(A)(ii), is classified to section 501 of Title 26, Internal Revenue Code.

AMENDMENTS

2010—Subsec. (*l*). Pub. L. 111–148 added subsec. (*l*).

2006—Subsec. (k). Pub. L. 109–171 added subsec. (k).

2000—Subsec. (j). Pub. L. 106–554 added subsec. (j).

1997—Subsec. (i)(1) to (3). Pub. L. 105–33, §4631(a)(2), substituted ''1395y(b)(1)(B)(iii) of this title'' for ''1395y(b)(1)(B)(iv) of this title'' wherever appearing.

Subsec. (i)(4). Pub. L. 105–33, §4581(b)(1), added par. (4).

1994—Subsec. (i)(1). Pub. L. 103–432, §151(c)(2)(A), in closing provisions substituted ''(as that term is defined in section 1395y(b)(1)(B)(iv) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual)'' for ''as an active individual (as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)''.

Subsec. (i)(1)(A). Pub. L. 103–432, §151(c)(2)(D), inserted ''status'' after ''current employment''.

Subsec. (i)(2). Pub. L. 103–432, §151(c)(2)(A), (C), in closing provisions substituted ''(as that term is defined in section 1395y(b)(1)(B)(iv) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual)'' for ''as an active individual (as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)'' and ''by reason of the individual's current employment status (or the current employment status of a family member of the individual)'' for ''as an active individual''.

Subsec. (i)(2)(B), (C). Pub. L. 103–432, §151(c)(2)(D), inserted ''status'' after ''current employment''.

Subsec. (i)(3)(A). Pub. L. 103–432, §151(c)(2)(D), inserted ''status'' after ''current employment''.

Pub. L. 103–432, §147(f)(1)(A), substituted ''including each month during any part of which the individual is enrolled'' for ''beginning with the first day of the first month in which the individual is no longer enrolled'' and ''ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled'' for ''and ending seven months later''.

Subsec. (i)(3)(B). Pub. L. 103–432, §151(c)(2)(B), substituted ''in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iv) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual)'' for ''as an active individual in a large group health plan (as such terms are defined in section 1395y(b)(1)(B)(iv) of this title)''.

Pub. L. 103–432, §147(f)(1)(A), substituted ''including each month during any part of which the individual is

enrolled'' for ''beginning with the first day of the first month in which the individual is no longer enrolled'' and ''ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled'' for ''and ending seven months later''.

1989—Subsec. (i)(1). Pub. L. 101–239, § 6202(c)(1)(A), redesignated subpars. (B) and (C) as (A) and (B), respectively, struck out former subpar. (A) which read as follows: ''has attained the age of 65,'', and inserted ''not described in the previous sentence'' after ''In the case of an individual'' in second sentence.

Pub. L. 101–239, § 6202(b)(4)(C), substituted ''section 1395y(b)(1)(A)(v)'' and ''section 1395y(b)(1)(B)(iv)'' for ''section 1395y(b)(3)(A)(iv)'' and ''section 1395y(b)(4)(B)'', respectively.

Subsec. (i)(2). Pub. L. 101–239, § 6202(c)(1)(B), substituted ''(1)(A)'' for ''(1)(B)'' in subpar. (B)(i), redesignated subpars. (B) and (C) as (A) and (B), respectively, struck out former subpar. (A) which read as follows: ''has attained the age of 65;'', and inserted ''not described in the previous sentence'' after ''In the case of an individual'' in second sentence.

Pub. L. 101–239, § 6202(b)(4)(C), substituted ''section 1395y(b)(1)(A)(v)'' and ''section 1395y(b)(1)(B)(iv)'' for ''section 1395y(b)(3)(A)(iv)'' and ''section 1395y(b)(4)(B)'', respectively.

Subsec. (i)(3). Pub. L. 101–239, § 6202(b)(4)(C), substituted ''section 1395y(b)(1)(A)(v)'' and ''section 1395y(b)(1)(B)(iv)'' for ''section 1395y(b)(3)(A)(iv)'' and ''section 1395y(b)(4)(B)'', respectively.

1986—Subsec. (i)(1). Pub. L. 99–509, § 9319(c)(1), inserted sentence at end providing for a special enrollment period described in paragraph (3)(B) for individuals not age 65, enrolled in a large health plan, and having elected not to enroll during initial enrollment period.

Subsec. (i)(1)(A). Pub. L. 99–514 realigned margins of subpar. (A).

Pub. L. 99–272, § 9219(a)(2)(A), amended subpar. (A) generally, substituting ''has attained the age of 65'' for ''meets the conditions described in clauses (i) and (iii) of section 1395y(b)(3)(A) of this title''.

Subsec. (i)(2). Pub. L. 99–509, § 9319(c)(2), inserted sentence at end providing for a special enrollment period described in paragraph (3)(B) for individuals not age 65, enrolled or deemed enrolled in the medical insurance program established under this part, or is an individual described in the second sentence of paragraph (1), has enrolled in such program during a subsequent special enrollment period during which the individual was not enrolled in a large group health plan, and has not terminated enrollment.

Subsec. (i)(2)(A). Pub. L. 99–272, § 9219(a)(2)(B), amended subpar. (A) generally, substituting ''has attained the age of 65;'' for ''meets the conditions described in clauses (i) and (iii) of section 1395y(b)(3)(A) of this title,''.

Subsec. (i)(2)(B). Pub. L. 99–272, § 9219(a)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part during the individual's initial enrollment period and any subsequent special enrollment period under this subsection during which the individual was not enrolled in a group health plan described in section 1395y(b)(3)(A)(iv) of this title by reason of the individual's (or individual's spouse's) current employment, and''.

Subsec. (i)(2)(C), (D). Pub. L. 99–272, § 9219(a)(2)(B), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (i)(3). Pub. L. 99–509, § 9319(c)(3), designated existing provisions as subpar. (A), inserted ''the first sentences of'' after ''referred to in'', and added subpar. (B).

Pub. L. 99–272, § 9201(c)(1), amended par. (3) generally, striking out provision that special enrollment period could be period beginning with first day of third month before month in which the individual attains age of 70 and ending seven months later.

1984—Subsec. (g)(1). Pub. L. 98–369, § 2354(b)(10), substituted ''section 426(b) of this title'' for ''section 426(a)(2)(B) of this title'' and ''section 1395r(d) of this title'' for ''section 1395(e) of this title''.

Subsec. (i). Pub. L. 98–369, § 2338(b), added subsec. (i).

1981—Subsec. (e). Pub. L. 97–35, § 2151(a)(1), substituted ''during the period beginning on January 1 and ending on March 31 of each year'' for ''which is any period after the period described in subsection (d) of this section''.

Subsec. (g)(3). Pub. L. 97–35, § 2151(a)(2), substituted ''the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section)'' for ''the month in which the individual files an application establishing such entitlement''.

1980—Subsec. (b). Pub. L. 96–499, § 945(a), struck out subsec. (b) which provided that no individual could enroll under this part more than twice.

Subsec. (e). Pub. L. 96–499, § 945(b)(1), substituted ''which is any period after the period described in subsection (d) of this section'' for '', after the period described in subsection (c) of this section, during the period beginning on January 1 and ending on March 31 of each year beginning with 1969''.

Subsec. (g)(1). Pub. L. 96–265 substituted ''the 25th month'' for ''the 25th consecutive month''.

Subsec. (g)(3). Pub. L. 96–499, § 945(b)(2), substituted ''the month in which the individual files an application establishing such entitlement'' for ''the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section)''.

1972—Subsec. (b). Pub. L. 92–603, § 260, struck out provisions preventing enrollment under this part more than three years after first opportunity for such enrollment.

Subsec. (c). Pub. L. 92–603, § 201(c)(2)(A), (B), substituted ''paragraph (1) or (2)'' for ''paragraphs (1) and (2)'', and substituted provisions relating to the treatment of an individual who has attained age 65 and who satisfies paragraph (1) of section 1395*o* of this title but not paragraph (2) of such section, for provisions relating to the treatment of an individual who satisfies paragraph (2) of section 1395*o* of this title solely by reason of subparagraph (B) thereof.

Subsec. (d). Pub. L. 92–603, § 201(c)(2)(C), substituted ''paragraph (1) or (2)'' for ''paragraphs (1) and (2)''.

Subsecs. (f), (g). Pub. L. 92–603, § 206(a), added subsecs. (f) and (g).

Subsec. (h). Pub. L. 92–603, § 259(a), added subsec. (h).

1968—Subsec. (b)(1). Pub. L. 90–248, § 145(a), permitted an individual enrolling in supplementary medical insurance program for first time to enroll at any time in a general enrollment period which begins within 3 years of close of his initial enrollment period.

Subsec. (d). Pub. L. 90–248, § 136(a), inserted last sentence providing that if an individual who has attained age 65 failed to enroll in program because, relying on erroneous documentary evidence, he was mistaken about his age, he may enroll using date of attainment of age 65 that he alleges under documentary evidence.

Subsec. (e). Pub. L. 90–248, § 145(b), provided for an annual general enrollment period for supplementary medical insurance program beginning January 1 and ending March 31 of each year, commencing in 1969.

1966—Subsec. (c). Pub. L. 89–384, § 3(a), delayed eligibility date from January 1, 1966, to March 1, 1966, and closing date for enrollment period from March 31, 1966, to May 31, 1966.

Subsec. (d). Pub. L. 89–384, § 3(b), substituted March 1, 1966, for January 1, 1966.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3110(a)(2), Mar. 23, 2010, 124 Stat. 420, as amended by Pub. L. 111–309, title II, § 201, Dec. 15, 2010, 124 Stat. 3289, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to elections made on and after the date of the enactment of this Act [Mar. 23, 2010].''

[Pub. L. 111–309, title II, § 201, Dec. 15, 2010, 124 Stat. 3289, provided that the amendment made by section 201

to section 3110(a)(2) of Pub. L. 111–148, set out above, is effective as if included in the enactment of Pub. L. 111–148.]

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–171, title V, § 5115(b), Feb. 8, 2006, 120 Stat. 46, provided that: ''The amendment made by subsection (a)(1) [amending section 1395r of this title] shall apply to months beginning with January 2007 and the amendments made by subsection (a)(2) [amending this section and section 1395q of this title] shall take effect on January 1, 2007.''

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106–554 applicable to benefits for months beginning July 1, 2001, see section 1(a)(6) [title I, § 115(c)] of Pub. L. 106–554, set out as a note under section 426 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–33, title IV, § 4581(c), Aug. 5, 1997, 111 Stat. 465, provided that: ''The amendments made by this section [amending this section and sections 1395q and 1395r of this title] shall apply to involuntary terminations of coverage under a group health plan occurring on or after the date of the enactment of this Act [Aug. 5, 1997].''

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, § 147(f)(1)(C), Oct. 31, 1994, 108 Stat. 4431, provided that: ''The amendments made by subparagraphs (A) and (B) [amending this section and section 1395q of this title] shall take effect on the first day of the first month that begins after the expiration of the 120-day period that begins on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, § 151(c)(2), Oct. 31, 1994, 108 Stat. 4435, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–66.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6202(b)(4)(C) of Pub. L. 101–239 applicable to items and services furnished after Dec. 19, 1989, see section 6202(b)(5) of Pub. L. 101–239, set out as a note under section 162 of Title 26, Internal Revenue Code.

Pub. L. 101–239, title VI, § 6202(c)(3), Dec. 19, 1989, 103 Stat. 2234, provided that: ''The amendments made by this subsection [amending this section and section 1395r of this title] shall apply to enrollments occurring after, and premiums for months after, the second calendar quarter beginning after the date of the enactment of this Act [Dec. 19, 1989].''

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by 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.

Amendment by Pub. L. 99–509 applicable to enrollments occurring on or after Jan. 1, 1987, see section 9319(f)(2) of Pub. L. 99–509, set out as a note under section 1395y of this title.

Pub. L. 99–272, title IX, § 9201(d)(2), Apr. 7, 1986, 100 Stat. 171, provided that: ''The amendments made by subsections (b) and (c) [amending this section, section 1395q of this title, and sections 623 and 631 of Title 29, Labor] shall become effective on May 1, 1986.''

Pub. L. 99–272, title IX, § 9219(a)(3)(B), Apr. 7, 1986, 100 Stat. 182, provided that:

''(i) The amendments made by paragraph (2) [amending this section] shall apply to enrollments in months beginning with the first effective month (as defined in clause (ii)), except that in the case of any individual who would have a special enrollment period under section 1837(i) of the Social Security Act [42 U.S.C. 1395p(i)] that would have begun after November 1984 and before the first effective month, the period shall be deemed to begin with the first day of the first effective month.

''(ii) For purposes of clause (i), the term 'first effective month' means the first month that begins more than 90 days after the date of the enactment of this Act [Apr. 7, 1986].''

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98–369, div. B, title III, § 2338(d)(2), July 18, 1984, 98 Stat. 1093, provided that:

''(A) The amendments made by subsections (b) and (c) [amending this section and section 1395q of this title] shall apply to enrollments in months beginning with the first effective month, except that in the case of any individual who would have had a special enrollment period under section 1837(i) of the Social Security Act [42 U.S.C. 1395p(i)] that would have begun before such first effective month, such period shall be deemed to begin with the first day of such first effective month.

''(B) For purposes of subparagraph (A), the term 'first effective month' means the first month which begins more than 90 days after the date of the enactment of this Act [July 18, 1984].''

Amendment by section 2354(b)(10) 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.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXI, § 2151(b), Aug. 13, 1981, 95 Stat. 802, provided that: ''The amendments made by this section [amending this section and sections 1395q and 1395r of this title] shall not apply to enrollments pursuant to written requests for enrollment filed before October 1, 1981.''

EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96–499, title IX, § 945(d), Dec. 5, 1980, 94 Stat. 2642, provided that: ''The amendments made by subsections (a), (b), and (c) [amending this section and sections 1395q and 1395r of this title] shall apply to enrollments occurring on or after April 1, 1981.''

Amendment by Pub. L. 96–265 applicable with respect to hospital insurance or supplementary medical insurance benefits for services provided on or after the first day of the sixth month which begins after June 9, 1980, see section 103(c) of Pub. L. 96–265, set out as a note under section 426 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–603, title II, § 259(b), Oct. 30, 1972, 86 Stat. 1448, provided that: ''The amendment made by subsection (a) [amending this section] shall be effective as of July 1, 1966.''

EFFECTIVE DATE OF 1968 AMENDMENT

Pub. L. 90–248, title I, § 136(b), Jan. 2, 1968, 81 Stat. 853, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to individuals enrolling under part B of title XVIII [42 U.S.C. 1395j et seq.] in months beginning after the date of the enactment of this Act [Jan. 2, 1968].''

Pub. L. 90–248, title I, § 145(e), Jan. 2, 1968, 81 Stat. 859, provided that: ''The amendments made by subsections (a), (b), and (c) [amending this section and section 1395q of this title] shall become effective April 1, 1968. Notwithstanding the provisions of section 2 of Public Law 90–97, the amendments made by subsection (d) [amending section 1395r of this title] shall become effective December 1, 1968.''

MEDICARE PART B SPECIAL ENROLLMENT PERIOD

Pub. L. 108–173, title VI, § 625(b), Dec. 8, 2003, 117 Stat. 2318, provided that:

''(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act [Dec. 8, 2003], is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

''(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] shall begin on the first day of the month following the month in which the individual enrolls.''

EXTENSION THROUGH MARCH 31, 1968 OF 1967 GENERAL ENROLLMENT PERIOD

Pub. L. 90–97, § 1, Sept. 30, 1967, 81 Stat. 249, extended the general enrollment period under subsec. (e) of this section, beginning Oct. 1, 1967, and ending Dec. 31, 1967, for purposes of enrolling in the insurance program established under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] and of terminating such enrollment as provided in section 1395q(b)(1) of this title, through Mar. 31, 1968.

ENROLLMENT BEFORE OCT. 1, 1966, OF ELIGIBLE INDIVIDUALS FAILING FOR GOOD CAUSE TO ENROLL BEFORE JUNE 1, 1966; COMMENCEMENT OF COVERAGE PERIOD

Pub. L. 89–97, title I, § 102(b), July 30, 1965, 79 Stat. 332, as amended by Pub. L. 89–384, § 3(c), Apr. 8, 1966, 80 Stat. 105, provided that: ''If—

''(1) an individual was eligible to enroll under section 1837(c) of the Social Security Act [42 U.S.C. 1395p(c)] before June 1, 1966, but failed to enroll before such date, and

''(2) it is shown to the satisfaction of the Secretary of Health, Education, and Welfare [now Health and Human Services] that there was good cause for such failure to enroll before June 1, 1966,

such individual may enroll pursuant to this subsection at any time before October 1, 1966. The determination of what constitutes good cause for purposes of the preceding sentence shall be made in accordance with regulations of the Secretary. In the case of any individual who enrolls pursuant to this subsection, the coverage period (within the meaning of section 1838 of the Social Security Act [42 U.S.C. 1395q]) shall begin on the first day of the 6th month after the month in which he enrolls.''

§ 1395q. Coverage period

(a) Commencement

The period during which an individual is entitled to benefits under the insurance program established by this part (hereinafter referred to as his ''coverage period'') shall begin on whichever of the following is the latest:

(1) July 1, 1966, or (in the case of a disabled individual who has not attained age 65) July 1, 1973; or

(2)(A) in the case of an individual who enrolls pursuant to subsection (d) of section 1395p of this title before the month in which he first satisfies paragraph (1) or (2) of section 1395*o* of this title, the first day of such month, or

(B) in the case of an individual who enrolls pursuant to such subsection (d) in the month in which he first satisfies such paragraph, the first day of the month following the month in which he so enrolls, or

(C) in the case of an individual who enrolls pursuant to such subsection (d) in the month following the month in which he first satisfies such paragraph, the first day of the second month following the month in which he so enrolls, or

(D) in the case of an individual who enrolls pursuant to such subsection (d) more than one month following the month in which he satisfies such paragraph, the first day of the third month following the month in which he so enrolls, or

(E) in the case of an individual who enrolls pursuant to subsection (e) of section 1395p of this title, the July 1 following the month in which he so enrolls; or

(3)(A) in the case of an individual who is deemed to have enrolled on or before the last day of the third month of his initial enrollment period, the first day of the month in which he first meets the applicable requirements of section 1395*o* of this title or July 1, 1973, whichever is later, or

(B) in the case of an individual who is deemed to have enrolled on or after the first day of the fourth month of his initial enrollment period, as prescribed under subparagraphs (B), (C), (D), and (E) of paragraph (2) of this subsection.

(b) Continuation

An individual's coverage period shall continue until his enrollment has been terminated—

(1) by the filing of notice that the individual no longer wishes to participate in the insurance program established by this part, or

(2) for nonpayment of premiums.

The termination of a coverage period under paragraph (1) shall (except as otherwise provided in section 1395v(e) of this title) take effect at the close of the month following the month in which the notice is filed. The termination of a coverage period under paragraph (2) shall take effect on a date determined under regulations, which may be determined so as to provide a grace period in which overdue premiums may be paid and coverage continued. The grace period determined under the preceding sentence shall not exceed 90 days; except that it may be extended to not to exceed 180 days in any case where the Secretary determines that there was good cause for failure to pay the overdue premiums within such 90-day period.

Where an individual who is deemed to have enrolled for medical insurance pursuant to section 1395p(f) of this title files a notice before the first day of the month in which his coverage period begins advising that he does not wish to be so enrolled, the termination of the coverage period resulting from such deemed enrollment shall take effect with the first day of the month the coverage would have been effective. Where an individual who is deemed enrolled for medical insurance benefits pursuant to section 1395p(f) of this title files a notice requesting termination of his deemed coverage in or after the month in which such coverage becomes effective, the termination of such coverage shall take effect at the close of the month following the month in which the notice is filed.

(c) Termination

In the case of an individual satisfying paragraph (1) of section 1395*o* of this title whose entitlement to hospital insurance benefits under part A of this subchapter is based on a disability rather than on his having attained the age of 65, his coverage period (and his enrollment under this part) shall be terminated as of the close of the last month for which he is entitled to hospital insurance benefits.

(d) Payment of expenses incurred during coverage period

No payments may be made under this part with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to him, is a coverage period.

(e) Commencement of coverage for special enrollment periods

Notwithstanding subsection (a) of this section, in the case of an individual who enrolls during a special enrollment period pursuant to section 1395p(i)(3) or 1395p(i)(4)(B) of this title—

(1) in any month of the special enrollment period in which the individual is at any time enrolled in a plan (specified in subparagraph (A) or (B), as applicable, of section 1395p(i)(3) of this title or specified in section 1395p(i)(4)(A)(i) of this title) or in the first month following such a month, the coverage period shall begin on the first day of the month in which the individual so enrolls (or, at the option of the individual, on the first day of any of the following three months), or

(2) in any other month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.

(f) Commencement of coverage for certain volunteers serving outside United States

Notwithstanding subsection (a), in the case of an individual who enrolls during a special enrollment period pursuant to section 1395p(k) of this title, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.

(Aug. 14, 1935, ch. 531, title XVIII, § 1838, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 305; amended Pub. L. 90–248, title I, § 145(c), Jan. 2, 1968, 81 Stat. 859; Pub. L. 92–603, title II, §§ 201(c)(3), 206(b), (c), 257(a), Oct. 30, 1972, 86 Stat. 1373, 1378, 1447; Pub. L. 96–499, title IX, §§ 945(c)(1), 947(b), Dec. 5, 1980, 94 Stat. 2642, 2643; Pub. L. 97–35, title XXI, §§ 2106(b)(2), 2151(a)(3), Aug. 13, 1981, 95 Stat. 792, 802; Pub. L. 98–369, div. B, title III, § 2338(c), July 18, 1984, 98 Stat. 1092; Pub. L. 99–272, title IX, § 9201(c)(2), Apr. 7, 1986, 100 Stat. 171; Pub. L. 99–509, title IX, § 9344(b)(1), Oct. 21, 1986, 100 Stat. 2042; Pub. L. 103–432, title I, § 147(f)(1)(B), Oct. 31, 1994, 108 Stat. 4430; Pub. L. 105–33, title IV, § 4581(b)(2), Aug. 5, 1997, 111 Stat. 465; Pub. L. 108–173, title VII, § 736(b)(6), Dec. 8, 2003, 117 Stat. 2356; Pub. L. 109–171, title V, § 5115(a)(2)(B), Feb. 8, 2006, 120 Stat. 46.)

AMENDMENTS

2006—Subsec. (f). Pub. L. 109–171 added subsec. (f).

2003—Subsec. (a)(1). Pub. L. 108–173 inserted comma after ''1966''.

1997—Subsec. (e). Pub. L. 105–33 inserted ''or 1395p(i)(4)(B)'' after ''1395p(i)(3)'' in introductory provisions and ''or specified in section 1395p(i)(4)(A)(i) of this title'' after ''1395p(i)(3) of this title'' in par. (1).

1994—Subsec. (e). Pub. L. 103–432 amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

''(1) in the first month of the special enrollment period, the coverage period shall begin on the first day of that month, or

''(2) in a month after the first month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.''

1986—Subsec. (b). Pub. L. 99–509 substituted ''month following the month'' for ''calendar quarter following the calendar quarter'' in second and sixth sentences.

Subsec. (e). Pub. L. 99–272 amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: ''Notwithstanding subsection (a) of this section, in the case of an individual who enrolls during a special enrollment period pursuant to—

''(1) subparagraph (A) of section 1395p(i)(3) of this title—

''(A) before the month in which he attains the age of 70, the coverage period shall begin on the first day of the month in which he has attained the age of 70, or

''(B) in or after the month in which he attains the age of 70, the coverage period shall begin on the first day of the month following the month in which he so enrolls; or

''(2) subparagraph (B) of section 1395p(i)(3) of this title—

''(A) in the first month of the special enrollment period, the coverage period shall begin on the first day of such month, or

''(B) in a month after the first month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which he so enrolls.''

1984—Subsec. (e). Pub. L. 98–369, § 2338(c), added subsec. (e).

1981—Subsec. (a)(2)(E). Pub. L. 97–35, § 2151(a)(3), substituted ''the July 1 following'' for ''the first day of the third month following''.

Subsec. (b). Pub. L. 97–35, § 2106(b)(2), struck out provision that notice filed by an individual enrolled pursuant to section 1395p(f) of this title shall not be considered a disenrollment for purposes of section 1395p(b) of this title.

1980—Subsec. (a)(2)(E). Pub. L. 96–499, § 945(c)(1), substituted ''the first day of the third month'' for ''the July 1''.

Subsec. (b). Pub. L. 96–499, § 947(b), inserted ''(except as otherwise provided in section 1395v(e) of this title)''.

1972—Subsec. (a)(1). Pub. L. 92–603, § 201(c)(3)(A), inserted ''or (in the case of a disabled individual who has not attained age 65) July 1, 1973'' after ''July 1, 1966''.

Subsec. (a)(2). Pub. L. 92–603, § 201(c)(3)(B), substituted in subpar. (A) ''paragraph (1) or (2)'' for ''paragraphs (1) and (2)'' and in subpars. (B) to (D) ''paragraph'' for ''paragraphs''.

Subsec. (a)(3). Pub. L. 92–603, § 206(b), added par. (3).

Subsec. (b). Pub. L. 92–603, §§ 206(c), 257(a), inserted provisions relating to an individual who is deemed to have enrolled for medical insurance pursuant to section 1395p(f) of this title and an individual who is deemed enrolled for medical insurance benefits pursuant to section 1395p(f) of this title and struck out provisions limiting the allowable grace period to 90 days and inserted provision for extension of such period of up to 180 days where failure to pay premiums is due to good cause.

Subsecs. (c), (d). Pub. L. 92–603, § 202(c)(3)(C), added subsec. (c) and redesignated former subsec. (c) as (d).

1968—Subsec. (b). Pub. L. 90–248 struck out '', during a general enrollment period described in section 1395p(e) of this title,'' after ''notice'' in par. (1), and substituted in first sentence following par. (2) ''the calendar quarter following the calendar quarter'' for ''December 31 of the year''.

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by Pub. L. 109–171 effective Jan. 1, 2007, see section 5115(b) of Pub. L. 109–171, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–33 applicable to involuntary terminations of coverage under a group health plan occurring on or after Aug. 5, 1997, see section 4581(c) of Pub. L. 105–33, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–432 effective on first day of first month beginning after expiration of the 120-day period that begins on Oct. 31, 1994, see section 147(f)(1)(C) of Pub. L. 103–432, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–509, title IX, § 9344(b)(2), Oct. 21, 1986, 100 Stat. 2042, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to notices filed on or after July 1, 1987.''

Amendment by Pub. L. 99–272 effective May 1, 1986, see section 9201(d)(2) of Pub. L. 99–272, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

For effective date of amendment by Pub. L. 98–369, see section 2338(d)(2) of Pub. L. 98–369, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by section 2106(b)(2) of Pub. L. 97–35 effective Apr. 1, 1981, see section 2106(c) of Pub. L. 97–35, set out as a note under section 1395*l* of this title.

Amendment by section 2151(a)(3) of Pub. L. 97–35 not applicable to enrollments pursuant to written requests for enrollment filed before Oct. 1, 1981, see section 2151(b) of Pub. L. 97–35, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by section 945(c)(1) of Pub. L. 96–499 applicable to enrollments occurring on or after Apr. 1, 1981, see section 945(d) of Pub. L. 96–499, set out as a note under section 1395p of this title.

Amendment by section 947(b) of Pub. L. 96–499 applicable to notices filed after third calendar month beginning after Dec. 5, 1980, see section 947(d) of Pub. L. 96–499, set out as a note under section 1395v of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–603, title II, § 257(b), Oct. 30, 1972, 86 Stat. 1447, provided that: ''The amendments made by subsection (a) [amending this section] shall apply with respect to nonpayment of premiums which become due and payable on or after the date of the enactment of this Act [Oct. 30, 1972] or which became payable within the 90-day period immediately preceding such date; and for purposes of such amendments any premium which became due and payable within such 90-day period shall be considered a premium becoming due and payable on the date of the enactment of this Act.''

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–248 effective Apr. 1, 1968, see section 145(e) of Pub. L. 90–248, set out as a note under section 1395p of this title.

COVERAGE PERIOD; TERMINATION DATES

Pub. L. 90–97, § 3(a), Sept. 30, 1967, 81 Stat. 249, provided that: ''In the case of any individual who, pursuant to section 1838(b)(1) of the Social Security Act [42 U.S.C. 1395q(b)(1)], terminates his enrollment in the insurance program established under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.], his coverage period (as defined in section 1838(a) of such Act) [42 U.S.C. 1395q(a)]—

''(1) shall terminate at the close of December 31, 1967, if he filed his notice of termination before January 1, 1968, or

''(2) shall terminate at the close of March 31, 1968, if he filed his notice of termination after December 31, 1967, and before April 1, 1968.

An individual whose coverage period terminated pursuant to paragraph (1) at the close of December 31, 1967, may, notwithstanding section 1837(b)(2) of such Act [42 U.S.C. 1395p(b)(2)], enroll in such program before April 1, 1968, and for purposes of sections 1838(a)(2)(E) [42 U.S.C. 1395q(a)(2)(E)] and 1837(b)(2) of such Act [42 U.S.C. 1395p(b)(2)] such enrollment shall be deemed an enrollment under section 1837(e) of such Act [42 U.S.C. 1395p(e)] and a second enrollment under such part.''

EXTENSION OF 1967 GENERAL ENROLLMENT PERIOD THROUGH MARCH 31, 1968

Extension of the general enrollment period under section 1395p(e) of this title through March 31, 1968, see section 1 of Pub. L. 90–97, Sept. 30, 1967, 81 Stat. 249, set out as a note under section 1395p of this title.

COVERAGE PERIOD FOR INDIVIDUALS BECOMING ELIGIBLE IN MARCH 1966 WHO ENROLL IN MAY 1966

Pub. L. 89–384, § 3(d), Apr. 8, 1966, 80 Stat. 105, provided that: ''In the case of an individual who first satisfies paragraphs (1) and (2) of section 1836 of the Social Security Act [42 U.S.C. 1395*o*] in March, 1966, and who enrolls pursuant to subsection (d) of section 1837 of such Act [42 U.S.C. 1395p] in May 1966, his coverage period shall, notwithstanding section 1838(a)(2)(D) of such Act [42 U.S.C. 1395q(a)(2)(D)], begin on July 1, 1966.''

COMMENCEMENT OF COVERAGE PERIOD OF CERTAIN ENROLLEES

Commencement of coverage period upon enrollment before Oct. 1, 1966 of eligible individuals failing for good cause to enroll before June 1, 1966, see section 102(b) of Pub. L. 89–97, set out as a note under section 1395p of this title.

§ 1395r. Amount of premiums for individuals enrolled under this part

(a) Determination of monthly actuarial rates and premiums

(1) The Secretary shall, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for enrollees age 65 and over which shall be applicable for the succeeding calendar year. Subject to paragraphs (5) and (6), such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to those enrollees age 65 and older will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related administrative costs incurred in such calendar year with respect to such enrollees. In calculating the monthly actuarial rate, the Secretary shall include an appropriate amount for a contingency margin. In applying this paragraph there shall not be taken into account additional payments under section 1395w–4(*o*) of this title and section 1395w–23(*l*)(3) of this title and the Government contribution under section 1395w(a)(3) of this title.

(2) The monthly premium of each individual enrolled under this part for each month after December 1983 shall be the amount determined

under paragraph (3), adjusted as required in accordance with subsections (b), (c), (f), and (i) of this section, and to reflect any credit provided under section 1395w–24(b)(1)(C)(ii)(III) of this title.

(3) The Secretary, during September of each year, shall determine and promulgate a monthly premium rate for the succeeding calendar year that (except as provided in subsection (g) of this section) is equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1), for that succeeding calendar year. Whenever the Secretary promulgates the dollar amount which shall be applicable as the monthly premium rate for any period, he shall, at the time such promulgation is announced, issue a public statement setting forth the actuarial assumptions and bases employed by him in arriving at the amount of an adequate actuarial rate for enrollees age 65 and older as provided in paragraph (1).

(4) The Secretary shall also, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for disabled enrollees under age 65 which shall be applicable for the succeeding calendar year. Such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to disabled enrollees under age 65 will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related administrative costs incurred in such calendar year with respect to such enrollees. In calculating the monthly actuarial rate under this paragraph, the Secretary shall include an appropriate amount for a contingency margin.

(5)(A) In applying this part (including subsection (i) and section 1395*l*(b) of this title), the monthly actuarial rate for enrollees age 65 and over for 2016 shall be determined as if subsection (f) did not apply.

(B) Subsection (f) shall continue to be applied to paragraph (6)(A) (during a repayment month, as described in paragraph (6)(B)) and without regard to the application of subparagraph (A).

(6)(A) With respect to a repayment month (as described in subparagraph (B)), the monthly premium otherwise established under paragraph (3) shall be increased by, subject to subparagraph (D), $3.

(B) For purposes of this paragraph, a repayment month is a month during a year, beginning with 2016, for which a balance due amount is computed under subparagraph (C) as greater than zero.

(C) For purposes of this paragraph, the balance due amount computed under this subparagraph, with respect to a month, is the amount estimated by the Chief Actuary of the Centers for Medicare & Medicaid Services to be equal to—

(i) the amount transferred under section 1395w(d)(1) of this title; plus

(ii) the amount that is equal to the aggregate reduction, for all individuals enrolled under this part, in the income related monthly adjustment amount as a result of the application of paragraph (5); minus

(iii) the amounts payable under this part as a result of the application of this paragraph for preceding months.

(D) If the balance due amount computed under subparagraph (C), without regard to this subparagraph, for December of a year would be less than zero, the Chief Actuary of the Centers for Medicare & Medicaid Services shall estimate, and the Secretary shall apply, a reduction to the dollar amount increase applied under subparagraph (A) for each month during such year in a manner such that the balance due amount for January of the subsequent year is equal to zero.

(b) Increase in monthly premium

In the case of an individual whose coverage period began pursuant to an enrollment after his initial enrollment period (determined pursuant to subsection (c) or (d) of section 1395p of this title) and not pursuant to a special enrollment period under subsection (i)(4) or (*l*) of section 1395p of this title, the monthly premium determined under subsection (a) of this section (without regard to any adjustment under subsection (i) of this section) shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled. For purposes of the preceding sentence, there shall be taken into account (1) the months which elapsed between the close of his initial enrollment period and the close of the enrollment period in which he enrolled, plus (in the case of an individual who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which he reenrolled, but there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual's (or the individual's spouse's) current employment status or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual) or months for which the individual can demonstrate that the individual was an individual described in section 1395p(k)(3) of this title. Any increase in an individual's monthly premium under the first sentence of this subsection with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which such individual may have. No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.

(c) Premiums rounded to nearest multiple of ten cents

If any monthly premium determined under the foregoing provisions of this section is not a multiple of 10 cents, such premium shall be rounded to the nearest multiple of 10 cents.

(d) "Continuous period of eligibility" defined

For purposes of subsection (b) of this section (and section 1395p(g)(1) of this title), an individual's ''continuous period of eligibility'' is the period beginning with the first day on which he is eligible to enroll under section 1395*o* of this title and ending with his death; except that any period during all of which an individual satisfied paragraph (1) of section 1395*o* of this title and which terminated in or before the month preceding the month in which he attained age 65 shall be a separate ''continuous period of eligibility'' with respect to such individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this section).

(e) State payment of part B late enrollment premium increases

(1) Upon the request of a State (or any appropriate State or local governmental entity specified by the Secretary), the Secretary may enter into an agreement with the State (or such entity) under which the State (or such entity) agrees to pay on a quarterly or other periodic basis to the Secretary (to be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund) an amount equal to the amount of the part B late enrollment premium increases with respect to the premiums for eligible individuals (as defined in paragraph (3)(A)).

(2) No part B late enrollment premium increase shall apply to an eligible individual for premiums for months for which the amount of such an increase is payable under an agreement under paragraph (1).

(3) In this subsection:

(A) The term ''eligible individual'' means an individual who is enrolled under this part B and who is within a class of individuals specified in the agreement under paragraph (1).

(B) The term ''part B late enrollment premium increase'' means any increase in a premium as a result of the application of subsection (b) of this section.

(f) Limitation on increase in monthly premium

For any calendar year after 1988, if an individual is entitled to monthly benefits under section 402 or 423 of this title or to a monthly annuity under section 3(a), 4(a), or 4(f) of the Railroad Retirement Act of 1974 [45 U.S.C. 231b(a), 231c(a), (f)] for November and December of the preceding year, if the monthly premium of the individual under this section for December and for January is deducted from those benefits under section 1395s(a)(1) of this title or section 1395s(b)(1) of this title, and if the amount of the individual's premium is not adjusted for such January under subsection (i) of this section, the monthly premium otherwise determined under this section for an individual for that year shall not be increased, pursuant to this subsection, to the extent that such increase would reduce the amount of benefits payable to that individual for that December below the amount of benefits payable to that individual for that November (after the deduction of the premium under this section). For purposes of this subsection, retroactive adjustments or payments and deductions on account of work shall not be taken into account in determining the monthly benefits to which an individual is entitled under section 402 or 423 of this title or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.].

(g) Exclusions from estimate of benefits and administrative costs

In estimating the benefits and administrative costs which will be payable from the Federal Supplementary Medical Insurance Trust Fund for a year for purposes of determining the monthly premium rate under subsection (a)(3) of this section, the Secretary shall exclude an estimate of any benefits and administrative costs attributable to—

(1) the application of section 1395x(v)(1)(L)(viii) of this title or to the establishment under section 1395x(v)(1)(L)(i)(V) of this title of a per visit limit at 106 percent of the median (instead of 105 percent of the median), but only to the extent payment for home health services under this subchapter is not being made under section 1395fff of this title (relating to prospective payment for home health services); and

(2) the medicare prescription drug discount card and transitional assistance program under section 1395w–141 of this title.

(h) Potential application of comparative cost adjustment in CCA areas

(1) In general

Certain individuals who are residing in a CCA area under section 1395w–29[1] of this title who are not enrolled in an MA plan under part C of this subchapter may be subject to a premium adjustment under subsection (f) of such section for months in which the CCA program under such section is in effect in such area.

(2) No effect on late enrollment penalty or income-related adjustment in subsidies

Nothing in this subsection or section 1395w–29(f)[1] of this title shall be construed as affecting the amount of any premium adjustment under subsection (b) or (i) of this section. Subsection (f) of this section shall be applied without regard to any premium adjustment referred to in paragraph (1).

(3) Implementation

In order to carry out a premium adjustment under this subsection and section 1395w–29(f)[1] of this title (insofar as it is effected through the manner of collection of premiums under section 1395s(a) of this title), the Secretary shall transmit to the Commissioner of Social Security—

(A) at the beginning of each year, the name, social security account number, and the amount of the premium adjustment (if any) for each individual enrolled under this part for each month during the year; and

[1] See References in Text note below.

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

(i) Reduction in premium subsidy based on income

(1) In general

In the case of an individual whose modified adjusted gross income exceeds the threshold amount under paragraph (2), the monthly amount of the premium subsidy applicable to the premium under this section for a month after December 2006 shall be reduced (and the monthly premium shall be increased) by the monthly adjustment amount specified in paragraph (3).

(2) Threshold amount

For purposes of this subsection, subject to paragraph (6), the threshold amount is—

(A) except as provided in subparagraph (B), $80,000 (or, beginning with 2018, $85,000), and

(B) in the case of a joint return, twice the amount applicable under subparagraph (A) for the calendar year.

(3) Monthly adjustment amount

(A) In general

Subject to subparagraph (B), the monthly adjustment amount specified in this paragraph for an individual for a month in a year is equal to the product of the following:

(i) Sliding scale percentage

Subject to paragraph (6), the applicable percentage specified in the applicable table in subparagraph (C) for the individual minus 25 percentage points.

(ii) Unsubsidized part B premium amount

(I) 200 percent of the monthly actuarial rate for enrollees age 65 and over (as determined under subsection (a)(1) of this section for the year); plus

(II) 4 times the amount of the increase in the monthly premium under subsection (a)(6) for a month in the year.

(B) 3-year phase in

The monthly adjustment amount specified in this paragraph for an individual for a month in a year before 2009 is equal to the following percentage of the monthly adjustment amount specified in subparagraph (A):

(i) For 2007, 33 percent.

(ii) For 2008, 67 percent.

(C) Applicable percentage

(i) In general

(I) Subject to paragraphs (5) and (6), for years before 2018:

If the modified adjusted gross income is:	The applicable percentage is:
More than $80,000 but not more than $100,000	35 percent
More than $100,000 but not more than $150,000	50 percent
More than $150,000 but not more than $200,000	65 percent
More than $200,000	80 percent.

(II) Subject to paragraph (5), for years beginning with 2018:

If the modified adjusted gross income is:	The applicable percentage is:
More than $85,000 but not more than $107,000	35 percent
More than $107,000 but not more than $133,500	50 percent
More than $133,500 but not more than $160,000	65 percent
More than $160,000	80 percent.

(ii) Joint returns

In the case of a joint return, clause (i) shall be applied by substituting dollar amounts which are twice the dollar amounts otherwise applicable under clause (i) for the calendar year.

(iii) Married individuals filing separate returns

In the case of an individual who—

(I) is married as of the close of the taxable year (within the meaning of section 7703 of the Internal Revenue Code of 1986) but does not file a joint return for such year, and

(II) does not live apart from such individual's spouse at all times during the taxable year,

clause (i) shall be applied by reducing each of the dollar amounts otherwise applicable under such clause for the calendar year by the threshold amount for such year applicable to an unmarried individual.

(4) Modified adjusted gross income

(A) In general

For purposes of this subsection, the term ''modified adjusted gross income'' means adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986)—

(i) determined without regard to sections 135, 911, 931, and 933 of such Code; and

(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax under such Code.

In the case of an individual filing a joint return, any reference in this subsection to the modified adjusted gross income of such individual shall be to such return's modified adjusted gross income.

(B) Taxable year to be used in determining modified adjusted gross income

(i) In general

In applying this subsection for an individual's premiums in a month in a year, subject to clause (ii) and subparagraph (C), the individual's modified adjusted gross income shall be such income determined for the individual's last taxable year beginning in the second calendar year preceding the year involved.

(ii) Temporary use of other data

If, as of October 15 before a calendar year, the Secretary of the Treasury does not have adequate data for an individual in appropriate electronic form for the taxable year referred to in clause (i), the individual's modified adjusted gross income

shall be determined using the data in such form from the previous taxable year. Except as provided in regulations prescribed by the Commissioner of Social Security in consultation with the Secretary, the preceding sentence shall cease to apply when adequate data in appropriate electronic form are available for the individual for the taxable year referred to in clause (i), and proper adjustments shall be made to the extent that the premium adjustments determined under the preceding sentence were inconsistent with those determined using such taxable year.

(iii) Non-filers

In the case of individuals with respect to whom the Secretary of the Treasury does not have adequate data in appropriate electronic form for either taxable year referred to in clause (i) or clause (ii), the Commissioner of Social Security, in consultation with the Secretary, shall prescribe regulations which provide for the treatment of the premium adjustment with respect to such individual under this subsection, including regulations which provide for—

(I) the application of the highest applicable percentage under paragraph (3)(C) to such individual if the Commissioner has information which indicates that such individual's modified adjusted gross income might exceed the threshold amount for the taxable year referred to in clause (i), and

(II) proper adjustments in the case of the application of an applicable percentage under subclause (I) to such individual which is inconsistent with such individual's modified adjusted gross income for such taxable year.

(C) Use of more recent taxable year

(i) In general

The Commissioner of Social Security in consultation with the Secretary of the Treasury shall establish a procedures under which an individual's modified adjusted gross income shall, at the request of such individual, be determined under this subsection—

(I) for a more recent taxable year than the taxable year otherwise used under subparagraph (B), or

(II) by such methodology as the Commissioner, in consultation with such Secretary, determines to be appropriate, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.

(ii) Standard for granting requests

A request under clause (i)(I) to use a more recent taxable year may be granted only if—

(I) the individual furnishes to such Commissioner with respect to such year such documentation, such as a copy of a filed Federal income tax return or an equivalent document, as the Commissioner specifies for purposes of determining the premium adjustment (if any) under this subsection; and

(II) the individual's modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual's spouse, the marriage or divorce of such individual, or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

(5) Inflation adjustment

(A) In general

In the case of any calendar year beginning after 2007 (other than 2018 and 2019), each dollar amount in paragraph (2) or (3) shall be increased by an amount equal to—

(i) such dollar amount, multiplied by

(ii) the percentage (if any) by which the average of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with August of the preceding calendar year exceeds such average for the 12-month period ending with August 2006 (or, in the case of a calendar year beginning with 2020, August 2018).

(B) Rounding

If any dollar amount after being increased under subparagraph (A) is not a multiple of $1,000, such dollar amount shall be rounded to the nearest multiple of $1,000.

(6) Temporary adjustment to income thresholds

Notwithstanding any other provision of this subsection, during the period beginning on January 1, 2011, and ending on December 31, 2017—

(A) the threshold amount otherwise applicable under paragraph (2) shall be equal to such amount for 2010; and

(B) the dollar amounts otherwise applicable under paragraph (3)(C)(i) shall be equal to such dollar amounts for 2010.

(7) Joint return defined

For purposes of this subsection, the term ''joint return'' has the meaning given to such term by section 7701(a)(38) of the Internal Revenue Code of 1986.

(Aug. 14, 1935, ch. 531, title XVIII, § 1839, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 305; amended Pub. L. 90–248, title I, § 145(d), Jan. 2, 1968, 81 Stat. 859; Pub. L. 92–603, title II, §§ 201(c)(4), (5), 203 (a)–(d), Oct. 30, 1972, 86 Stat. 1373, 1376, 1377; Pub. L. 94–182, title I, § 104(a), Dec. 31, 1975, 89 Stat. 1052; Pub. L. 95–216, title II, § 205(e), Dec. 20, 1977, 91 Stat. 1529; Pub. L. 96–499, title IX, § 945(c)(2), Dec. 5, 1980, 94 Stat. 2642; Pub. L. 97–35, title XXI, § 2151(a)(4), Aug. 13, 1981, 95 Stat. 802; Pub. L. 97–248, title I, § 124(a), (b), Sept. 3, 1982, 96 Stat. 364; Pub. L. 97–448, title III, § 309(b)(8), Jan. 12, 1983, 96 Stat. 2409; Pub. L. 98–21, title VI, § 606(a)(1)–(3)(C), Apr. 20, 1983, 97 Stat. 169, 170; Pub. L. 98–369, div. B, title III, §§ 2302(a), (b), 2338(a), July 18, 1984, 98 Stat. 1063, 1091; Pub. L. 98–617, § 3(b)(4), Nov. 8, 1984, 98 Stat.

3295; Pub. L. 99–272, title IX, §§9219(a)(1), 9313, Apr. 7, 1986, 100 Stat. 182, 194; Pub. L. 99–509, title IX, §§9001(c), 9319(c)(4), Oct. 21, 1986, 100 Stat. 1970, 2012; Pub. L. 100–203, title IV, §4080, Dec. 22, 1987, 101 Stat. 1330–126; Pub. L. 100–360, title II, §211(a)–(c)(1), July 1, 1988, 102 Stat. 733, 738; Pub. L. 100–485, title VI, §608(d)(9), Oct. 13, 1988, 102 Stat. 2415; Pub. L. 101–234, title II, §202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101–239, title VI, §§6202(b)(4)(C), (c)(2), 6301, Dec. 19, 1989, 103 Stat. 2233, 2234, 2258; Pub. L. 101–508, title IV, §4301, Nov. 5, 1990, 104 Stat. 1388–125; Pub. L. 103–66, title XIII, §13571, Aug. 10, 1993, 107 Stat. 609; Pub. L. 103–432, title I, §§144, 151(c)(3), Oct. 31, 1994, 108 Stat. 4427, 4435; Pub. L. 105–33, title IV, §§4571(a), (b)(1), 4581(a), 4582, 4631(a)(2), Aug. 5, 1997, 111 Stat. 464, 465, 486; Pub. L. 105–277, div. J, title V, §5101(e), Oct. 21, 1998, 112 Stat. 2681–915; Pub. L. 106–554, §1(a)(6) [title VI, §606(a)(2)(B)(i)], Dec. 21, 2000, 114 Stat. 2763, 2763A–557; Pub. L. 108–173, title I, §105(a), title II, §§222(*l*)(2)(A), 241(b)(2)(A), title VI, §625(a)(1), title VII, §736(b)(7), title VIII, §811(a), (b)(1), Dec. 8, 2003, 117 Stat. 2166, 2206, 2220, 2317, 2356, 2364, 2367; Pub. L. 109–171, title V, §§5111, 5115(a)(1), Feb. 8, 2006, 120 Stat. 43, 45; Pub. L. 111–5, div. B, title IV, §4103(a)(1), Feb. 17, 2009, 123 Stat. 487; Pub. L. 111–148, title III, §§3110(b), 3402, Mar. 23, 2010, 124 Stat. 420, 488; Pub. L. 114–10, title IV, §402, Apr. 16, 2015, 129 Stat. 160; Pub. L. 114–74, title VI, §601(a), (c), Nov. 2, 2015, 129 Stat. 594, 595.)

REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (f), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, §101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231t of Title 45, and Tables.

Section 1395w–29 of this title, referred to in subsec. (h), was repealed by Pub. L. 111–152, title I, §1102(f), Mar. 30, 2010, 124 Stat. 1046.

The Internal Revenue Code of 1986, referred to in subsec. (i)(3)(C)(iii)(I), (4)(A), (7), is classified generally to Title 26, Internal Revenue Code.

AMENDMENTS

2015—Subsec. (a)(1). Pub. L. 114–74, §601(a)(1), substituted ''Subject to paragraphs (5) and (6), such actuarial'' for ''Such actuarial'' in second sentence.

Subsec. (a)(5), (6). Pub. L. 114–74, §601(a)(2), added pars. (5) and (6).

Subsec. (i)(2)(A). Pub. L. 114–10, §402(b)(1), inserted ''(or, beginning with 2018, $85,000)'' after ''$80,000''.

Subsec. (i)(3)(A)(i). Pub. L. 114–10, §402(b)(2), inserted ''applicable'' before ''table''.

Subsec. (i)(3)(A)(ii). Pub. L. 114–74, §601(c), designated existing provisions as subcl. (I), substituted ''year); plus'' for ''year).'', and added subcl. (II).

Subsec. (i)(3)(C)(i). Pub. L. 114–10, §402(a), designated existing provisions as subcl. (I) and inserted introductory provisions and added subcl. (II).

Subsec. (i)(5)(A). Pub. L. 114–10, §402(b)(3)(A), inserted ''(other than 2018 and 2019)'' after ''2007'' in introductory provisions.

Subsec. (i)(5)(A)(ii). Pub. L. 114–10, §402(b)(3)(B), inserted ''(or, in the case of a calendar year beginning with 2020, August 2018)'' after ''August 2006''.

Subsec. (i)(6). Pub. L. 114–10, §402(b)(4), substituted ''2017'' for ''2019'' in introductory provisions.

2010—Subsec. (b). Pub. L. 111–148, §3110(b), substituted ''subsection (i)(4) or (*l*) of section 1395p'' for ''section 1395p(i)(4)''.

Subsec. (i)(2). Pub. L. 111–148, §3402(1), inserted ''subject to paragraph (6),'' after ''subsection,'' in introductory provisions.

Subsec. (i)(3)(A)(i). Pub. L. 111–148, §3402(2), substituted ''Subject to paragraph (6), the applicable'' for ''The applicable''.

Subsec. (i)(6), (7). Pub. L. 111–148, §3402(3), (4), added par. (6) and redesignated former par. (6) as (7).

2009—Subsec. (a)(1). Pub. L. 111–5 inserted at end ''In applying this paragraph there shall not be taken into account additional payments under section 1395w–4(*o*) of this title and section 1395w–23(*l*)(3) of this title and the Government contribution under section 1395w(a)(3) of this title.''

2006—Subsec. (b). Pub. L. 109–171, §5115(a)(1), inserted ''or months for which the individual can demonstrate that the individual was an individual described in section 1395p(k)(3) of this title'' before period at end of second sentence.

Subsec. (i)(3)(B). Pub. L. 109–171, §5111(1), (2), substituted ''3-year'' for ''5-year'' in heading and ''2009'' for ''2011'' in introductory provisions.

Subsec. (i)(3)(B)(i). Pub. L. 109–171, §5111(3), substituted ''33 percent'' for ''20 percent''.

Subsec. (i)(3)(B)(ii). Pub. L. 109–171, §5111(4), substituted ''67 percent'' for ''40 percent''.

Subsec. (i)(3)(B)(iii), (iv). Pub. L. 109–171, §5111(5), struck out cls. (iii) and (iv), which read as follows:

''(iii) For 2009, 60 percent.

''(iv) for 2010, 80 percent.''

2003—Subsec. (a)(2). Pub. L. 108–173, §811(b)(1)(A), substituted ''(f), and (i)'' for ''and (f)''.

Pub. L. 108–173, §222(*l*)(2)(A), substituted ''any credit provided under section 1395w–24(b)(1)(C)(ii)(III)'' for ''80 percent of any reduction elected under section 1395w–24(f)(1)(E)''.

Subsec. (a)(4). Pub. L. 108–173, §736(b)(7), substituted ''will equal one-half of the total'' for ''which will equal one-half of the total''.

Subsec. (b). Pub. L. 108–173, §811(b)(1)(B), inserted ''(without regard to any adjustment under subsection (i) of this section)'' after ''subsection (a) of this section''.

Pub. L. 108–173, §625(a)(1), inserted at end ''No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.''

Subsec. (f). Pub. L. 108–173, §811(b)(1)(C), substituted ''if the monthly premium'' for ''and if the monthly premium'' and inserted ''and if the amount of the individual's premium is not adjusted for such January under subsection (i) of this section,'' after ''section 1395s(b)(1) of this title,''.

Subsec. (g). Pub. L. 108–173, §105(a), substituted ''attributable to—'' for ''attributable to'', inserted par. (1) designation before ''the application of'', substituted ''; and'' for period at end, and added par. (2).

Subsec. (h). Pub. L. 108–173, §241(b)(2)(A), added subsec. (h).

Subsec. (i). Pub. L. 108–173, §811(a), added subsec. (i).

2000—Subsec. (a)(2). Pub. L. 106–554 substituted ''shall be the amount determined under paragraph (3), adjusted as required in accordance with subsections (b), (c), and (f) of this section, and to reflect 80 percent of any reduction elected under section 1395w–24(f)(1)(E) of this title.'' for ''shall, except as provided in subsections (b), (c), and (f) of this section, be the amount determined under paragraph (3).''

1998—Subsec. (a)(3). Pub. L. 105–277, §5101(e)(1), inserted ''(except as provided in subsection (g) of this section)'' after ''year that''.

Subsec. (g). Pub. L. 105–277, §5101(e)(2), added subsec. (g).

1997—Subsec. (a)(2). Pub. L. 105–33, §4571(b)(1)(A), substituted ''subsections (b), (c), and (f)'' for ''subsections (b) and (e)''.

Subsec. (a)(3). Pub. L. 105–33, § 4571(b)(1)(B), in last sentence, inserted ''rate'' after ''monthly premium'' and struck out ''and the derivation of the dollar amounts specified in this paragraph'' before period at end.

Pub. L. 105–33, § 4571(a), substituted ''The Secretary, during September of each year, shall determine and promulgate a monthly premium rate for the succeeding calendar year that is equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1), for that succeeding calendar year.'' for ''The Secretary shall, during September of 1983 and of each year thereafter, determine and promulgate the monthly premium applicable for individuals enrolled under this part for the succeeding calendar year. The monthly premium shall (except as otherwise provided in subsection (e) of this section) be equal to the smaller of—

''(A) the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1) of this subsection, for that calendar year, or

''(B) the monthly premium rate most recently promulgated by the Secretary under this paragraph, increased by a percentage determined as follows: The Secretary shall ascertain the primary insurance amount computed under section 415(a)(1) of this title, based upon average indexed monthly earnings of $900, that applied to individuals who became eligible for and entitled to old-age insurance benefits on November 1 of the year before the year of the promulgation. He shall increase the monthly premium rate by the same percentage by which that primary insurance amount is increased when, by reason of the law in effect at the time the promulgation is made, it is so computed to apply to those individuals for the following November 1.''

Subsec. (b). Pub. L. 105–33, § 4631(a)(2), substituted ''1395y(b)(1)(B)(iii) of this title'' for ''1395y(b)(1)(B)(iv) of this title'' in second sentence.

Pub. L. 105–33, § 4571(b)(1)(C), struck out ''or (e)'' after ''determined under subsection (a)'' in first sentence.

Pub. L. 105–33, § 4581(a), inserted ''and not pursuant to a special enrollment period under section 1395p(i)(4) of this title'' after ''section 1395p of this title)'' in first sentence.

Subsec. (e). Pub. L. 105–33, § 4571(b)(1)(D), (E), redesignated subsec. (g) as (e) and struck out former subsec. (e) which read as follows:

''(1)(A) Notwithstanding the provisions of subsection (a) of this section, the monthly premium for each individual enrolled under this part for each month after after December 1995 and prior to January 1999 shall be an amount equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, as determined under subsection (a)(1) of this section and applicable to such month.

''(B) Notwithstanding the provisions of subsection (a) of this section, the monthly premium for each individual enrolled under this part for each month in—

''(i) 1991 shall be $29.90,

''(ii) 1992 shall be $31.80,

''(iii) 1993 shall be $36.60,

''(iv) 1994 shall be $41.10, and

''(v) 1995 shall be $46.10.

''(2) Any increases in premium amounts taking effect prior to January 1998 by reason of paragraph (1) shall be taken into account for purposes of determining increases thereafter under subsection (a)(3) of this section.''

Subsec. (e)(1). Pub. L. 105–33, § 4582, inserted ''(or any appropriate State or local governmental entity specified by the Secretary)'' after ''request of a State'' and inserted ''(or such entity)'' after ''agreement with the State'' and after ''which the State''.

Subsec. (g). Pub. L. 105–33, § 4571(b)(1)(E), redesignated subsec. (g) as (e).

1994—Subsec. (b). Pub. L. 103–432, § 151(c)(3), in second sentence, inserted ''status'' after ''current employment'' and substituted ''(as that term is defined in section 1395y(b)(1)(B)(iv) of this title) by reason of the individual's current employment status (or the current employment status of a family member of the individual)'' for ''as an active individual (as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)''.

Subsec. (g). Pub. L. 103–432, § 144, added subsec. (g).

1993—Subsec. (e)(1)(A). Pub. L. 103–66, § 13571(1), substituted ''after December 1995 and prior to January 1999 shall be an amount equal to 50 percent'' for ''December 1983 and prior to January 1991 shall be an amount equal to 50 percent''.

Subsec. (e)(2). Pub. L. 103–66, § 13571(2), substituted ''1998'' for ''1991''.

1990—Subsec. (e)(1). Pub. L. 101–508 designated existing provisions as subpar. (A) and added subpar. (B).

1989—Subsec. (a). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(A)–(D), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment notes below.

Subsec. (b). Pub. L. 101–239, § 6202(c)(2), struck out ''during which the individual has attained the age of 65 and'' after ''into account months'' in second sentence.

Pub. L. 101–239, § 6202(b)(4)(C), substituted ''section 1395y(b)(1)(A)(v)'' and ''section 1395y(b)(1)(B)(iv)'' for ''section 1395y(b)(3)(A)(iv)'' and ''section 1395y(b)(4)(B)'', respectively.

Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(E), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (e). Pub. L. 101–239, § 6301, substituted ''1991'' for ''1990'' wherever appearing.

Subsec. (e)(1). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(F), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (g). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(a), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

1988—Subsec. (a)(1). Pub. L. 100–360, § 211(c)(1)(A), (B), inserted ''(other than costs relating to the amendments made by the Medicare Catastrophic Coverage Act of 1988)'' before period at end of second sentence, and '', but shall not take into account any amounts in the Trust Fund that may be attributable to receipts or outlays relating to the Medicare Catastrophic Coverage Account'' before period at end of last sentence.

Subsec. (a)(2). Pub. L. 100–360, § 211(c)(1)(C), substituted '', (e), and (g)'' for ''and (e)''.

Subsec. (a)(3). Pub. L. 100–360, § 211(c)(1)(D), substituted ''subsections (e) and (g)'' for ''subsection (e)'' in introductory provisions.

Subsec. (a)(4). Pub. L. 100–360, § 211(c)(1)(A), (B), inserted ''(other than costs relating to the amendments made by the Medicare Catastrophic Coverage Act of 1988)'' before period at end of second sentence, and '', but shall not take into account any amounts in the Trust Fund that may be attributable to receipts or outlays relating to the Medicare Catastrophic Coverage Account'' before period at end of last sentence.

Subsec. (b). Pub. L. 100–360, § 211(c)(1)(E), substituted ''otherwise determined under this section (without regard to subsections (f) and (g)(6) of this section)'' for ''determined under subsection (a) or (e) of this section''.

Subsec. (e)(1). Pub. L. 100–360, § 211(c)(1)(F), inserted ''except as provided in subsection (g) of this section,'' after ''subsection (a) of this section''.

Subsec. (f). Pub. L. 100–485, § 608(d)(8)(B), substituted ''for that December below the amount of benefits payable to that individual for that November'' for ''for that January below the amount of benefits payable to that individual for that December''.

Pub. L. 100–360, § 211(b), amended subsec. (f) generally, substituting a single paragraph for former pars. (1) and (2).

Subsec. (g). Pub. L. 100–360, §211(a), added subsec. (g) relating to adjustment in medicare part B premium.

Subsec. (g)(1)(B)(iii)(I). Pub. L. 100–485, §608(d)(9)(A)(i), substituted ''year, over'' for ''year, and''.

Subsec. (g)(1)(B)(iii)(II). Pub. L. 100–485, §608(d)(9)(A)(ii), substituted ''supplemental premium rate'' for ''supplemental rate''.

Subsec. (g)(7)(A)(ii). Pub. L. 100–485, §608(d)(9)(A)(iii), substituted ''of each such year'' for ''of such year''.

1987—Subsec. (e). Pub. L. 100–203, §4080(1), substituted ''1990'' for ''1989'' wherever appearing.

Subsec. (f)(1). Pub. L. 100–203, §4080(2), substituted ''1987, or 1988'' for ''or 1987''.

Subsec. (f)(2). Pub. L. 100–203, §4080(3), substituted ''1988, or 1989'' for ''or 1988''.

1986—Subsec. (b). Pub. L. 99–509, §9319(c)(4), inserted ''or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan as an active individual (as those terms are defined in section 1395y(b)(4)(B) of this title)'' at end of second sentence.

Pub. L. 99–272, §9219(a)(1), substituted ''months during which the individual has attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1395y(b)(3)(A)(iv) of this title'' for ''months in which the individual has met the conditions specified in clauses (i) and (iii) of section 1395y(b)(3)(A) of this title and can demonstrate that the individual was enrolled in a group health plan described in clause (iv) of such section''.

Subsec. (e). Pub. L. 99–272, §9313(1), substituted ''1989'' for ''1988'' wherever appearing.

Subsec. (f)(1). Pub. L. 99–272, §9313(2), substituted '', 1986, or 1987'' for ''or 1986''.

Subsec. (f)(2). Pub. L. 99–272, §9313(3), substituted '', 1987, or 1988'' for ''or 1987''.

Subsec. (f)(2)(A). Pub. L. 99–509, §9001(c), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''the monthly premium amount determined under subsection (a)(2) of this section for that January reduced by the amount (if any) necessary to make the monthly benefits under section 402 or 423 of this title for that December after the deduction of the monthly premium (disregarding subsection (b) of this section) for that January at least equal to the monthly benefits under section 402 or 423 of this title for the preceding November after the deduction of the premium (disregarding subsection (b) of this section) for that individual for that December, or''.

1984—Subsec. (b). Pub. L. 98–369, §2338(a), inserted provision that there shall not be taken into account months in which the individual has met conditions specified in clauses (i) and (iii) of section 1395y(b)(3)(A) of this title and can demonstrate that the individual was enrolled in a group health plan described in clause (iv) of such section by reason of the individual's (or the individual's spouse's) current employment.

Subsec. (e). Pub. L. 98–369, §2302(a), substituted ''1988'' for ''1986'' in pars. (1) and (2).

Subsec. (f). Pub. L. 98–369, §2302(b), added subsec. (f).

Subsec. (f)(2)(A). Pub. L. 98–617, §3(b)(4), substituted ''for that December after the deduction'' for ''for that January after the deduction'' and ''for that December'' for ''for that November''.

1983—Subsec. (a). Pub. L. 98–21, §606(a)(1), added subsec. (a) and struck out former subsec. (a) which provided that monthly premium of each individual enrolled under this part for each month before 1968 would be $3.

Subsec. (b). Pub. L. 98–21, §606(a)(3)(A), substituted ''subsection (a) or (e)'' for ''subsection (b), (c), or (g)''.

Pub. L. 98–21, §606(a)(1), (2), redesignated subsec. (d) as (b), and struck out former subsec. (b) which provided for determination by Secretary of monthly premium for each individual enrolled under this part for each month after 1967 and before July 1, 1973.

Subsec. (c). Pub. L. 98–21, §606(a)(1), (2), redesignated subsec. (e) as (c), and struck out former subsec. (c) which directed Secretary to determine during December of each year after 1972 the monthly actuarial rate for enrollees age 65 and over applicable to succeeding fiscal year (beginning July 1), provided for his determination of monthly premium for such period, and directed him to determine monthly actuarial rate for disabled enrollees under age 65.

Subsec. (d). Pub. L. 98–21, §606(a)(3)(B), which directed that ''purposes of subsection (b)'' be substituted for ''purposes of subsection (c)'' was executed by substituting ''purposes of subsection (b)'' for ''purposes of subsection (d)'', as the probable intent of Congress in view of previous substitution of ''subsection (d)'' for ''subsection (c)'' by Pub. L. 92–603, §203(d)(2).

Pub. L. 98–21, §606(a)(2), redesignated subsec. (f) as (d). Former subsec. (d) redesignated (b).

Pub. L. 97–448 inserted reference to determination of monthly premium pursuant to subsec. (g) of this section.

Subsec. (e). Pub. L. 98–21, §606(a)(2), redesignated subsec. (g) as (e). Former subsec. (e) redesignated (c).

Subsec. (e)(1). Pub. L. 98–21, §606(a)(3)(C), substituted ''(a)'' for ''(c)'', ''(a)(1)'' for ''(c)(1)'', ''December 1983'' for ''June 1983'', and ''January 1986'' for ''July 1985''.

Subsec. (e)(2). Pub. L. 98–21, §606(a)(3)(C)(i), (iii), substituted ''(a)(3)'' for ''(c)(3)'' and ''January 1986'' for ''July 1985''.

Subsecs. (f), (g). Pub. L. 98–21, §606(a)(2), redesignated subsecs. (f) and (g) as (d) and (e), respectively.

1982—Subsec. (c)(2). Pub. L. 97–248, §124(a)(1), substituted ''except as provided in subsections (d) and (g)'' for ''except as provided in subsection (d)''.

Subsec. (c)(3). Pub. L. 97–248, §124(a)(2), inserted ''(except as otherwise provided in subsection (g) of this section)''.

Subsec. (g). Pub. L. 97–248, §124(b), added subsec. (g).

1981—Subsec. (d). Pub. L. 97–35 substituted ''the close of the enrollment period in which he reenrolled'' for ''the month after the month in which he reenrolled'' in cl. (2).

1980—Subsec. (d). Pub. L. 96–499 substituted ''who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the month after the month in which he reenrolled'' for ''who enrolls for a second time) (2) the months which elapsed between the date of the termination of his first coverage period and the close of the enrollment period in which he enrolled for the second time''.

1977—Subsec. (c)(3)(B). Pub. L. 95–216 substituted ''the monthly premium rate most recently promulgated by the Secretary under this paragraph, increased by a percentage determined as follows: The Secretary shall ascertain the primary insurance amount computed under section 415(a)(1) of this title, based upon average indexed monthly earnings of $900, that applied to individuals who became eligible for and entitled to old-age insurance benefits on May 1 of the year of the promulgation'' for ''the monthly premium rate most recently promulgated by the Secretary under this paragraph or, in the case of the determination made in December 1971, such rate promulgated under subsection (b)(2) of this section multiplied by the ratio of (i) the amount in column IV of the table which, by reason of the law in effect at the time the promulgation is made, will be in effect as of May 1 next following such determination appears (or is deemed to appear) in section 415(a) of this title on the line which includes the figure '750' in column III of such table to (ii) the amount in column IV of the table which appeared (or was deemed to appear) in section 415(a) of this title on the line which included the figure '750' in column III as of May 1 of the year in which such determination is made'' and inserted ''He shall increase the monthly premium rate by the same percentage by which that primary insurance amount is increased when, by reason of the law in effect at the time the promulgation is made, it is so computed to apply to those individuals on the following May 1.''

1975—Subsec. (c)(3). Pub. L. 94–182 substituted ''May 1'' for ''June 1'' wherever appearing.

1972—Subsec. (b)(1). Pub. L. 92–603, §203(a), inserted ''and before July 1, 1973'' following ''1967''.

Subsec. (b)(2). Pub. L. 92–603, § 203(b), substituted ''ending on or before December 31, 1971'' for ''thereafter''.

Subsec. (c). Pub. L. 92–603, § 203(c), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 92–603, §§ 201(c)(4), 203(c), (d)(1), redesignated former subsec. (c) as (d), inserted reference to subsec. (c) after reference to subsec. (b), inserted ''(in the same continuous period of eligibility)'' after ''for each full 12 months'', and inserted provisions relating to any increase in an individual's monthly premium under the first sentence of this subsection. Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 92–603, § 203(c), redesignated former subsec. (d) as (e). Former subsec. (e) redesignated (f).

Pub. L. 92–603, § 201(c)(5), added subsec. (e).

Subsec. (f). Pub. L. 92–603, § 203(c), (d)(2), redesignated former subsec. (e) as (f) and substituted ''subsection (d)'' for ''subsection (c)''.

1968—Subsec. (b)(2). Pub. L. 90–248 required Secretary, during December of each year, beginning in 1968, to determine and announce amount (whether or not such amount was applicable for premiums for any prior month) of supplementary medical insurance premium for 12-month period beginning on July 1 of each following year, which premium is to be such that aggregate premiums will equal one-half estimated benefit and administrative expenses of supplementary medical insurance program for such 12-month period, and that at time of announcement of premium amount, Secretary must make public actuarial assumptions and bases used in deciding amount of premium.

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by section 5115(a)(1) of Pub. L. 109–171 applicable to months beginning with Jan. 2007, see section 5115(b) of Pub. L. 109–171, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(*l*)(2)(A) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Pub. L. 108–173, title VI, § 625(a)(2), Dec. 8, 2003, 117 Stat. 2318, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to premiums for months beginning with January 2004. The Secretary [of Health and Human Services] shall establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously collected.''

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, § 1(a)(6) [title VI, § 606(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–558, provided that: ''The amendments made by subsection (a) [amending this section and sections 1395s, 1395w, 1395w–21, 1395w–23, and 1395w–24 of this title] shall apply to years beginning with 2003.''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4581(a) of Pub. L. 105–33 applicable to involuntary terminations of coverage under a group health plan occurring on or after Aug. 5, 1997, see section 4581(c) of Pub. L. 105–33, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, § 151(c)(3), Oct. 31, 1994, 108 Stat. 4435, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–66.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6202(b)(4)(C) of Pub. L. 101–239 applicable to items and services furnished after Dec. 19, 1989, see section 6202(b)(5) of Pub. L. 101–239, set out as a note under section 162 of Title 26, Internal Revenue Code.

Amendment by section 6202(c)(2) of Pub. L. 101–239 applicable to enrollments occurring after, and premiums for months after, second calendar quarter beginning after Dec. 19, 1989, see section 6202(c)(3) of Pub. L. 101–239, set out as a note under section 1395p of this title.

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, and applicable to premiums for months beginning after Dec. 31, 1989, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

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, § 211(d), July 1, 1988, 102 Stat. 739, which provided that the amendments made by section 211 of Pub. L. 100–360 [amending this section and sections 1395w and 1395mm of this title] applied (except as otherwise specified in such amendments) to monthly premiums for months beginning with January 1989, was repealed by Pub. L. 101–234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 1981.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 9001(c) of Pub. L. 99–509 applicable with respect to monthly premiums under this section for months after December 1986, see section 9001(d)(3) of Pub. L. 99–509, set out as a note under section 415 of this title.

Amendment by section 9319(c)(4) of Pub. L. 99–509 applicable to enrollments occurring on or after Jan. 1, 1987, see section 9319(f)(2) of Pub. L. 99–509 set out as a note under section 1395y of this title.

Pub. L. 99–272, title IX, § 9219(a)(3)(A), Apr. 7, 1986, 100 Stat. 182, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to months beginning with January 1983 for premiums for months beginning with the first month that begins more than 30 days after the date of the enactment of this Act [Apr. 7, 1986].''

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.

Pub. L. 98–369, div. B, title III, § 2302(c), July 18, 1994, 98 Stat. 1064, provided that: ''The amendments made by this section [amending this section] shall apply to premiums for months beginning with January 1986.''

Pub. L. 98–369, div. B, title III, § 2338(d)(1), July 18, 1994, 98 Stat. 1093, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to months beginning with January 1983 for premiums for months beginning with the first month which begins more than 30 days after the date of the enactment of this Act [July 18, 1984].''

EFFECTIVE DATE OF 1983 AMENDMENT; TRANSITIONAL RULE

Pub. L. 98–21, title VI, § 606(c), Apr. 20, 1983, 97 Stat. 171, provided that: ''The amendments made by this section [amending this section and sections 1395i–2, 1395v, 1395w, and 1395mm of this title] shall apply to premiums for months beginning with January 1984, and for months after June 1983 and before January 1984—

''(1) the monthly premiums under part A and under part B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] for individuals enrolled under each respective part shall be the monthly premium under that part for the month of June 1983, and

''(2) the amount of the Government contributions under section 1844(a)(1) of such Act [42 U.S.C.

1395w(a)(1)] shall be computed on the basis of the actuarially adequate rate which would have been in effect under part B of title XVIII of such Act for such months without regard to the amendments made by this section, but using the amount of the premium in effect for the month of June 1983.''

Amendment by Pub. L. 97–448 effective as if originally included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 309(c)(2) of Pub. L. 97–448, set out as a note under section 426–1 of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 not applicable to enrollments pursuant to written requests for enrollment filed before Oct. 1, 1981, see section 2151(b) of Pub. L. 97–35, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96–499 applicable to enrollments occurring on or after Apr. 1, 1981, see section 945(d) of Pub. L. 96–499, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Amendment by Pub. L. 95–216 effective with respect to monthly benefits and lump-sum death payments for deaths occurring after December 1978, see section 206 of Pub. L. 95–216, set out as a note under section 402 of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–182, title I, §104(b), Dec. 31, 1975, 89 Stat. 1052, provided that: ''The amendments made by subsection (a) [amending this section] shall apply with respect to determinations made under section 1839(c)(3) of the Social Security Act [42 U.S.C. 1395r(c)(3)] after the date of the enactment of this Act [Dec. 31, 1975].''

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–248 effective Dec. 1, 1968, see section 145(e) of Pub. L. 90–248, set out as a note under section 1395p of this title.

CONSTRUCTION REGARDING NO AUTHORITY TO INITIATE APPLICATION TO YEARS AFTER 2017

Pub. L. 114–74, title VI, §601(e), Nov. 2, 2015, 129 Stat. 596, provided that: ''Nothing in subsection (d) [set out as a note below] or the amendments made by this section [amending this section and secton 1395w of this title] shall be construed as authorizing the Secretary of Health and Human Services to initiate application of such subsection or amendments for a year after 2017.''

CONDITIONAL APPLICATION TO 2017 IF NO SOCIAL SECURITY COLA FOR 2017

Pub. L. 114–74, title VI, §601(d), Nov. 2, 2015, 129 Stat. 596, provided that: ''If there is no increase in the monthly insurance benefits payable under title II [probably means title II of act Aug. 14, 1935, ch. 531, which is classified to 42 U.S.C. 401 et seq.] with respect to December 2016 pursuant to section 215(i) [probably means section 215(i) of act Aug. 14, 1935, ch. 531, which is classified to 42 U.S.C. 415(i)], then the amendments made by this section [amending this section and secton 1395w of this section] shall be applied as if—

''(1) the reference to '2016' in paragraph (5)(A) of section 1839(a) of the Social Security Act (42 U.S.C. 1395r(a)), as added by subsection (a)(2), was a reference to '2016 and 2017';

''(2) the reference to 'a month during a year, beginning with 2016' in paragraph (6)(B) of section 1839 of such Act (42 U.S.C. 1395r(a)), as added by subsection (a)(2), was a reference to 'a month in a year, beginning with 2016 and beginning with 2017, respectively'; and

''(3) the reference to '2016' in subsection (d)(1) of section 1844 of such Act (42 U.S.C. 1395w), as added by subsection (b)(2), was a reference to 'each of 2016 and 2017'

Any increase in premiums effected under this subsection shall be in addition to the increase effected by the amendments made by subsection (a) [amending this section].''

NO CHANGE IN MEDICARE'S DEFINED BENEFIT PACKAGE

Pub. L. 108–173, title II, §241(c), Dec. 8, 2003, 117 Stat. 2221, provided that: ''Nothing in this part [probably should be this section, enacting former section 1395w–29 of this title and amending this section and sections 1395w and 1395w–23 of this title] (or the amendments made by this part) shall be construed as changing the entitlement to defined benefits under parts A and B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.].''

DETERMINATION OF PREMIUM AMOUNTS BY SECRETARY

Pub. L. 90–97, §2, Sept. 30, 1967, 81 Stat. 249, provided that: ''Notwithstanding the provisions of section 1839(a) and (b) of the Social Security Act [42 U.S.C. 1395r(a), (b)]—

''(1) the dollar amount applicable for premiums under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] for each month before April 1968 shall be $3, and

''(2) the Secretary of Health, Education, and Welfare may determine and promulgate such dollar amount for months after March 1968 and before January 1970 at any time on or before December 31, 1967.''

PERSONS ENROLLING BEFORE APRIL 1, 1968, WHO DID NOT ENROLL DURING THEIR INITIAL ENROLLMENT PERIOD

Pub. L. 90–97, §3(b), Sept. 30, 1967, 81 Stat. 250, provided that: ''In the case of any individual who did not enroll in the insurance program established under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in his initial enrollment period, but does so enroll before April 1, 1968, the enrollment period in which he so enrolls shall, for purposes of section 1839(c) of such Act [42 U.S.C. 1395r(c)], be deemed to have closed on December 31, 1967.''

§ 1395s. Payment of premiums

(a) Deductions from section 402 or 423 monthly benefits

(1) In the case of an individual who is entitled to monthly benefits under section 402 or 423 of this title, his monthly premiums under this part shall (except as provided in subsections (b)(1) and (c) of this section) be collected by deducting the amount thereof from the amount of such monthly benefits. Such deduction shall be made in such manner and at such times as the Commissioner of Social Security shall by regulation prescribe. Such regulations shall be prescribed after consultation with the Secretary.

(2) The Secretary of the Treasury shall, from time to time, transfer from the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates from benefits under section 402 or 423 of this title which are payable from such Trust Fund. Such transfer shall be made on the basis of a certification by the Commissioner of Social Security and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(b) Deductions from railroad retirement annuities or pensions

(1) In the case of an individual who is entitled to receive for a month an annuity under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.] (whether or not such individual is also entitled for such month to a monthly insurance benefit under section 402 of this title), his monthly premiums under this part shall (except as provided in subsection (c) of this section) be collected by deducting the amount thereof from such annuity or pension. Such deduction shall be made in such manner and at such times as the Secretary shall by regulations prescribe. Such regulations shall be prescribed only after consultation with the Railroad Retirement Board.

(2) The Secretary of the Treasury shall, from time to time, transfer from the Railroad Retirement Account to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such transfers shall be made on the basis of a certification by the Railroad Retirement Board and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(c) Portion of monthly premium in excess of deducted amount

If an individual to whom subsection (a) or (b) of this section applies estimates that the amount which will be available for deduction under such subsection for any premium payment period will be less than the amount of the monthly premiums for such period, he may (under regulations) pay to the Secretary such portion of the monthly premiums for such period as he desires.

(d) Deductions from civil service retirement annuities

(1) In the case of an individual receiving an annuity under subchapter III of chapter 83 of title 5 or any other law administered by the Director of the Office of Personnel Management providing retirement or survivorship protection, to whom neither subsection (a) nor subsection (b) of this section applies, his monthly premiums under this part (and the monthly premiums of the spouse of such individual under this part if neither subsection (a) nor subsection (b) of this section applies to such spouse and if such individual agrees) shall, upon notice from the Secretary of Health and Human Services to the Director of the Office of Personnel Management, be collected by deducting the amount thereof from each installment of such annuity. Such deduction shall be made in such manner and at such times as the Director of the Office of Personnel Management may determine. The Director of the Office of Personnel Management shall furnish such information as the Secretary of Health and Human Services may reasonably request in order to carry out his functions under this part with respect to individuals to whom this subsection applies. A plan described in section 8903 or 8903a of title 5 may reimburse each annuitant enrolled in such plan an amount equal to the premiums paid by him under this part if such reimbursement is paid entirely from funds of such plan which are derived from sources other than the contributions described in section 8906 of such title.

(2) The Secretary of the Treasury shall, from time to time, but not less often than quarterly, transfer from the Civil Service Retirement and Disability Fund, or the account (if any) applicable in the case of such other law administered by the Director of the Office of Personnel Management, to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such transfer shall be made on the basis of a certification by the Director of the Office of Personnel Management and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(e) Manner and time of payment prescribed by Secretary

In the case of an individual who participates in the insurance program established by this part but with respect to whom none of the preceding provisions of this section applies, or with respect to whom subsection (c) of this section applies, the premiums shall be paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe.

(f) Deposit of amounts in Treasury

Amounts paid to the Secretary under subsection (c) or (e) of this section shall be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund.

(g) Premium payability period

In the case of an individual who participates in the insurance program established by this part, premiums shall be payable for the period commencing with the first month of his coverage period and ending with the month in which he dies or, if earlier, in which his coverage under such program terminates.

(h) Exempted monthly benefits

In the case of an individual who is enrolled under the program established by this part as a member of a coverage group to which an agreement with a State entered into pursuant to section 1395v of this title is applicable, subsections (a), (b), (c), and (d) of this section shall not apply to his monthly premium for any month in his coverage period which is determined under section 1395v(d) of this title.

(i) Adjustments for individuals enrolled in Medicare+Choice plans

In the case of an individual enrolled in a Medicare+Choice plan, the Secretary shall provide for necessary adjustments of the monthly beneficiary premium to reflect 80 percent of any reduction elected under section 1395w–24(f)(1)(E) of this title and to reflect any credit provided under section 1395w–24(b)(1)(C)(iv)[1] of this title. To the extent to which the Secretary determines that such an adjustment is appropriate, with the concurrence of any agency responsible for the administration of such benefits, such premium adjustment may be provided directly, as an adjustment to any social security, railroad

[1] See References in Text note below.

retirement, or civil service retirement benefits, or, in the case of an individual who receives medical assistance under subchapter XIX of this chapter for medicare costs described in section 1396d(p)(3)(A)(ii) of this title, as an adjustment to the amount otherwise owed by the State for such medical assistance.

(Aug. 14, 1935, ch. 531, title XVIII, § 1840, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 306; amended Pub. L. 89–384, § 4(c), Apr. 8, 1966, 80 Stat. 106; Pub. L. 90–248, title I, § 166, title IV, § 403(g), Jan. 2, 1968, 81 Stat. 874, 932; Pub. L. 92–603, title II, §§ 201(c)(6), 263(a)–(d)(3), Oct. 30, 1972, 86 Stat. 1373, 1448, 1449; Pub. L. 93–445, title III, § 306, Oct. 16, 1974, 88 Stat. 1358; Pub. L. 98–369, div. B, title III, § 2354(b)(11), title VI, § 2663(j)(2)(F)(ii), July 18, 1984, 98 Stat. 1101, 1170; Pub. L. 99–53, § 2(g), June 17, 1985, 99 Stat. 94; Pub. L. 100–360, title II, § 212(b)(1), July 1, 1988, 102 Stat. 740; Pub. L. 100–485, title VI, § 608(d)(10)(B), Oct. 13, 1988, 102 Stat. 2415; Pub. L. 101–234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 103–296, title I, § 108(c)(2), Aug. 15, 1994, 108 Stat. 1485; Pub. L. 106–554, § 1(a)(6) [title VI, § 606(a)(2)(B)(ii)], Dec. 21, 2000, 114 Stat. 2763, 2763A–557; Pub. L. 108–173, title II, § 222(*l*)(2)(B), Dec. 8, 2003, 117 Stat. 2206.)

REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (b)(1), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, § 101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§ 231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231t of Title 45, and Tables.

Section 1395w–24(b)(1)(C)(iv) of this title, referred to in subsec. (i), was redesignated section 1395w–24(b)(1)(C)(v) of this title by Pub. L. 111–148, title III, § 3202(b)(1)(B), Mar. 23, 2010, 124 Stat. 454, and subsequently redesignated section 1395w–24(b)(1)(C)(viii) of this title by Pub. L. 111–152, title I, § 1102(d)(2), Mar. 30, 2010, 124 Stat. 1045.

AMENDMENTS

2003—Subsec. (i). Pub. L. 108–173 inserted ''and to reflect any credit provided under section 1395w–24(b)(1)(C)(iv) of this title'' after ''section 1395w–24(f)(1)(E) of this title'' in first sentence.

2000—Subsec. (i). Pub. L. 106–554 added subsec. (i).

1994—Subsec. (a)(1). Pub. L. 103–296, § 108(c)(2)(A), substituted ''Commissioner of Social Security'' for ''Secretary'' and inserted at end ''Such regulations shall be prescribed after consultation with the Secretary.''

Subsec. (a)(2). Pub. L. 103–296, § 108(c)(2)(B), substituted ''Commissioner of Social Security'' for ''Secretary of Health and Human Services''.

1989—Subsec. (i). Pub. L. 101–234 repealed Pub. L. 100–360, § 212(b)(1), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

1988—Subsec. (i). Pub. L. 100–485 substituted ''Supplementary'' for ''Supplemental''.

Pub. L. 100–360 added subsec. (i) relating to transfer to flat prescription drug premiums to Federal Catastrophic Drug Insurance Trust Fund.

1985—Subsec. (d)(1). Pub. L. 99–53 inserted reference to section 8903a of title 5.

1984—Subsec. (a)(2). Pub. L. 98–369, § 2663(j)(2)(F)(ii), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (d)(1). Pub. L. 98–369, § 2354(b)(11), substituted ''Director of the Office of Personnel Management'' for ''Civil Service Commission''.

Pub. L. 98–369, § 2663(j)(2)(F)(ii), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (d)(2). Pub. L. 98–369, § 2354(b)(11), substituted ''Director of the Office of Personnel Management'' for ''Civil Service Commission''.

1974—Subsec. (b)(1). Pub. L. 93–445 substituted ''under the Railroad Retirement Act of 1974'' for ''or pension under the Railroad Retirement Act of 1937''.

1972—Subsec. (a)(1). Pub. L. 92–603, §§ 201(c)(6)(A), 263(a), substituted ''subsections (b)(1) and (c)'' for ''subsection (d)'' and inserted reference to section 423 of this title.

Subsec. (a)(2). Pub. L. 92–603, § 201(c)(6)(B), inserted reference to section 423 of this title.

Subsec. (b)(1). Pub. L. 92–603, § 263(b), inserted ''(whether or not such individual is also entitled for such month to a monthly insurance benefit under section 402 of this title)'' after ''1937'' and substituted ''subsection (c)'' for ''subsection (d)''.

Subsec. (c). Pub. L. 92–603, § 263(c), struck out subsec. (c) covering individuals entitled both to monthly benefits under section 402 of this title and to an annuity or pension under Railroad Retirement Act of 1937 and redesignated former subsec. (d) as (c).

Subsec. (d). Pub. L. 92–603, § 263(c), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (e). Pub. L. 92–603, § 263(c), (d)(1), redesignated subsec. (f) as (e) and substituted ''subsection (c)'' for ''subsection (d)''. Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 92–603, § 263(c), (d)(2), redesignated subsec. (g) as (f) and substituted ''subsections (c) or (e)'' for ''subsections (d) or (f)''. Former subsec. (f) redesignated (e) and amended.

Subsec. (g). Pub. L. 92–603, § 263(c), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f) and amended.

Subsecs. (h), (i). Pub. L. 92–603, § 263(c), (d)(3), redesignated subsec. (i) as (h) and substituted ''(c) and (d)'' for ''(c), (d), and (e)''. Former subsec. (h) redesignated (g).

1968—Subsec. (e). Pub. L. 90–248 provided for reimbursement of civil service retirement annuitants for certain premium payments under supplementary medical insurance program, and substituted ''subchapter III of chapter 83 of Title 5 or any other law'' and ''such other law'' for ''the Civil Service Retirement Act, or other Act'' and ''such other Act'', in pars. (1) and (2), respectively.

1966—Subsec. (i). Pub. L. 89–384 added subsec. (i).

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of Title 42, The Public Health and Welfare.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, § 606(b)] of Pub. L. 106–554, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103–296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

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.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 2354(b)(11) 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)(ii) 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 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

Pub. L. 92–603, title II, § 263(f), Oct. 30, 1972, 86 Stat. 1449, provided that: ''The amendments made by this section [amending this section and sections 1395t and 1395u of this title] with respect to collection of premiums shall apply to premiums becoming due and payable after the fourth month following the month in which this Act is enacted [October 1972].''

§ 1395t. Federal Supplementary Medical Insurance Trust Fund

(a) Creation; deposits; fund transfers

There is hereby created on the books of the Treasury of the United States a trust fund to be known as the ''Federal Supplementary Medical Insurance Trust Fund'' (hereinafter in this section referred to as the ''Trust Fund''). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, such amounts as may be deposited in, or appropriated to, such fund as provided in this part or section 9008(c)[1] of the Patient Protection and Affordable Care Act of 2009, and such amounts as may be deposited in, or appropriated to, the Medicare Prescription Drug Account established by section 1395w–116 of this title or the Transitional Assistance Account established by section 1395w–141(k)(1) of this title.

(b) Board of Trustees; composition; meetings; duties

With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the ''Board of Trustees'') composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the ''Managing Trustee''). The Administrator of the Centers for Medicare & Medicaid Services shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. It shall be the duty of the Board of Trustees to—

(1) Hold the Trust Fund;

(2) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years; Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[2]

(3) Report immediately to the Congress whenever the Board is of the opinion that the amount of the Trust Fund is unduly small; and

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The report provided for in paragraph (2) shall include a statement of the assets of, and the disbursements made from, the Trust Fund during the preceding fiscal year, an estimate of the expected income to, and disbursements to be made from, the Trust Fund during the current fiscal year and each of the next 2 fiscal years, and a statement of the actuarial status of the Trust Fund. Such report shall also include an actuarial opinion by the Chief Actuary of the Centers for Medicare & Medicaid Services certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable. Such report shall be printed as a House document of the session of the Congress to which the report is made. A person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.

(c) Investment of Trust Fund by Managing Trustee

It shall be the duty of the Managing Trustee to invest such portion of the Trust Fund as is not, in his judgment, required to meet current withdrawals. Such investments may be made

[1] See References in Text note below.

[2] So in original. See 2003 Amendment note below.

only in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. For such purpose such obligations may be acquired (1) on original issue at the issue price, or (2) by purchase of outstanding obligations at the market price. The purposes for which obligations of the United States may be issued under chapter 31 of title 31 are hereby extended to authorize the issuance at par of public-debt obligations for purchase by the Trust Fund. Such obligations issued for purchase by the Trust Fund shall have maturities fixed with due regard for the needs of the Trust Fund and shall bear interest at a rate equal to the average market yield (computed by the Managing Trustee on the basis of market quotations as of the end of the calendar month next preceding the date of such issue) on all marketable interest-bearing obligations of the United States then forming a part of the public debt which are not due or callable until after the expiration of 4 years from the end of such calendar month; except that where such average market yield is not a multiple of one-eighth of 1 per centum, the rate of interest on such obligations shall be the multiple of one-eighth of 1 per centum nearest such market yield. The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where he determines that the purchase of such other obligations is in the public interest.

(d) Authority of Managing Trustee to sell obligations

Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-debt obligations may be redeemed at par plus accrued interest.

(e) Interest on or proceeds from sale or redemption of obligations

The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(f) Transfers to other Funds

There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Federal Old-Age and Survivors Insurance Trust Fund and from the Federal Disability Insurance Trust Fund amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments (other than amounts so certified to the Railroad Retirement Board) pursuant to section 1395gg(b) of this title. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Railroad Retirement Account amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments to the Railroad Retirement Board pursuant to section 1395gg(b) of this title.

(g) Payments from Trust Fund of amounts provided for by this part or with respect to administrative expenses

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to make the payments provided for by this part, and the payments with respect to administrative expenses in accordance with section 401(g)(1) of this title. The payments provided for under part D of this subchapter, other than under section 1395w–141(k)(2) of this title, shall be made from the Medicare Prescription Drug Account in the Trust Fund. The payments provided for under section 1395w–141(k)(2) of this title shall be made from the Transitional Assistance Account in the Trust Fund.

(h) Payments from Trust Fund of costs incurred by Director of Office of Personnel Management

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Director of the Office of Personnel Management in making deductions pursuant to section 1395s(d) of this title or pursuant to section 1395w–113(c)(1) or 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year, or after the close of such fiscal year, the Director of the Office of Personnel Management shall certify to the Secretary the amount of the costs the Director incurred in making such deductions, and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

(i) Payments from Trust Fund of costs incurred by Railroad Retirement Board

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Railroad Retirement Board for services performed pursuant to section 1395s(b)(1) and section 1395u(g) of this title and pursuant to sections 1395w–113(c)(1) and 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year or after the close of such fiscal year, the Railroad Retirement Board shall certify to the Secretary the amount of the costs it incurred in performing such services and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

(Aug. 14, 1935, ch. 531, title XVIII, §1841, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 308; amended Pub. L. 90–248, title I, §169(a), Jan. 2, 1968, 81 Stat. 875; Pub. L. 92–603, title I, §132(e), title II, §263(d)(4), (e), Oct. 30, 1972, 86 Stat. 1361, 1449; Pub. L. 95–292, §5, June 13, 1978, 92 Stat. 315; Pub. L. 98–21, title I, §154(c), title III, §341(c), Apr. 20, 1983, 97 Stat. 107, 135; Pub. L. 98–369, div. B, title III, §2354(b)(2), (11), (12), title VI, §2663(j)(2)(F)(iii), July 18, 1984, 98 Stat. 1100, 1101, 1170; Pub. L. 99–272, title IX, §9213(b), Apr.

7, 1986, 100 Stat. 180; Pub. L. 100–360, title II, § 212(b)(2), (c)(4), July 1, 1988, 102 Stat. 740, 741; Pub. L. 100–647, title VIII, § 8005(a), Nov. 10, 1988, 102 Stat. 3781; Pub. L. 101–234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 103–296, title I, § 108(c)(3), Aug. 15, 1994, 108 Stat. 1485; Pub. L. 108–173, title I, §§ 101(e)(3)(C), 105(d), title VIII, § 801(d)(2), title IX, § 900(e)(1)(E), Dec. 8, 2003, 117 Stat. 2151, 2166, 2359, 2371; Pub. L. 111–148, title IX, § 9008(k), Mar. 23, 2010, 124 Stat. 862.)

REFERENCES IN TEXT

Section 9008(c) of the Patient Protection and Affordable Care Act of 2009, referred to in subsec. (a), probably means section 9008(c) of Pub. L. 111–148, known as the Patient Protection and Affordable Care Act, which is set out as a note preceding section 4001 of Title 26, Internal Revenue Code.

Section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (b)(2), is section 801(a) of Pub. L. 108–173, which is set out as a note under section 1395i of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148 inserted ''or section 9008(c) of the Patient Protection and Affordable Care Act of 2009'' after ''this part''.

2003—Subsec. (a). Pub. L. 108–173, § 105(d)(1), inserted ''or the Transitional Assistance Account established by section 1395w–141(k)(1) of this title'' after ''section 1395w–116 of this title''.

Pub. L. 108–173, § 101(e)(3)(C)(i), substituted ''section 401(i)(1) of this title,'' for ''section 401(i)(1) of this title, and'' and inserted '', and such amounts as may be deposited in, or appropriated to, the Medicare Prescription Drug Account established by section 1395w–116 of this title'' before period at end.

Subsec. (b). Pub. L. 108–173, § 900(e)(1)(E), in introductory provisions, substituted ''Centers for Medicare & Medicaid Services'' for ''Health Care Financing Administration'' and, in concluding provisions, substituted ''Chief Actuary of the Centers for Medicare & Medicaid Services'' for ''Chief Actuarial Officer of the Health Care Financing Administration''.

Subsec. (b)(2). Pub. L. 108–173, § 801(d)(2), inserted at end ''Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.''

Subsec. (g). Pub. L. 108–173, § 105(d)(2), inserted at end ''The payments provided for under section 1395w–141(k)(2) of this title shall be made from the Transitional Assistance Account in the Trust Fund.''

Pub. L. 108–173, § 101(e)(3)(C)(ii), inserted at end ''The payments provided for under part D of this subchapter, other than under section 1395w–141(k)(2) of this title, shall be made from the Medicare Prescription Drug Account in the Trust Fund.''

Subsec. (h). Pub. L. 108–173, § 101(e)(3)(C)(iii), inserted ''or pursuant to section 1395w–113(c)(1) or 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)'' after ''section 1395s(d) of this title''.

Subsec. (i). Pub. L. 108–173, § 101(e)(3)(C)(iv), inserted ''and pursuant to sections 1395w–113(c)(1) and 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)'' after ''section 1395u(g) of this title''.

1994—Subsec. (b). Pub. L. 103–296 inserted ''the Commissioner of Social Security,'' after ''composed of'' in introductory provisions.

1989—Subsecs. (a), (b). Pub. L. 101–234 repealed Pub. L. 100–360, § 212(b)(2), (c)(4), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment notes below.

1988—Subsec. (a). Pub. L. 100–360, § 212(b)(2), inserted three sentences at end providing for transfer of supplemental catastrophic coverage premiums into the Federal Supplementary Medical Insurance Trust Fund.

Subsec. (b). Pub. L. 100–647 inserted after first sentence ''A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term.''

Pub. L. 100–360, § 212(c)(4), inserted after sixth sentence ''Such report shall also identify (and treat separately) those receipts and outlays in the Trust Fund which are also receipts and outlays in the Medicare Catastrophic Coverage Account created under section 1395t–2 of this title.''

1986—Subsec. (b). Pub. L. 99–272 struck out provision at end of penultimate sentence that the certification shall not refer to economic assumptions underlying Trustee's report.

1984—Subsec. (c). Pub. L. 98–369, § 2354(b)(2), substituted ''under chapter 31 of title 31'' for ''under the Second Liberty Bond Act, as amended''.

Subsecs. (f), (g). Pub. L. 98–369, § 2663(j)(2)(F)(iii), substituted ''Health and Human Services'' for ''Health, Education, and Welfare'' wherever appearing.

Subsec. (h). Pub. L. 98–369, § 2663(j)(2)(F)(iii), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Pub. L. 98–369, § 2354(b)(11), substituted ''Director of the Office of Personnel Management'' for ''Civil Service Commission'' in two places.

Pub. L. 98–369, § 2354(b)(12), substituted ''the Director'' for ''it''.

Subsec. (i). Pub. L. 98–369, § 2663(j)(2)(F)(iii), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

1983—Subsec. (b). Pub. L. 98–21, § 341(c)(1), substituted ''Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate'' for ''Secretary of Health, Education, and Welfare, all ex officio'' in provisions preceding par. (1).

Pub. L. 98–21, § 154(c), inserted at end provision that the report referred to in par. (2) shall also include an actuarial opinion by the Chief Actuarial Officer of the Health Care Financing Administration certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable, and provided further that the certification shall not refer to economic assumptions underlying the Trustee's report.

Pub. L. 98–21, § 341(c)(2), inserted at end provision that a person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.

1978—Subsec. (b). Pub. L. 95–292 substituted ''Administrator of the Health Care Financing Administration'' for ''Commissioner of Social Security'' in provisions preceding par. (1).

1972—Subsec. (a). Pub. L. 92–603, § 132(e), inserted ''such gifts and bequests as may be made as provided in section 401(i)(1) of this title, and'' after ''consist of'' and before ''such amounts''.

Subsec. (h). Pub. L. 92–603, § 263(d)(4), substituted ''1395s(d)'' for ''1395s(e)''.

Subsec. (i). Pub. L. 92–603, § 263(e), added subsec. (i).

1968—Subsec. (b)(2). Pub. L. 90–248 substituted ''April'' for ''March''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103–296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–647 applicable to members of Board of Trustees of Federal Supplementary Medical Insurance Trust Fund serving on such Board as members of the public on or after Nov. 10, 1988, see section 8005(b) of Pub. L. 100–647, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 2354(b)(2), (11), (12) 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)(iii) 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 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, §1841A, as added July 1, 1988, Pub. L. 100–360, title II, §212(a), 102 Stat. 739; amended Oct. 13, 1988, Pub. L. 100–485, title VI, §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.

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; [1]

(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 12-month 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 year-to-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,

[1] So in original. Probably should be followed by ''and''.

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 pursuant 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) 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 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) of this section) 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) of this section) 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) of this section) 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) of this section) 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) of this section) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section 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) of this section) 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) of this section) 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) of this section) 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 (j)(1)(C) of this section.

(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) of this section), 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) of this section) as would be otherwise determined for primary care services (as defined in subsection (i)(4) of this section).

(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) of this section).

(5) Repealed. Pub. L. 108–173, title IX, § 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 en-

tity, 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, 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) of this section) 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, and (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.

(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 Secretary—

(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 of this chapter 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 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) of this section.

(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 (j)(1)(D) of this section.

(12) Repealed. Pub. L. 105–33, title IV, § 4512(b)(2), Aug. 5, 1997, 111 Stat. 444.

(13)(A) In determining payments under section 1395*l*(*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, ⅓ 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 specification 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.

(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) of this section.

(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) of this section.

(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) of this section, 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) of this section in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) of this section 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 1395*l*(a)(1) of this title, the reasonable charge for ambulance services (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) of this section, 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

[2] So in original. Probably should be followed by ''a''.

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 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 1395*l*(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) 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.

(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) of this section); the term ''nonparticipating 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) of this section).

(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) of this section) 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 this section) 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 this section) 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, ¼,
(II) for 1988, ⅓,
(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) of this section 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 to—

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

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) of this section (relating to certain overpriced procedures),

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

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

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

(VI) an adjustment under section 1395*l*(*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) of this section, the inherently reasonable charge established under subsection (b)(8) of this section;

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) of this section or under section 1395*l*(*l*)(3)(B) of this title, the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii) of this section, 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) of this section 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) of this section 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 of this chapter 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 of this chapter 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) of this section.

(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) of this section.

(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 services

(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) of this section.

***(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, the amount provided under section 1395w–3 of this title, section 1395w–3a of this title, section 1395w–3b of this title, or section 1395rr(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 furnished through an item of durable medical equipment covered under section 1395x(n) of this title on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1395w–3 of this title on or after January 1, 2007, 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) of this section 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) of this section.

(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 1395*oo* of this title, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p) Requiring submission of diagnostic information

(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) of this section 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) of this section 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) of this section.

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) of this section, 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) of this section 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) 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) of this section 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 1395*l*(g) of this title, including services described in section 1395*l*(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, §§ 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), 9311(c), 9320(e)(3), 9331(a)(1)–(3), (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, §§ 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, §§ 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), (7)(A), (9), (g)(2)(A), (B), (i)(1)(A), July 1, 1988, 102 Stat. 702, 713, 716–718, 747, 768, 776–780, 783, 787; Pub. L. 100–485, title VI, § 608(d)(5)(A)–(D), (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), 6102(b), (e)(2)–(4), (9), 6104, 6106(a), 6107(b), 6108(a)(1), (b)(1), (2), 6114(b), (c), 6202(d)(2), Dec. 19, 1989, 103 Stat. 2153, 2184, 2187, 2188, 2208, 2210, 2212, 2213, 2218, 2234; Pub. L. 101–508, title IV, §§ 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, §§ 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, §§ 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, § 405(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.)

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. (*o*)(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 1395*l*, 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.

AMENDMENTS

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 increase 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), substituted ''28 days'' for ''26 days''.

Subsec. (u). Pub. L. 109–432, § 110(a), added subsec. (u).

2003—Pub. L. 108–173, § 911(c)(1), substituted ''Provisions relating to the administration of part B'' for ''Use of carriers for administration of benefits'' in section catchline.

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 section 1395h of this title.

Subsec. (b)(3). Pub. L. 108–173, §911(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.

Subsec. (b)(3)(C) to (E). Pub. L. 108–173, §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 purposes 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 implement'' 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 ''carrier''.

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 ''carrier''.

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, §736(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), substituted ''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 pay-

ments 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. (h)(5)(A), (B)(iii). Pub. L. 108–173, §911(c)(7)(D), substituted ''medicare administrative contractors'' for ''carriers''.

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 ''carrier''.

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. (*o*)(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. (*o*)(4). Pub. L. 108–173, §303(b)(2), added par. (4).

Subsec. (*o*)(5), (6). Pub. L. 108–173, §303(e), added pars. (5) and (6).

Subsec. (*o*)(7). Pub. L. 108–173, §303(g)(1), added par. (7).

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. (3).

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, §432(b)(2)], added subpar. (G).

Subsec. (b)(18)(C)(vi). Pub. L. 106–554, §1(a)(6) [title I, §105(d)], added cl. (vi).

Subsec. (*o*)(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, §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 described in such clause are performed.''

Subsec. (b)(6)(A)(ii). Pub. L. 105–33, §4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (b)(6)(C). Pub. L. 105–33, §4205(d)(3)(B), amended 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 practitioners)—

''(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 assistant 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.

''(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. (19).

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) of this section'' 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), 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''.

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 as follows: ''Except for deductible and coinsurance amounts applicable under section 1395*l* 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 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—

''(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 ''subparagraph (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) of this section)''.

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 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.

Subsec. (b)(14)(B)(iii)(II). Pub. L. 101–508, § 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. 101–508, § 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. (r).

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, 1987,''.

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), inserted ''rural primary care hospital,'' after ''hospital,''.

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. (15).

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, § 202(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 below.

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) of this section'' 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, § 411(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, § 411(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 below.

Subsec. (b)(4)(F)(ii)(I). Pub. L. 100–360, § 411(f)(2)(B), substituted ''subsection (i)(4) of this section'' for ''subparagraph (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 below.

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, § 411(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 procedure''.

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, § 411(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, § 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, § 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 year''.

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 the carrier''.

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),'' for ''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 below.

Subsec. (i)(3). Pub. L. 100–485, § 608(d)(21)(A), substituted ''subsection (b)(3) of this section'' for ''paragraph (3)''.

Subsec. (i)(4). Pub. L. 100–360, § 411(f)(2)(C), added Pub. L. 100–203, § 4042(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), substituted ''bills'' for ''imposes a charge''.

Subsec. (j)(2). Pub. L. 100–360, § 411(i)(4)(C)(vi), as amended by Pub. L. 100–485, § 608(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, § 411(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, § 411(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. (*o*). Pub. L. 100–360, § 202(c)(1)(C), added subsec. (*o*) 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.

Subsec. (*o*)(1)(A)(i). Pub. L. 100–485, § 608(d)(5)(A)(i), substituted ''paragraph (4)'' for ''subparagraph (D)(i)''.

Subsec. (*o*)(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) of this section'' 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. 100–203, § 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, § 4063(a)(1)(A), designated existing provisions as cl. (i) and added cl. (ii).

Pub. L. 100–203, § 4046(a)(1)(B), (C), added subpar. (C) and redesignated former subpar. (C) as (D).

Pub. L. 100–203, § 4045(c)(1)(A), 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) of this section.'' 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 (j)(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, § 4085(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. (14).

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. (3).

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, § 4085(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, § 4042(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 physician's''.

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 this section) 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, § 411(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 section.

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).

Subsec. (j)(1)(D)(ii)(V), (VI). Pub. L. 100–203, § 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. (II).

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, § 8(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), substituted ''exclude'' for ''bar''.

Subsec. (k)(1), (2). Pub. L. 100–203, § 4085(g)(1), substituted ''subsection (j)(2) of this section in the case of surgery performed on or after March 1, 1987'' for ''subsection (j)(2) of this section''.

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. (n).

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 30, 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, § 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 subpar. (G).

Subsec. (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. (ii).

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 fur-

nished 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. 99–272.

Pub. L. 99–514, § 1895(b)(14)(A), as amended by Pub. L. 99–509, § 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. (ii).

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) of this section) 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) of this section)'', and added cls. (ii) and (iii).

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 subpar. (E).

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, § 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'' for ''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), redesignated par. (3) of this subsection as par. (5) of subsec. (h).

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. (h).

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 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. (*l*).

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

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.

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, § 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, § 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, § 2307(a)(2)(E)–(G), added subcl. (III).

Subsec. (b)(7)(B)(iii). Pub. L. 98–617, § 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.

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 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. (D).

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 title.

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. (g).

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''.

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 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*l* 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, §105(d)] of Pub. L. 106–554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I, §105(e)] of Pub. L. 106–554, set out as a note under section 1395*l* 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 1395*l* 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*l* 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 1395*l* 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, §4105(b)(3), Nov. 5, 1990, 104 Stat. 1388–60, as amended by Pub. L. 103–432, title I, §126(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, §4118(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, 1395*ll*, and 1395ww 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, 1395*ll*, and 1395ww 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 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, 1395*ll*, 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, 1395*l*, 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.'].''

[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*l* and 1395w–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.''

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.''

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(*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.''

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. 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.

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(c)(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 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].''

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 98–617.''

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.''

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 1395*l* 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.

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 1395*l*, 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 1395*l*, 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. 1395j 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 Methodology 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(*o*) of the Social Security Act (42 U.S.C. 1395u(*o*))) 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 (3).

''(3) RECOMMENDATIONS FOR REVISED PAYMENT METHODOLOGIES.—

''(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 1395*l* of this title] (113 Stat. 1501A–350).

''(b) IMPLEMENTATION OF NEW PAYMENT METHODOLOGY.—

''(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. 1395u(*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*l* 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, Aug. 5, 1997, 111 Stat. 460, 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:

''(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*l*(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. 1395j 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(c), 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. 1395j 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. 1395j 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. 1395j 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. 1395j 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.

''(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 9-month 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 di-

rectories 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 DRUGS

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 period 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. 1395j 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 PAYMENT 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. 1395j 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. 1395j 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. 1395j 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 sentence 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. 1330–84.

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. 1395j 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. 1395j 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 subsec. (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 sec-

tion 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 PHYSICIANS 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.

§ 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) of this section (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) of this section 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 of this chapter or subchapter XVI of this chapter; or

(2) individuals receiving money payments under all of the plans of such State approved under subchapters I, X, XIV, and XVI of this chapter, and part A of subchapter IV of this chapter.

Except as provided in subsection (g) of this section, there shall be excluded from any coverage group any individual who is entitled to monthly insurance benefits under subchapter II of this chapter or who is entitled to receive an annuity under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.]. Effective January 1, 1974, and subject to section 1396a(f) of this title, the Secretary shall, at the request of any State not eligible to participate in the State plan program established under subchapter XVI of this chapter, continue in effect the agreement entered into under this section with such State subject to such modifications as the Secretary may by regulations provide to take account of the termination of any plans of such State approved under subchapters I, X, XIV, and XVI of this chapter and the establishment of the supplemental security income program under subchapter XVI of this chapter.

(c) Eligible individuals

For purposes of this section, an individual shall be treated as an eligible individual only if he is an eligible individual (within the meaning of section 1395*o* of this title) on the date an agreement covering him is entered into under subsection (a) of this section or he becomes an eligible individual (within the meaning of such section) at any time after such date; and he shall be treated as receiving money payments described in subsection (b) of this section if he receives such payments for the month in which the agreement is entered into or any month thereafter.

(d) Monthly premiums; coverage periods

In the case of any individual enrolled pursuant to this section—

(1) the monthly premium to be paid by the State shall be determined under section 1395r

of this title (without any increase under subsection (b) thereof);

(2) his coverage period shall begin on whichever of the following is the latest:

(A) July 1, 1966;

(B) the first day of the third month following the month in which the State agreement is entered into;

(C) the first day of the first month in which he is both an eligible individual and a member of a coverage group specified in the agreement under this section; or

(D) such date as may be specified in the agreement; and

(3) his coverage period attributable to the agreement with the State under this section shall end on the last day of whichever of the following first occurs:

(A) the month in which he is determined by the State agency to have become ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (h) of this section) for medical assistance, or

(B) the month preceding the first month for which he becomes entitled to monthly benefits under subchapter II of this chapter or to an annuity or pension under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.].

(e) Subsection (d)(3) terminations deemed resulting in section 1395p enrollment

Any individual whose coverage period attributable to the State agreement is terminated pursuant to subsection (d)(3) of this section shall be deemed for purposes of this part (including the continuation of his coverage period under this part) to have enrolled under section 1395p of this title in the initial general enrollment period provided by section 1395p(c) of this title. The coverage period under this part of any such individual who (in the last month of his coverage period attributable to the State agreement or in any of the following six months) files notice that he no longer wishes to participate in the insurance program established by this part, shall terminate at the close of the month in which the notice is filed.

(f) "Carrier" as including State agency; provisions facilitating deductions, coinsurance, etc., and leading to economy and efficiency of operation

With respect to eligible individuals receiving money payments under the plan of a State approved under subchapter I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this chapter, or eligible to receive medical assistance under the plan of such State approved under subchapter XIX of this chapter, if the agreement entered into under this section so provides, the term ''carrier'' as defined in section 1395u(f)[1] of this title also includes the State agency, specified in such agreement, which administers or supervises the administration of the plan of such State approved under subchapter I, XVI, or XIX of this chapter. The agreement shall also contain such provisions as will facilitate the financial transactions of the State and the carrier with respect to deductions, coinsurance, and otherwise, and as will lead to economy and efficiency of operation, with respect to individuals receiving money payments under plans of the State approved under subchapters I, X, XIV, and XVI of this chapter, and part A of subchapter IV of this chapter, and individuals eligible to receive medical assistance under the plan of the State approved under subchapter XIX of this chapter.

(g) Subsection (b) exclusions from coverage groups

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) of this section under which the second sentence of subsection (b) of this section shall not apply with respect to such agreement.

(2) In the case of any individual who would (but for this subsection) be excluded from the applicable coverage group described in subsection (b) of this section by the second sentence of such subsection—

(A) subsections (c) and (d)(2) of this section shall be applied as if such subsections referred to the modification under this subsection (in lieu of the agreement under subsection (a) of this section), and

(B) subsection (d)(3)(B) of this section shall not apply so long as there is in effect a modification entered into by the State under this subsection.

(h) Modifications respecting subsection (b) coverage groups

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) of this section under which the coverage group described in subsection (b) of this section and specified in such agreement is broadened to include (A) individuals who are eligible to receive medical assistance under the plan of such State approved under subchapter XIX of this chapter, or (B) qualified medicare beneficiaries (as defined in section 1396d(p)(1) of this title).

(2) For purposes of this section, an individual shall be treated as eligible to receive medical assistance under the plan of the State approved under subchapter XIX of this chapter if, for the month in which the modification is entered into under this subsection or for any month thereafter, he has been determined to be eligible to receive medical assistance under such plan. In the case of any individual who would (but for this subsection) be excluded from the agreement, subsections (c) and (d)(2) of this section shall be applied as if they referred to the modification under this subsection (in lieu of the agreement under subsection (a) of this section), and subsection (d)(2)(C) of this section shall be applied (except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title) by substituting ''second month following the first month'' for ''first month''.

[1] See References in Text note below.

(3) In this subsection, the term ''qualified medicare beneficiary'' also includes an individual described in section 1396a(a)(10)(E)(iii) of this title.

(i) Enrollment of qualified medicare beneficiaries

For provisions relating to enrollment of qualified medicare beneficiaries under part A of this subchapter, see section 1395i–2(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1843, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 312; amended Pub. L. 89–384, § 4(a), (b), Apr. 8, 1966, 80 Stat. 105; Pub. L. 90–248, title II, §§ 222(a), (b), (e), 241(e), Jan. 2, 1968, 81 Stat. 900, 901, 917; Pub. L. 93–233, § 18(*l*), Dec. 31, 1973, 87 Stat. 970; Pub. L. 93–445, title III, § 308, Oct. 16, 1974, 88 Stat. 1358; Pub. L. 96–499, title IX, §§ 945(e), 947(a), (c), Dec. 5, 1980, 94 Stat. 2642, 2643; Pub. L. 98–21, title VI, § 606(a)(3)(E), Apr. 20, 1983, 97 Stat. 171; Pub. L. 98–369, div. B, title III, § 2354(b)(15), July 18, 1984, 98 Stat. 1101; Pub. L. 100–360, title III, § 301(e)(1), July 1, 1988, 102 Stat. 749; Pub. L. 100–485, title VI, § 608(d)(14)(H), Oct. 13, 1988, 102 Stat. 2416; Pub. L. 101–239, title VI, § 6013(b), Dec. 19, 1989, 103 Stat. 2164; Pub. L. 101–508, title IV, § 4501(d), Nov. 5, 1990, 104 Stat. 1388–165.)

REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (d)(3)(B), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, § 101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§ 231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231t of Title 45, and Tables.

Section 1395u(f) of this title, referred to in subsec. (f), was repealed by Pub. L. 108–173, title IX, § 911(c)(5), Dec. 8, 2003, 117 Stat. 2384.

AMENDMENTS

1990—Subsec. (h)(3). Pub. L. 101–508 added par. (3).

1989—Subsec. (i). Pub. L. 101–239 added subsec. (i).

1988—Subsecs. (a), (g)(1). Pub. L. 100–360, § 301(e)(1)(A), formerly § 301(e)(1), as redesignated by Pub. L. 100–485, § 608(d)(14)(H)(i), inserted ''or after 1988'' after ''during 1981''.

Subsec. (h)(1). Pub. L. 100–360, § 301(e)(1)(A), formerly § 301(e)(1), as redesignated by Pub. L. 100–485, § 608(d)(14)(H)(i), inserted ''or after 1988'' after ''during 1981''.

Pub. L. 100–360, § 301(e)(1)(B), as added by Pub. L. 100–485, § 608(d)(14)(H)(ii), inserted cl. (A) designation after ''include'' and added cl. (B).

Subsec. (h)(2). Pub. L. 100–360, § 301(e)(1)(C), as added by Pub. L. 100–485, § 608(d)(14)(H)(ii), inserted ''(except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title)'' after ''shall be applied''.

1984—Subsec. (d)(3)(B). Pub. L. 98–369 substituted ''1974'' for ''1937''.

1983—Subsec. (d)(1). Pub. L. 98–21 substituted ''without any increase under subsection (b) thereof'' for ''without any increase under subsection (c) thereof''.

1980—Subsec. (a). Pub. L. 96–499, § 945(e), inserted ''or during 1981,'' after ''January 1, 1970,''.

Subsec. (e). Pub. L. 96–499, § 947(a), inserted provision that the coverage period under this part of any individual who filed notice that he no longer wished to participate in the insurance program established by this part was to terminate at the close of the month in which the notice was filed.

Subsec. (g)(1). Pub. L. 96–499, § 945(e), inserted ''or during 1981,'' after ''January 1, 1970,''.

Subsec. (g)(2)(C). Pub. L. 96–499, § 947(c)(3), struck out cl. (C) which authorized individuals facing exclusion from the applicable coverage group to terminate their enrollment under this part by the filing of a notice indicating he no longer wished to participate in the insurance program established by this part.

Subsec. (h)(1). Pub. L. 96–499, § 945(e), inserted ''or during 1981,'' after ''January 1, 1970,''.

1974—Subsec. (b). Pub. L. 93–445 substituted ''under the Railroad Retirement Act of 1974'' for ''or pension under the Railroad Retirement Act of 1937''.

1973—Subsec. (b). Pub. L. 93–233 provided for continuation of State agreements for coverage of certain individuals in connection with establishment of supplemental security income program.

1968—Pub. L. 90–248, § 222(b)(4), inserted ''(or are eligible for medical assistance)'' in section catchline.

Subsec. (a). Pub. L. 90–248, § 222(e)(1), substituted ''1970'' for ''1968''.

Subsec. (b)(2). Pub. L. 90–248, § 241(e)(1), struck out ''IV,'' after ''I,'' and inserted '', and part A of subchapter IV of this chapter'' after ''XVI of this chapter''.

Subsec. (c). Pub. L. 90–248, § 222(e)(2), struck out ''and before January 1, 1968'' after ''such date'' and ''before January 1968'' after ''thereafter'' just before the period.

Subsec. (d)(2)(D). Pub. L. 90–248, § 222(e)(3), struck out ''(not later than January 1, 1968)'' after ''such date''.

Subsec. (d)(3)(A). Pub. L. 90–248, § 222(b)(1), substituted ''ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (h) of this section) for medical assistance'' for ''ineligible for money payments of a kind specified in the agreement''.

Subsec. (f). Pub. L. 90–248, § 222(b)(2), inserted ''or eligible to receive medical assistance under the plan of such State approved under subchapter XIX of this chapter'' and '', and individuals eligible to receive medical assistance under the plan of the State approved under subchapter XIX of this chapter'' after ''or part A of subchapter IV of this chapter'' and '', and part A of subchapter IV of this chapter'', respectively.

Pub. L. 90–248, § 241(e)(2), struck out ''IV,'' before ''X,'' in two places, and inserted ''or part A of subchapter IV of this chapter,'' after ''XVI of this chapter,'' first place it appears in first sentence and '', and part A of subchapter IV of this chapter'' after ''XVI of this chapter'' in second sentence.

Subsec. (g)(1). Pub. L. 90–248, § 222(b)(3), substituted ''1970'' for ''1968''.

Subsec. (h). Pub. L. 90–248, § 222(a), added subsec. (h).

1966—Subsec. (b). Pub. L. 89–384, § 4(a), inserted reference to subsec. (g) in exclusionary provision.

Subsec. (g). Pub. L. 89–384, § 4(b), added subsec. (g).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–508 applicable to calendar quarters beginning on or after Jan. 1, 1991, without regard to whether or not regulations to implement such amendment are promulgated by such date, see section 4501(f) of Pub. L. 101–508, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 effective Jan. 1, 1990, see section 6013(c) of Pub. L. 101–239, set out as a note under section 1395i–2 of this title.

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 III, § 301(e)(3), July 1, 1988, 102 Stat. 750, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect on January 1, 1989, and the amendments made by paragraph (2) [amending section 1396a of this title] shall take effect on July 1, 1989.''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1983 AMENDMENT; TRANSITIONAL RULE

Amendment by Pub. L. 98–21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the monthly premium for June 1983 shall apply to individuals enrolled under parts A and B of this subchapter, see section 606(c) of Pub. L. 98–21, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96–499, title IX, §947(d), Dec. 5, 1980, 94 Stat. 2643, provided that: ''The amendments made by this section [amending this section and section 1395q of this title] apply to notices filed after the third calendar month beginning after the date of the enactment of this Act [Dec. 5, 1980].''

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 1973 AMENDMENT

Amendment by Pub. L. 93–233 effective Jan. 1, 1974, see Pub. L. 93–233, §18(z–3)(1), Dec. 31, 1973, 87 Stat. 974.

TERMINATION PERIOD FOR CERTAIN INDIVIDUALS COVERED PURSUANT TO STATE AGREEMENTS

Pub. L. 96–499, title IX, §947(e), Dec. 5, 1980, 94 Stat. 2643, provided that: ''The coverage period under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] of an individual whose coverage period attributable to a State agreement under section 1843 of such Act [42 U.S.C. 1395v] is terminated and who has filed notice before the end of the third calendar month beginning after the date of the enactment of this Act [Dec. 5, 1980] that he no longer wishes to participate in the insurance program established by part B of title XVIII shall terminate on the earlier of (1) the day specified in section 1838 [42 U.S.C. 1395q] without the amendments made by this section, or (2) (unless the individual files notice before the day specified in this clause that he wishes his coverage period to terminate as provided in clause (1)) the day on which his coverage period would terminate if the individual filed notice in the fourth calendar month beginning after the date of the enactment of this Act.''

DISTRICT OF COLUMBIA; AGREEMENT OF COMMISSIONER WITH SECRETARY FOR SUPPLEMENTARY MEDICAL INSURANCE

Pub. L. 90–227, §2, Dec. 27, 1967, 81 Stat. 745, provided that: ''The Commissioner [now Mayor of District of Columbia] may enter into an agreement (and any modifications of such agreement) with the Secretary under section 1843 of the Social Security Act [42 U.S.C. 1395v] pursuant to which (1) eligible individuals (as defined in section 1836 of the Social Security Act) [42 U.S.C. 1395*o*] who are eligible to receive medical assistance under the District of Columbia's plan for medical assistance approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] will be enrolled in the supplementary medical insurance program established under part B of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and (2) provisions will be made for payment of the monthly premiums of such individuals for such program.''

§ 1395w. Appropriations to cover Government contributions and contingency reserve

(a) In general

There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund—

(1)(A) a Government contribution equal to the aggregate premiums payable for a month for enrollees age 65 and over under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee age 65 and over as determined under section 1395r(a)(1) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month, plus

(B) a Government contribution equal to the aggregate premiums payable for a month for enrollees under age 65 under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee under age 65 as determined under section 1395r(a)(4) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month; minus

(C) the aggregate amount of additional premium payments attributable to the application of section 1395r(i) of this title; plus

(2) such sums as the Secretary deems necessary to place the Trust Fund, at the end of any fiscal year occurring after June 30, 1967, in the same position in which it would have been at the end of such fiscal year if (A) a Government contribution representing the excess of the premiums deposited in the Trust Fund during the fiscal year ending June 30, 1967, over the Government contribution actually appropriated to the Trust Fund during such fiscal year had been appropriated to it on June 30, 1967, and (B) the Government contribution for premiums deposited in the Trust Fund after June 30, 1967, had been appropriated to it when such premiums were deposited; plus

(3) a Government contribution equal to the amount of payment incentives payable under sections 1395w–4(*o*) and 1395w–23(*l*)(3) of this title.

In applying paragraph (1), the amounts transferred under subsection (d)(1) with respect to enrollees described in subparagraphs (A) and (B) of such subsection shall be treated as premiums payable and deposited in the Trust Fund under subparagraphs (A) and (B), respectively, of paragraph (1).

(b) Contingency reserve

In order to assure prompt payment of benefits provided under this part and the administrative expenses thereunder during the early months of

the program established by this part, and to provide a contingency reserve, there is also authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, to remain available through the calendar year 1969 for repayable advances (without interest) to the Trust Fund, an amount equal to $18 multiplied by the number of individuals (as estimated by the Secretary) who could be covered in July 1966 by the insurance program established by this part if they had theretofore enrolled under this part.

(c) Election under section 1395w–24

The Secretary shall determine the Government contribution under subparagraphs (A) and (B) of subsection (a)(1) of this section without regard to any premium reduction resulting from an election under section 1395w–24(f)(1)(E) of this title or any credits provided under section 1395w–24(b)(1)(C)(iv)[1] of this title and without regard to any premium adjustment effected under sections 1395r(h) and 1395w–29(f)[1] of this title and without regard to any premium adjustment under section 1395r(i) of this title.

(d) Transfer of certain General Fund amounts for 2016

(1) For 2016, there shall be transferred from the General Fund to the Trust Fund an amount, as estimated by the Chief Actuary of the Centers for Medicare & Medicaid Services, equal to the reduction in aggregate premiums payable under this part for a month in such year (excluding any changes in amounts collected under section 1395r(i) of this title) that is attributable to the application of section 1395r(a)(5)(A) of this title with respect to—

(A) enrollees age 65 and over; and

(B) enrollees under age 65.

Such amounts shall be transferred from time to time as appropriate.

(2) Premium increases affected under section 1395r(a)(6) of this title shall not be taken into account in applying subsection (a).

(3) There shall be transferred from the Trust Fund to the General Fund of the Treasury amounts equivalent to the additional premiums payable as a result of the application of section 1395r(a)(6) of this title, excluding the aggregate payments attributable to the application of section 1395r(i)(3)(A)(ii)(II) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1844, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 313; amended Pub. L. 90–248, title I, § 167, Jan. 2, 1968, 81 Stat. 874; Pub. L. 92–603, title II, § 203(e), Oct. 30, 1972, 86 Stat. 1377; Pub. L. 97–248, title I, § 124(c), Sept. 3, 1982, 96 Stat. 364; Pub. L. 98–21, title VI, § 606(a)(3)(F), (G), Apr. 20, 1983, 97 Stat. 171; Pub. L. 98–369, div. B, title III, § 2354(b)(16), July 18, 1984, 98 Stat. 1101; Pub. L. 100–360, title II, § 211(c)(2), July 1, 1988, 102 Stat. 738; Pub. L. 101–234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 105–33, title IV, § 4571(b)(2), Aug. 5, 1997, 111 Stat. 464; Pub. L. 106–554, § 1(a)(6) [title VI, § 606(a)(2)(D)], Dec. 21, 2000, 114 Stat. 2763, 2763A–558; Pub. L. 108–173, title II, §§ 222(*l*)(2)(C), 241(b)(2)(B), title VIII, § 811(b)(2), Dec. 8, 2003, 117 Stat. 2206, 2221, 2368; Pub. L. 111–5, div. B, title IV, § 4103(a)(2), Feb. 17, 2009, 123 Stat. 487; Pub. L. 114–74, title VI, § 601(b), Nov. 2, 2015, 129 Stat. 595.)

[1] See References in Text note below.

REFERENCES IN TEXT

Section 1395w–24(b)(1)(C)(iv) of this title, referred to in subsec. (c), was redesignated section 1395w–24(b)(1)(C)(v) of this title by Pub. L. 111–148, title III, § 3202(b)(1)(B), Mar. 23, 2010, 124 Stat. 454, and subsequently redesignated section 1395w–24(b)(1)(C)(viii) of this title by Pub. L. 111–152, title I, § 1102(d)(2), Mar. 30, 2010, 124 Stat. 1045.

Section 1395w–29 of this title, referred to in subsec. (c), was repealed by Pub. L. 111–152, title I, § 1102(f), Mar. 30, 2010, 124 Stat. 1046.

AMENDMENTS

2015—Subsec. (a). Pub. L. 114–74, § 601(b)(1), inserted concluding provisions.

Subsec. (d). Pub. L. 114–74, § 601(b)(2), added subsec. (d).

2009—Subsec. (a)(2), (3). Pub. L. 111–5 in par. (2) substituted ''; plus'' for period at end and added par. (3).

2003—Subsec. (a)(1)(B)(ii). Pub. L. 108–173, § 811(b)(2)(A)(i), substituted ''minus'' for ''plus''.

Subsec. (a)(1)(C). Pub. L. 108–173, § 811(b)(2)(A)(ii), added subpar. (C).

Subsec. (c). Pub. L. 108–173, § 811(b)(2)(B), inserted ''and without regard to any premium adjustment under section 1395r(i) of this title'' before period at end.

Pub. L. 108–173, § 241(b)(2)(B), inserted ''and without regard to any premium adjustment effected under sections 1395r(h) and 1395w–29(f) of this title'' before period at end.

Pub. L. 108–173, § 222(*l*)(2)(C), inserted ''or any credits provided under section 1395w–24(b)(1)(C)(iv) of this title'' after ''section 1395w–24(f)(1)(E) of this title''.

2000—Subsec. (c). Pub. L. 106–554 added subsec. (c).

1997—Subsec. (a)(1)(A)(i), (B)(i). Pub. L. 105–33 substituted ''section 1395r(a)(3) of this title'' for ''section 1395r(a)(3) or 1395r(e) of this title, as the case may be''.

1989—Subsec. (a). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(2), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

1988—Subsec. (a). Pub. L. 100–360 inserted at end ''In computing the amount of aggregate premiums and premiums per enrollee under paragraph (1), there shall not be taken into account premiums attributable to section 1395r(g) of this title or section 59B of the Internal Revenue Code of 1986.''

1984—Subsec. (a)(1)(B)(ii). Pub. L. 98–369 substituted ''; plus'' for a period.

1983—Subsec. (a)(1)(A)(i). Pub. L. 98–21, § 606(a)(3)(F), substituted ''section 1395r(a)(1)'' for ''section 1395r(c)(1)'' and ''section 1395r(a)(3) or 1395r(e)'' for ''section 1395r(c)(3) or 1395r(g)''.

Subsec. (a)(1)(B)(i). Pub. L. 98–21, § 606(a)(3)(G), substituted ''1395r(a)(4)'' for ''1395r(c)(4)'' and ''1395r(a)(3) or 1395r(e)'' for ''1395r(c)(3) or 1395r(g)''.

1982—Subsec. (a)(1)(A)(i), (B)(i). Pub. L. 97–248 substituted ''section 1395r(c)(3) or 1395r(g) of this title, as the case may be'' for ''section 1395r(c)(3) of this title''.

1972—Subsec. (a)(1). Pub. L. 92–603 designated existing provisions as subpar. (A), substituted provisions relating to Government contributions equal to aggregate premiums payable for a month for enrollees age 65 and over under this part and deposited in Trust Fund, and multiplied by specified ratio, for provisions relating to Government contributions equal to aggregate premiums payable under this part and deposited in Trust Fund, and added subpar. (B).

1968—Subsec. (a). Pub. L. 90–248, § 167(a), designated existing provisions as par. (1), inserted provision for deposit of Government contribution in Trust Fund, and added par. (2).

Subsec. (b). Pub. L. 90–248, § 167(b), substituted ''1969'' for ''1967''.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(*l*)(2)(C) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, § 606(b)] of Pub. L. 106–554, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, and applicable to premiums for months beginning after Dec. 31, 1989, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–360 applicable, except as otherwise specified in such amendment, to monthly premiums for months beginning with January 1989, see section 211(d) of Pub. L. 100–360, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1983 AMENDMENT; TRANSITIONAL RULE

Amendment by Pub. L. 98–21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the amount of Government contributions under subsec. (a)(1) of this section shall be computed with the actuarially adequate rate which would have been in effect but for the amendments made by this section and using the amount of the premium in effect for June 1983, see section 606(c) of Pub. L. 98–21, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–603, title II, § 203(e), Oct. 30, 1972, 86 Stat. 1377, provided that the amendment made by that section is effective with respect to enrollee premiums payable for months after June 1973.

CONSTRUCTION OF 2015 AMENDMENT; CONDITIONAL APPLICATION TO 2017

For provisions relating to construction and application of amendment by Pub. L. 114–74, see sections 601(d) and 601(e) of Pub. L. 114–74, set out as notes under section 1395r of this title.

§ 1395w–1. Repealed. Pub. L. 105–33, title IV, § 4022(b)(2)(A), Aug. 5, 1997, 111 Stat. 354

Section, act Aug. 14, 1935, ch. 531, title XVIII, § 1845, as added and amended Apr. 7, 1986, Pub. L. 99–272, title IX, § 9305, 100 Stat. 190; Oct. 21, 1986, Pub. L. 99–509, title IX, §§ 9331(e), 9344(a)(1), 100 Stat. 2021, 2042; Dec. 22, 1987, Pub. L. 100–203, title IV, §§ 4045(b), 4083(a)(1), (c)(1), 4085(a), (i)(8), 101 Stat. 1330–87, 1330–129, 1330–130, 1330–132; July 1, 1988, Pub. L. 100–360, title IV, § 411(i)(4)(A), 102 Stat. 788; Nov. 10, 1988, Pub. L. 100–647, title VIII, § 8425(a), 102 Stat. 3803; Nov. 5, 1990, Pub. L. 101–508, title IV, §§ 4002(g)(3), 4118(j)(1), 104 Stat. 1388–37, 1388–70; Oct. 31, 1994, Pub. L. 103–432, title I, § 126(g)(8), 108 Stat. 4416, related to Physician Payment Review Commission.

EFFECTIVE DATE OF REPEAL

Repeal effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105–33 set out as an Effective Date; Transition; Transfer of Functions note under section 1395b–6 of this title.

§ 1395w–2. Intermediate sanctions for providers or suppliers of clinical diagnostic laboratory tests

(a) If the Secretary determines that any provider or clinical laboratory approved for participation under this subchapter no longer substantially meets the conditions of participation or for coverage specified under this subchapter with respect to the provision of clinical diagnostic laboratory tests under this part, the Secretary may (for a period not to exceed one year) impose intermediate sanctions developed pursuant to subsection (b) of this section, in lieu of terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory.

(b)(1) The Secretary shall develop and implement—

(A) a range of intermediate sanctions to apply to providers or clinical laboratories under the conditions described in subsection (a), and

(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2)(A) The intermediate sanctions developed under paragraph (1) shall include—

(i) directed plans of correction,

(ii) civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance,

(iii) payment for the costs of onsite monitoring by an agency responsible for conducting surveys, and

(iv) suspension of all or part of the payments to which a provider or clinical laboratory would otherwise be entitled under this subchapter with respect to clinical diagnostic laboratory tests furnished on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (a) of this section.

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law.

(3) The Secretary shall develop and implement specific procedures with respect to when and how each of the intermediate sanctions developed under paragraph (1) is to be applied, the amounts of any penalties, and the severity of each of these penalties. Such procedures shall be designed so as to minimize the time between identification of violations and imposition of these sanctions and shall provide for the imposition of incrementally more severe penalties for repeated or uncorrected deficiencies.

(Aug. 14, 1935, ch. 531, title XVIII, § 1846, as added Pub. L. 100–203, title IV, § 4064(d)(1), Dec. 22, 1987, 101 Stat. 1330–111; amended Pub. L. 100–360, title

II, § 203(e)(4), title IV, § 411(g)(3)(G), July 1, 1988, 102 Stat. 725, 784; Pub. L. 100–485, title VI, § 608(d)(22)(C), Oct. 13, 1988, 102 Stat. 2421; Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101–508, title IV, § 4154(e)(2), Nov. 5, 1990, 104 Stat. 1388–86.)

AMENDMENTS

1990—Pub. L. 101–508 substituted ''providers or suppliers of'' for ''providers of'' in section catchline.

1989—Pub. L. 101–234 repealed Pub. L. 100–360, § 203(e)(4), 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.

1988—Pub. L. 100–360, § 203(e)(4)(A), inserted ''and for qualified home intravenous drug therapy providers'' at end of section catchline.

Subsec. (a). Pub. L. 100–360, § 411(g)(3)(G)(i)(I), as amended by Pub. L. 100–485, substituted ''approved'' for ''certified''.

Pub. L. 100–360, § 411(g)(3)(G)(i)(II), inserted ''or for coverage'' after ''conditions of participation''.

Pub. L. 100–360, § 411(g)(3)(G)(i)(III), which directed amendment of subsec. (a) by substituting ''terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory'' for ''cancelling immediately the certification of the provider or clinical laboratory'', was executed by making the substitution for ''canceling immediately the certification of the provider or clinical laboratory'' to reflect the probable intent of Congress.

Pub. L. 100–360, § 203(e)(4)(B), inserted ''or that a qualified home intravenous drug therapy provider that is certified for participation under this subchapter no longer substantially meets the requirements of section 1395x(jj)(3) of this title'' after ''under this part''.

Subsec. (b)(1)(A). Pub. L. 100–360, § 411(g)(3)(G)(ii), struck out ''certified'' before ''clinical laboratories''.

Subsec. (b)(2)(A). Pub. L. 100–360, § 411(g)(3)(G)(iv), inserted at end ''The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.''

Subsec. (b)(2)(A)(ii). Pub. L. 100–360, § 411(g)(3)(G)(iii), substituted ''civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance'' for ''civil fines and penalties''.

Subsec. (b)(2)(A)(iii). Pub. L. 100–360, § 411(g)(3)(G)(v), struck out ''certification'' before ''surveys''.

Subsec. (b)(2)(A)(iv). Pub. L. 100–360, § 411(g)(3)(G)(ii), (vi), struck out ''certified'' before ''clinical laboratory'' and substituted ''furnished on or after the date on'' for ''provided on or after the date in''.

Pub. L. 100–360, § 203(e)(4)(C), inserted ''or home intravenous drug therapy services'' after ''clinical diagnostic laboratory tests''.

Subsec. (b)(3). Pub. L. 100–360, § 411(g)(3)(G)(vii), substituted ''any penalties'' for ''any fines'' and ''severe penalties'' for ''severe fines''.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–508 effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239, see section 4154(e)(5) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1988 AMENDMENTS

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.

Amendment by section 203(e)(4) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(g)(3)(G) 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

Pub. L. 100–203, title IV, § 4064(d)(2), Dec. 22, 1987, 101 Stat. 1330–111, provided that: ''The amendment made by paragraph (1) [enacting this section] shall become effective on January 1, 1990.''

§ 1395w–3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs

(i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the

competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation

(i) In general

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term ''covered document'' means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(G) Requiring bid bonds for bidding entities

With respect to rounds of competitions beginning under this subsection for contracts beginning not earlier than January 1, 2017, and not later than January 1, 2019, an entity may not submit a bid for a competitive acquisition area unless, as of the deadline for bid submission, the entity has obtained (and provided the Secretary with proof of having obtained) a bid surety bond (in this paragraph referred to as a ''bid bond'') in a form specified by the Secretary consistent with subparagraph (H) and in an amount that is not less than $50,000 and not more than $100,000 for each competitive acquisition area in which the entity submits the bid.

(H) Treatment of bid bonds submitted

(i) For bidders that submit bids at or below the median and are offered but do not accept the contract

In the case of a bidding entity that is offered a contract for any product category for a competitive acquisition area, if—

(I) the entity's composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for such product category and area; and

(II) the entity does not accept the contract offered for such product category and area,

the bid bond submitted by such entity for such area shall be forfeited by the entity and the Secretary shall collect on it.

(ii) Treatment of other bidders

In the case of a bidding entity for any product category for a competitive acquisition area, if the entity does not meet the bid forfeiture conditions in subclauses (I) and (II) of clause (i) for any product category for such area, the bid bond submitted by such entity for such area shall be returned within 90 days of the public announcement of the contract suppliers for such area.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment

otherwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) of this section shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)—

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) Program requirements

(1) In general

The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) of this section for each competitive acquisition area in which the program is implemented under subsection (a) of this section with respect to such items and services.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in an[1] competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(v) The entity meets applicable State licensure requirements.

(B) Timely implementation of program

Any delay in the implementation of quality standards under section 1395m(a)(20) of this title or delay in the receipt of advice from the program oversight committee established under subsection (c) of this section shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts

The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on—

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.

(ii) Subsequent disclosure

Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors

(A) In general

The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners

The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

[1] So in original. Probably should be ''a''.

(5) Payment

(A) In general

Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing

(i) Application of coinsurance

Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible

Before applying clause (i), the individual shall be required to meet the deductible described in section 1395*l*(b) of this title.

(C) Payment on assignment-related basis

Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction

Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

(6) Participating contractors

(A) In general

Except as provided in subsection (a)(4) of this section, payment shall not be made for items and services described in subsection (a)(2) of this section furnished by a contractor and for which competition is conducted under this section unless—

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined

In this section, the term ''bid'' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions

In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids

The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services

The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) Authority to contract for implementation

The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips

(A) In general

With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

(B) Study of types of testing strip products

Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquistion[2] program described in subparagraph (A).

(11) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

[2] So in original. Probably should be ''acquisition''.

(D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);

(E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;

(F) the bidding structure and number of contractors selected under this section; or

(G) the implementation of the special rule described in paragraph (10).

(c) Program Advisory and Oversight Committee

(1) Establishment

The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the ''Committee'').

(2) Membership; terms

The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties

(A) Advice

The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii) of this section.

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1395x(d) of this title), and individuals.

(v) The establishment of quality standards under section 1395m(a)(20) of this title.

(B) Additional duties

The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) Inapplicability of FACA

The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) Termination

The Committee shall terminate on December 31, 2011.

(d) Report

Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(e) Repealed. Pub. L. 110–275, title I, § 145(a)(1), July 15, 2008, 122 Stat. 2547

(f) Competitive acquisition ombudsman

The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1395b–9(c) of this title. The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1395b–9(c)(2)(C) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added Pub. L. 105–33, title IV, § 4319(a), Aug. 5, 1997, 111 Stat. 392; amended Pub. L. 106–113, div. B, § 1000(a)(6) [title III, § 321(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–366; Pub. L. 108–173, title III, § 302(b)(1), Dec. 8, 2003, 117 Stat. 2224; Pub. L. 110–275, title I, §§ 145(a)(1), 154(a)(1), (b)(2), (3), (c)(2)(A), (B), (d)(1), (3), (4), July 15, 2008, 122 Stat. 2547, 2560, 2565–2568; Pub. L. 111–148, title VI, § 6410(a), Mar. 23, 2010, 124 Stat. 773; Pub. L. 114–10, title V, § 522(a), (b)(1), Apr. 16, 2015, 129 Stat. 176, 177.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(2)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Advisory Committee Act, referred to in subsec. (c)(4), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1395w–3, act Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added July 1, 1988, Pub. L. 100–360, title II, § 202(j), 102 Stat. 719; amended Oct. 13, 1988, Pub. L. 100–485, title VI, § 608(d)(5)(I), 102 Stat. 2414, provided for appointment of Prescription Drug Payment Review Commission by Director of Congressional Office of Technology Assessment, prior to repeal by Pub. L. 101–234, title II, § 201(a), (c), Dec. 13, 1989, 103 Stat. 1981, effective Jan. 1, 1990.

AMENDMENTS

2015—Subsec. (a)(1)(G), (H). Pub. L. 114–10, § 522(a), added subpars. (G) and (H).

Subsec. (b)(2)(A)(v). Pub. L. 114–10, § 522(b)(1), added cl. (v).

2010—Subsec. (a)(1)(B)(i)(II). Pub. L. 111–148, § 6410(a)(1), substituted ''91'' for ''70''.

Subsec. (a)(1)(D)(ii)(II), (III). Pub. L. 111–148, § 6410(a)(2), added subcl. (II) and redesignated former subcl. (II) as (III).

2008—Subsec. (a)(1)(B)(i). Pub. L. 110–275, § 154(a)(1)(A)(i), inserted ''consistent with subparagraph (D)'' after ''in a manner'' in introductory provisions.

Subsec. (a)(1)(B)(i)(II). Pub. L. 110–275, § 154(a)(1)(A)(ii), substituted ''an additional 70'' for ''80'' and ''in 2011'' for ''in 2009''.

Subsec. (a)(1)(B)(i)(III). Pub. L. 110–275, § 154(a)(1)(A)(iii), substituted ''after 2011 (or, in the case of national mail order for items and services, after 2010)'' for ''after 2009''.

Subsec. (a)(1)(D) to (F). Pub. L. 110–275, § 154(a)(1)(A)(iv), added subpars. (D) to (F).

Subsec. (a)(2)(A). Pub. L. 110–275, § 154(a)(1)(B), which directed amendment of par. (2)(A) of subsec. (a)(1) by inserting ''and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheel-

chairs)'' before period at end, was executed by making the insertion in subsec. (a)(2)(A), to reflect the probable intent of Congress.

Subsec. (a)(7). Pub. L. 110–275, §154(d)(1), added par. (7).

Subsec. (b)(3)(C). Pub. L. 110–275, §154(b)(2), added subpar. (C).

Subsec. (b)(10). Pub. L. 110–275, §154(d)(3)(B), added par. (10). Former par. (10) redesignated (11).

Subsec. (b)(11). Pub. L. 110–275, §154(d)(3)(A), redesignated par. (10) as (11).

Subsec. (b)(11)(C). Pub. L. 110–275, §154(d)(4)(A), inserted ''and the identification of areas under subsection (a)(1)(D)(iii)'' after ''(a)(1)(A)''.

Subsec. (b)(11)(D). Pub. L. 110–275, §154(d)(4)(B), inserted ''and implementation of subsection (a)(1)(D)'' after ''(a)(1)(B)''.

Subsec. (b)(11)(G). Pub. L. 110–275, §154(d)(4)(C)–(E), added subpar. (G).

Subsec. (c)(5). Pub. L. 110–275, §154(c)(2)(A), substituted ''December 31, 2011'' for ''December 31, 2009''.

Subsec. (d). Pub. L. 110–275, §154(c)(2)(B), substituted ''July 1, 2011'' for ''July 1, 2009''.

Subsec. (e). Pub. L. 110–275, §145(a)(1), struck out subsec. (e) which related to a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests, terms and conditions of the project, and reporting requirement.

Subsec. (f). Pub. L. 110–275, §154(b)(3), added subsec. (f).

2003—Pub. L. 108–173 amended section catchline and text generally, substituting provisions relating to competitive acquisition of certain items and services for provisions relating to demonstration projects for competitive acquisition of items and services.

1999—Subsec. (b)(2). Pub. L. 106–113 inserted ''and'' after ''specified by the Secretary''.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 154 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 1999 AMENDMENT

Amendment by 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.

CONSTRUCTION OF 2015 AMENDMENT

Pub. L. 114–10, title V, §522(b)(2), Apr. 16, 2015, 129 Stat. 177, provided that: ''Nothing in the amendment made by paragraph (1) [amending this section] shall be construed as affecting the authority of the Secretary of Health and Human Services to require State licensure of an entity under the Medicare competitive acquisition program under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) before the date of the enactment of this Act [Apr. 16, 2015].''

GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS

Pub. L. 108–173, title III, §302(b)(3), Dec. 8, 2003, 117 Stat. 2230, as amended by Pub. L. 110–275, title I, §154(c)(1), July 15, 2008, 122 Stat. 2565, provided that:

''(A) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act [42 U.S.C. 1395w–3], as amended by paragraph (1) and as amended by section 2 of the Medicare DMEPOS Competitive Acquisition Reform Act of 2008 [probably should refer to section 154 of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275], on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment and the topics specified in subparagraph (C).

''(B) REPORT.—Not later than 1 year after the first date that payments are made under section 1847 of the Social Security Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

''(C) TOPICS.—The topics specified in this subparagraph, for the study under subparagraph (A) concerning the competitive acquisition program, are the following:

''(i) Beneficiary access to items and services under the program, including the impact on such access of awarding contracts to bidders that—

''(I) did not have a physical presence in an area where they received a contract; or

''(II) had no previous experience providing the product category they were contracted to provide.

''(ii) Beneficiary satisfaction with the program and cost savings to beneficiaries under the program.

''(iii) Costs to suppliers of participating in the program and recommendations about ways to reduce those costs without compromising quality standards or savings to the Medicare program.

''(iv) Impact of the program on small business suppliers.

''(v) Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code.

''(vi) Costs to the Centers for Medicare & Medicaid Services, including payments made to contractors, for administering the program compared with administration of a fee schedule, in comparison with the relative savings of the program.

''(vii) Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished.

''(viii) Such other topics as the Comptroller General determines to be appropriate.''

REPORT ON ACTIVITIES OF SUPPLIERS

Pub. L. 108–173, title III, §302(e), Dec. 8, 2003, 117 Stat. 2233, as amended by Pub. L. 110–275, title I, §154(c)(2)(C), July 15, 2008, 122 Stat. 2566, provided that: ''The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act [42 U.S.C. 1395w–3], as amended by subsection (a) [probably should be (b)(1)], are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2011, the Inspector General shall submit to Congress a report on such study.''

STUDY BY GAO

Pub. L. 105–33, title IV, §4319(c), Aug. 5, 1997, 111 Stat. 394, provided that: ''The Comptroller of the United States shall study the effectiveness of the establishment of competitive acquisition areas under section 1847(a) of the Social Security Act [42 U.S.C. 1395w–3(a)], as added by this section.''

§ 1395w–3a. Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395u(*o*)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection

(a)(1)(A)(ii) of section 1395w–3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e) of this section, the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C) of this section), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D) of this section), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1396r–8(b)(3)(A)(iii) of this title.

(B) Unit defined

In this section, the term ''unit'' means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) Multiple source drug

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r–8(b)(3)(A)(iii) of this title determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c) of this section); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) Single source drug or biological

The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) Average sales price

The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) Wholesale acquisition cost (WAC)

The wholesale acquisition cost (as defined in subsection (c)(6)(B) of this section) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) Basis for payment amount

The payment amount shall be determined under this subsection based on information reported under subsection (f) of this section and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) Use of volume-weighted average sales prices in calculation of average sales price

(A) In general

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r–8(b)(3)(A)(iii) of this title determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) Billing unit defined

For purposes of this subsection, the term ''billing unit'' means the identifiable quan-

tity associated with a billing and payment code, as established by the Secretary.

(7) Special rule

Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1395u(*o*)(1)(G) of this title that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1395u(*o*)(1)(G) of this title (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) Biosimilar biological product

The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(A) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(B) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(c) Manufacturer's average sales price

(1) In general

For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's ''average sales price'' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) Certain sales exempted from computation

In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) Sales exempt from best price

Sales exempt from the inclusion in the determination of ''best price'' under section 1396r–8(c)(1)(C)(i) of this title.

(B) Sales at nominal charge

Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1396r–8(c)(1)(C)(ii)(III) of this title, except as the Secretary may otherwise provide).

(3) Sale price net of discounts

In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r–8 of this title). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) Payment methodology in cases where average sales price during first quarter of sales is unavailable

In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

(A) the wholesale acquisition cost; or

(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) Frequency of determinations

(A) In general on a quarterly basis

The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) Updates in payment amounts

The payment amounts under subsection (b) of this section shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) Use of contractors; implementation

The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b) of this section. Notwithstanding any other provision of law, the Secretary may implement, by program

instruction or otherwise, any of the provisions of this section.

(6) Definitions and other rules

In this section:

(A) Manufacturer

The term ''manufacturer'' means, with respect to a drug or biological, the manufacturer (as defined in section 1396r–8(k)(5) of this title).

(B) Wholesale acquisition cost

The term ''wholesale acquisition cost'' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) Multiple source drug

(i) In general

The term ''multiple source drug'' means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) Exception

With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) Single source drug or biological

The term ''single source drug or biological'' means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) Exception from pharmaceutical equivalence and bioequivalence requirement

Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) Determination of pharmaceutical equivalence and bioequivalence

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) Inclusion of vaccines

In applying provisions of section 1396r–8 of this title under this section, ''other than a vaccine'' is deemed deleted from section 1396r–8(k)(2)(B) of this title.

(H) Biosimilar biological product

The term ''biosimilar biological product'' means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 262 of this title.

(I) Reference biological product

The term ''reference biological product'' means the biological product licensed under such section 262 of this title that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) Monitoring of market prices

(1) In general

The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) Comparison of prices

Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for such drugs and biologicals.

(3) Limitation on average sales price

(A) In general

The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined

In this paragraph, the term ''applicable threshold percentage'' means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) Authority to adjust average sales price

If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for the drug or biological.

(4) Civil money penalty

(A) In general

If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) Procedures

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

(5) Widely available market price

(A) In general

In this subsection, the term ''widely available market price'' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) Considerations

In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

(i) Manufacturers.
(ii) Wholesalers.
(iii) Distributors.
(iv) Physician supply houses.
(v) Specialty pharmacies.
(vi) Group purchasing arrangements.
(vii) Surveys of physicians.
(viii) Surveys of suppliers.
(ix) Information on such market prices from insurers.
(x) Information on such market prices from private health plans.

(e) Authority to use alternative payment in response to public health emergency

In the case of a public health emergency under section 247d of this title in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price,[1] of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) Quarterly report on average sales price

For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1396r–8(b)(3) of this title.

(g) Judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2) of this section;

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e) of this section.

(Aug. 14, 1935, ch. 531, title XVIII, § 1847A, as added Pub. L. 108–173, title III, § 303(c)(1), Dec. 8, 2003, 117 Stat. 2239; amended Pub. L. 110–173, title I, § 112, Dec. 29, 2007, 121 Stat. 2500; Pub. L. 111–148, title III, § 3139(a), Mar. 23, 2010, 124 Stat. 439.)

AMENDMENTS

2010—Subsec. (b)(1)(C). Pub. L. 111–148, § 3139(a)(1)(A), added subpar. (C).

Subsec. (b)(8). Pub. L. 111–148, § 3139(a)(1)(B), added par. (8).

[1] So in original. The comma probably should not appear.

Subsec. (c)(6)(H), (I). Pub. L. 111–148, §3139(a)(2), added subpars. (H) and (I).

2007—Subsec. (b)(1). Pub. L. 110–173, §112(b)(1), inserted ''paragraph (7) and'' after ''Subject to'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 110–173, §112(a)(1), inserted ''for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008'' after ''paragraph (3)''.

Subsec. (b)(4)(A), (B). Pub. L. 110–173, §112(a)(2), inserted ''for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008,'' after ''paragraph (3)''.

Subsec. (b)(6). Pub. L. 110–173, §112(a)(3), added par. (6).

Subsec. (b)(7). Pub. L. 110–173, §112(b)(2), added par. (7).

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3139(b), Mar. 23, 2010, 124 Stat. 440, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to payments for biosimilar biological products beginning with the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary [probably means the Secretary of Health and Human Services]).''

REPORT ON SALES TO PHARMACY BENEFIT MANAGERS

Pub. L. 108–173, title III, §303(c)(2), Dec. 8, 2003, 117 Stat. 2245, provided that:

''(A) STUDY.—The Secretary [of Health and Human Services] shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.

''(B) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price under section 1847A of the Social Security Act [42 U.S.C. 1395w–3a], as added by paragraph (1).''

INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY

Pub. L. 108–173, title III, §303(c)(3), Dec. 8, 2003, 117 Stat. 2245, provided that:

''(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially particularly large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act [42 U.S.C. 1395w–3a], as added by paragraph (1).

''(B) REPORT.—Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A [42 U.S.C. 1395w–3a].''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable 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, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

§ 1395w–3b. Competitive acquisition of outpatient drugs and biologicals

(a) Implementation of competitive acquisition

(1) Implementation of program

(A) In general

The Secretary shall establish and implement a competitive acquisition program under which—

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1395w–3a of this title; and

(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1395w–3a of this title to apply.

(B) Implementation

For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

(C) Waiver of certain provisions

In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Exclusion authority

The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals—

(i) is not likely to result in significant savings; or

(ii) is likely to have an adverse impact on access to such drugs or biologicals.

(2) Competitively biddable drugs and biologicals and program defined

For purposes of this section—

(A) Competitively biddable drugs and biologicals defined

The term ''competitively biddable drugs and biologicals'' means a drug or biological described in section 1395u(*o*)(1)(C) of this title and furnished on or after January 1, 2006.

(B) Program

The term ''program'' means the competitive acquisition program under this section.

(C) Competitive acquisition area; area

The terms ''competitive acquisition area'' and ''area'' mean an appropriate geographic region established by the Secretary under the program.

(D) Contractor

The term ''contractor'' means an entity that has entered into a contract with the Secretary under this section.

(3) Application of program payment methodology

(A) In general

With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply—

(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals shall be made only to such contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.

(B) Process for adjustments

The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

(C) Information for purposes of cost-sharing

The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

(D) Post-payment review process

The Secretary shall establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological under this section only if the drug or biological has been administered to a beneficiary. The Secretary shall recoup, offset, or collect any overpayments determined by the Secretary under such process.

(4) Contract required

Payment may not be made under this part for competitively biddable drugs and biologicals prescribed by a physician who has elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless—

(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

(B) the physician has elected such contractor under paragraph (5) for such category and area.

(5) Contractor selection process

(A) Annual selection

(i) In general

The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

(ii) Timing of selection

The selection of a contractor under clause (i) shall be made at the time of the election described in section 1395w–3a(a) of this title for this section to apply and shall be coordinated with agreements entered into under section 1395u(h) of this title.

(B) Information on contractors

The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

(C) Selecting physician defined

For purposes of this section, the term ''selecting physician'' means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

(b) Program requirements

(1) Contract for competitively biddable drugs and biologicals

The Secretary shall conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this subchapter, in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least

one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

(i) Capacity to supply competitively biddable drug or biological within category

(I) In general

The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

(II) Shipment methodology

The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

(ii) Quality, service, financial performance and solvency standards

The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

(II) a grievance and appeals process for the resolution of disputes.

(B) Additional considerations

The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

(ii) the exclusion of the entity under section 1320a–7 of this title from participation under this subchapter.

(C) Application of Medicare Provider Ombudsman

For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1395ee(b) of this title, as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[1]

[1] See References in Text note below.

(3) Awarding multiple contracts for a category and area

The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

(B) Bid price for distribution of such drugs and biologicals.

(C) Ability to ensure product integrity.

(D) Customer service.

(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

(F) Such other factors as the Secretary may specify.

(4) Terms of contracts

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

(B) Period of contracts

A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

(C) Integrity of drug and biological distribution system

A contractor (as defined in subsection (a)(2)(D) of this section) shall—

(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that relate to the wholesale distribution of prescription drugs or biologicals.

(D) Compliance with code of conduct and fraud and abuse rules

Under the contract—

(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

(E) Direct delivery of drugs and biologicals to physicians

Under the contract the contractor shall only supply competitively biddable drugs

and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

(i) require a physician to submit a prescription for each individual treatment; or

(ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

(5) Permitting access to drugs and biologicals

The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

(A) The drugs or biologicals are required immediately.

(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

(D) The drugs or biologicals were administered in an emergency situation.

(6) Construction

Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

(c) Bidding process

(1) In general

In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3) of this section.

(2) Bid defined

In this section, the term ''bid'' means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

(3) Bidding on a national or regional basis

Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

(4) Uniformity of bids within area

The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

(5) Confidentiality of bids

The provisions of subparagraph (D) of section 1396r–8(b)(3) of this title shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

(A) in that subparagraph to a ''manufacturer or wholesaler'' is deemed a reference to a ''bidder'' under this section;

(B) in that section to ''prices charged for drugs'' is deemed a reference to a ''bid'' submitted under this section; and

(C) in clause (i) of that section to ''this section'', is deemed a reference to ''part B of subchapter XVIII of this chapter''.

(6) Inclusion of costs

The bid price submitted in a contract offer for a competitively biddable drug or biological shall—

(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

(7) Price adjustments during contract period; disclosure of costs

Each contract awarded shall provide for—

(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

(d) Computation of payment amounts

(1) In general

Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

(2) Special rules

The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1395w–3a of this title to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

(A) New drugs and biologicals

A competitively biddable drug or biological for which a payment and billing code has not been established.

(B) Other cases

Such other exceptional cases as the Secretary may specify in regulations.

(e) Cost-sharing

(1) Application of coinsurance

Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1) of this section.

(2) Deductible

Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1395*l*(b) of this title.

(3) Collection

Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B) of this section, such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

(f) Special payment rules

(1) Use in exclusion cases

If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D) of this section, the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1395w–3a of this title.

(2) Application of requirement for assignment

For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1395u(*o*)(3) of this title.

(3) Protection for beneficiary in case of medical necessity denial

For protection of individuals against liability in the case of medical necessity determinations, see section 1395u(b)(3)(B)(ii)(III) of this title.

(g) Judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(1) the establishment of payment amounts under subsection (d)(1) of this section;

(2) the awarding of contracts under this section;

(3) the establishment of competitive acquisition areas under subsection (a)(2)(C) of this section;

(4) the phased-in implementation under subsection (a)(1)(B) of this section;

(5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or

(6) the bidding structure and number of contractors selected under this section.

(Aug. 14, 1935, ch. 531, title XVIII, §1847B, as added Pub. L. 108–173, title III, §303(d)(1), Dec. 8, 2003, 117 Stat. 2245; amended Pub. L. 109–432, div. B, title I, §108(a), Dec. 20, 2006, 120 Stat. 2983.)

REFERENCES IN TEXT

Section 1395ee(b) of this title, referred to in subsec. (b)(2)(C), was added by section 942(a)(5) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, not section 923 of that Act, and relates to the Council for Technology and Innovation, not to the Medicare Provider Ombudsman.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. subsec. (b)(4)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2006—Subsec. (a)(3)(A)(iii). Pub. L. 109–432, §108(a)(1), substituted ''and biologicals shall be made only to such contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.'' for ''and biologicals—

''(I) shall be made only to such contractor; and

''(II) shall be conditioned upon the administration of such drugs and biologicals.''

Subsec. (a)(3)(D). Pub. L. 109–432, §108(a)(2), added subpar. (D).

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §108(c), Dec. 20, 2006, 120 Stat. 2983, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to payment for drugs and biologicals supplied under section 1847B of the Social Security Act (42 U.S.C. 1395w–3b)—

''(1) on or after April 1, 2007; and

''(2) on or after July 1, 2006, and before April 1, 2007, for claims that are unpaid as of April 1, 2007.''

CONSTRUCTION OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §108(b), Dec. 20, 2006, 120 Stat. 2983, provided that: ''Nothing in this section [amending this section and enacting provisions set out as a note above] shall be construed as—

''(1) requiring the conduct of any additional competition under subsection (b)(1) of section 1847B of the Social Security Act (42 U.S.C. 1395w–3b); or

''(2) requiring any additional process for elections by physicians under subsection (a)(1)(A)(ii) of such section or additional selection by a selecting physician of a contractor under subsection (a)(5) of such section.''

REPORT

Pub. L. 108–173, title III, §303(d)(2), Dec. 8, 2003, 117 Stat. 2252, provided that: ''Not later than July 1, 2008, the Secretary [of Health and Human Services] shall submit to Congress a report on the program conducted under section 1847B of the Social Security Act [42 U.S.C. 1395w–3b], as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to physicians, the satisfaction of physicians and of individuals enrolled under this part [probably means part B of title XVIII of the Social Security Act, 42 U.S.C. 1395j et seq.], and information comparing prices for drugs and biologicals under such section and section 1847A of such Act [42 U.S.C. 1395w–3a], as added by subsection (c).''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable 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, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

§ 1395w–4. Payment for physicians' services

(a) Payment based on fee schedule

(1) In general

Effective for all physicians' services (as defined in subsection (j)(3) of this section) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1395m(b) of this title, payment under this part shall instead be based on the lesser of—

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) of this section for services furnished during that year (in this subsection referred to as the ''fee schedule amount'').

(2) Transition to full fee schedule

(A) Limiting reductions and increases to 15 percent in 1992

(i) Limit on increase

In the case of a service in a fee schedule area (as defined in subsection (j)(2) of this section) for which the adjusted historical payment basis (as defined in subparagraph (D)) is less than 85 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis plus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(ii) Limit in reduction

In the case of a service in a fee schedule area for which the adjusted historical payment basis exceeds 115 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis minus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(B) Special rule for 1993, 1994, and 1995

If a physicians' service in a fee schedule area is subject to the provisions of subparagraph (A) in 1992, for physicians' services furnished in the area—

(i) during 1993, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 75 percent of the fee schedule amount determined under subparagraph (A), adjusted by the update established under subsection (d)(3) of this section for 1993, and

(II) 25 percent of the fee schedule amount determined under paragraph (1) for 1993 without regard to this paragraph;

(ii) during 1994, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 67 percent of the fee schedule amount determined under clause (i), adjusted by the update established under subsection (d)(3) of this section for 1994 and as adjusted under subsection (c)(2)(F)(ii) of this section and under section 13515(b) of the Omnibus Budget Reconciliation Act of 1993, and

(II) 33 percent of the fee schedule amount determined under paragraph (1) for 1994 without regard to this paragraph; and

(iii) during 1995, there shall be substituted for the fee schedule amount an amount equal to the sum of—

(I) 50 percent of the fee schedule amount determined under clause (ii) adjusted by the update established under subsection (d)(3) of this section for 1995, and

(II) 50 percent of the fee schedule amount determined under paragraph (1) for 1995 without regard to this paragraph.

(C) Special rule for anesthesia and radiology services

With respect to physicians' services which are anesthesia services, the Secretary shall provide for a transition in the same manner as a transition is provided for other services under subparagraph (B). With respect to radiology services, ''109 percent'' and ''9 percent'' shall be substituted for ''115 percent'' and ''15 percent'', respectively, in subparagraph (A)(ii).

(D) "Adjusted historical payment basis" defined

(i) In general

In this paragraph, the term ''adjusted historical payment basis'' means, with respect to a physicians' service furnished in a fee schedule area, the weighted average prevailing charge applied in the area for the service in 1991 (as determined by the Secretary without regard to physician specialty and as adjusted to reflect payments for services with customary charges below the prevailing charge or other payment limitations imposed by law or regulation) adjusted by the update established under subsection (d)(3) of this section for 1992.

(ii) Application to radiology services

In applying clause (i) in the case of physicians' services which are radiology services (including radiologist services, as defined in section 1395m(b)(6) of this title), but excluding nuclear medicine services that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989, there shall be substituted for the weighted average prevailing charge the amount provided under the fee schedule established for the service for the fee schedule area under section 1395m(b) of this title.

(iii) Nuclear medicine services

In applying clause (i) in the case of physicians' services which are nuclear medicine services, there shall be substituted for the weighted average prevailing charge the amount provided under section 6105(b) of the Omnibus Budget Reconciliation Act of 1989.

(3) Incentives for participating physicians and suppliers

In applying paragraph (1)(B) in the case of a nonparticipating physician or a nonparticipating supplier or other person, the fee schedule amount shall be 95 percent of such amount otherwise applied under this subsection (without regard to this paragraph). In the case of physicians' services (including services which the Secretary excludes pursuant to subsection (j)(3) of this section) of a nonparticipating physician, supplier, or other person for which payment is made under this part on a basis other than the fee schedule amount, the payment shall be based on 95 percent of the payment basis for such services furnished by a participating physician, supplier, or other person.

(4) Special rule for medical direction

(A) In general

With respect to physicians' services furnished on or after January 1, 1994, and consisting of medical direction of two, three, or four concurrent anesthesia cases, except as provided in paragraph (5), the fee schedule amount to be applied shall be equal to one-half of the amount described in subparagraph (B).

(B) Amount

The amount described in this subparagraph, for a physician's medical direction of the performance of anesthesia services, is the following percentage of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the physician alone:

(i) For services furnished during 1994, 120 percent.

(ii) For services furnished during 1995, 115 percent.

(iii) For services furnished during 1996, 110 percent.

(iv) For services furnished during 1997, 105 percent.

(v) For services furnished after 1997, 100 percent.

(5) Incentives for electronic prescribing

(A) Adjustment

(i) In general

Subject to subparagraph (B) and subsection (m)(2)(B), with respect to covered professional services furnished by an eligible professional during 2012, 2013 or 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year (as determined under subsection (m)(3)(B)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) Applicable percent

For purposes of clause (i), the term ''applicable percent'' means—

(I) for 2012, 99 percent;

(II) for 2013, 98.5 percent; and

(III) for 2014, 98 percent.

(B) Significant hardship exception

The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

(C) Application

(i) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) Incentive payment validation rules

Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(D) Definitions

For purposes of this paragraph:

(i) Eligible professional; covered professional services

The terms ''eligible professional'' and ''covered professional services'' have the meanings given such terms in subsection (k)(3).

(ii) Physician reporting system

The term ''physician reporting system'' means the system established under subsection (k).

(iii) Reporting period

The term ''reporting period'' means, with respect to a year, a period specified by the Secretary.

(6) Special rule for teaching anesthesiologists

With respect to physicians' services furnished on or after January 1, 2010, in the case of teaching anesthesiologists involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount to be applied shall be 100 percent of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the teaching anesthesiologist alone and paragraph (4) shall not apply if—

(A) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and

(B) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(7) Incentives for meaningful use of certified EHR technology

(A) Adjustment

(i) In general

Subject to subparagraphs (B) and (D), with respect to covered professional services furnished by an eligible professional during each of 2015 through 2018, if the eligible professional is not a meaningful EHR user (as determined under subsection (*o*)(2)) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) Applicable percent

Subject to clause (iii), for purposes of clause (i), the term ''applicable percent'' means—

(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment adjustment under subsection (a)(5) for 2014, 98 percent);

(II) for 2016, 98 percent; and

(III) for 2017 and 2018, 97 percent.

(iii) Authority to decrease applicable percentage for 2018

For 2018, if the Secretary finds that the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (*o*)(2)) is less than 75 percent, the applicable percent shall be decreased by 1 percentage point from the applicable percent in the preceding year.

(B) Significant hardship exception

The Secretary may, on a case-by-case basis (and, with respect to the payment adjustment under subparagraph (A) for 2017, for categories of eligible professionals, as established by the Secretary and posted on the Internet website of the Centers for Medicare & Medicaid Services prior to December 15, 2015, an application for which must be submitted to the Secretary by not later than March 15, 2016), exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access. In no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.

(C) Application of physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(D) Non-application to hospital-based eligible professionals

No payment adjustment may be made under subparagraph (A) in the case of hospital-based eligible professionals (as defined in subsection (*o*)(1)(C)(ii)).

(E) Definitions

For purposes of this paragraph:

(i) Covered professional services

The term ''covered professional services'' has the meaning given such term in subsection (k)(3).

(ii) EHR reporting period

The term ''EHR reporting period'' means, with respect to a year, a period (or periods) specified by the Secretary.

(iii) Eligible professional

The term ''eligible professional'' means a physician, as defined in section 1395x(r) of this title.

(8) Incentives for quality reporting

(A) Adjustment

(i) In general

With respect to covered professional services furnished by an eligible professional during each of 2015 through 2018, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under subsection (m)(3)(A)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraphs (3), (5), and (7), but without regard to this paragraph).

(ii) Applicable percent

For purposes of clause (i), the term ''applicable percent'' means—

(I) for 2015, 98.5 percent; and

(II) for 2016, 2017, and 2018, 98 percent.

(B) Application

(i) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) Incentive payment validation rules

Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(C) Definitions

For purposes of this paragraph:

(i) Eligible professional; covered professional services

The terms ''eligible professional'' and ''covered professional services'' have the meanings given such terms in subsection (k)(3).

(ii) Physician reporting system

The term ''physician reporting system'' means the system established under subsection (k).

(iii) Quality reporting period

The term ''quality reporting period'' means, with respect to a year, a period specified by the Secretary.

(9) Information reporting on services included in global surgical packages

With respect to services for which a physician is required to report information in accordance with subsection (c)(8)(B)(i), the Secretary may through rulemaking delay payment of 5 percent of the amount that would otherwise be payable under the physician fee schedule under this section for such services until the information so required is reported.

(b) Establishment of fee schedules

(1) In general

Before November 1 of the preceding year, for each year beginning with 1998, subject to subsection (p), the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas (as defined in subsection (j)(2) of this section) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of—

(A) the relative value for the service (as determined in subsection (c)(2) of this section),

(B) the conversion factor (established under subsection (d) of this section) for the year, and

(C) the geographic adjustment factor (established under subsection (e)(2) of this section) for the service for the fee schedule area.

(2) Treatment of radiology services and anesthesia services

(A) Radiology services

With respect to radiology services (including radiologist services, as defined in section 1395m(b)(6) of this title), the Secretary shall base the relative values on the relative value scale developed under section 1395m(b)(1)(A) of this title, with appropriate modifications of the relative values to assure that the relative values established for radiology services which are similar or related to other physicians' services are consistent with the relative values established for those similar or related services.

(B) Anesthesia services

In establishing the fee schedule for anesthesia services for which a relative value guide has been established under section 4048(b) of the Omnibus Budget Reconciliation Act of 1987, the Secretary shall use, to the extent practicable, such relative value guide, with appropriate adjustment of the conversion factor, in a manner to assure that the fee schedule amounts for anesthesia services are consistent with the fee schedule amounts for other services determined by the Secretary to be of comparable value. In applying the previous sentence, the Secretary shall adjust the conversion factor by geographic adjustment factors in the same manner as such adjustment is made under paragraph (1)(C).

(C) Consultation

The Secretary shall consult with the Physician Payment Review Commission and organizations representing physicians or suppliers who furnish radiology services and anesthesia services in applying subparagraphs (A) and (B).

(3) Treatment of interpretation of electrocardiograms

The Secretary—

(A) shall make separate payment under this section for the interpretation of electrocardiograms performed or ordered to be performed as part of or in conjunction with a visit to or a consultation with a physician, and

(B) shall adjust the relative values established for visits and consultations under subsection (c) of this section so as not to include relative value units for interpretations of electrocardiograms in the relative value for visits and consultations.

(4) Special rule for imaging services

(A) In general

In the case of imaging services described in subparagraph (B) furnished on or after January 1, 2007, if—

(i) the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1)(C), exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1395*l*(t) of this title for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor described in paragraph (1)(C), for the fee schedule amount for such technical component for such year.

(B) Imaging services described

For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography, and for 2010, 2011, and the first 2 months of 2012, dual-energy x-ray absorptiometry services (as described in paragraph (6)).

(C) Adjustment in imaging utilization rate

With respect to fee schedules established for 2011, 2012, and 2013, in the methodology for determining practice expense relative value units for expensive diagnostic imaging equipment under the final rule published by the Secretary in the Federal Register on November 25, 2009 (42 CFR 410 et al.), the Secretary shall use a 75 percent assumption instead of the utilization rates otherwise established in such final rule. With respect to fee schedules established for 2014 and subsequent years, in such methodology, the Secretary shall use a 90 percent utilization rate.

(D) Adjustment in technical component discount on single-session imaging involving consecutive body parts

For services furnished on or after July 1, 2010, the Secretary shall increase the reduction in payments attributable to the multiple procedure payment reduction applicable to the technical component for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (part 405 of title 42, Code of Federal Regulations) from 25 percent to 50 percent.

(5) Treatment of intensive cardiac rehabilitation program

(A) In general

In the case of an intensive cardiac rehabilitation program described in section 1395x(eee)(4) of this title, the Secretary shall substitute the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department service under paragraph (3)(D) of section 1395*l*(t) of this title for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation).

(B) Definition of session

Each of the services described in subparagraphs (A) through (E) of section 1395x(eee)(3) of this title, when furnished for one hour, is a separate session of intensive cardiac rehabilitation.

(C) Multiple sessions per day

Payment may be made for up to 6 sessions per day of the series of 72 one-hour sessions of intensive cardiac rehabilitation services described in section 1395x(eee)(4)(B) of this title.

(6) Treatment of bone mass scans

For dual-energy x-ray absorptiometry services (identified in 2006 by HCPCS codes 76075 and 76077 (and any succeeding codes)) furnished during 2010, 2011, and the first 2 months of 2012, instead of the payment amount that would otherwise be determined under this section for such years, the payment amount shall be equal to 70 percent of the product of—

(A) the relative value for the service (as determined in subsection (c)(2)) for 2006;

(B) the conversion factor (established under subsection (d)) for 2006; and

(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area for 2010, 2011, and the first 2 months of 2012, respectively.

(7) Adjustment in discount for certain multiple therapy services

In the case of therapy services furnished on or after January 1, 2011, and before April 1, 2013, and for which payment is made under fee schedules established under this section, instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 20 percent. In the case of such services furnished on or after April 1, 2013, and for which payment is made under such fee schedules, instead of the 25 percent multiple procedure payment reduction specified in such final rule, the reduction percentage shall be 50 percent.

(8) Encouraging care management for individuals with chronic care needs

(A) In general

In order to encourage the management of care for individuals with chronic care needs the Secretary shall, subject to subparagraph (B), make payment (as the Secretary determines to be appropriate) under this section for chronic care management services furnished on or after January 1, 2015, by a physician (as defined in section 1395x(r)(1) of this title), physician assistant or nurse practitioner (as defined in section 1395x(aa)(5)(A) of this title), clinical nurse specialist (as defined in section 1395x(aa)(5)(B) of this title), or certified nurse midwife (as defined in section 1395x(gg)(2) of this title).

(B) Policies relating to payment

In carrying out this paragraph, with respect to chronic care management services, the Secretary shall—

(i) make payment to only one applicable provider for such services furnished to an individual during a period;

(ii) not make payment under subparagraph (A) if such payment would be duplicative of payment that is otherwise made under this subchapter for such services; and

(iii) not require that an annual wellness visit (as defined in section 1395x(hhh) of this title) or an initial preventive physical examination (as defined in section 1395x(ww) of this title) be furnished as a condition of payment for such management services.

(9) Special rule to incentivize transition from traditional X-ray imaging to digital radiography

(A) Limitation on payment for film X-ray imaging services

In the case of an imaging service (including the imaging portion of a service) that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 20 percent.

(B) Phased-in limitation on payment for computed radiography imaging services

In the case of an imaging service (including the imaging portion of a service) that is an X-ray taken using computed radiography technology—

(i) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 7 percent; and

(ii) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global service) of such service that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 10 percent.

(C) Computed radiography technology defined

For purposes of this paragraph, the term ''computed radiography technology'' means cassette-based imaging which utilizes an imaging plate to create the image involved.

(D) Implementation

In order to implement this paragraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(10) Reduction of discount in payment for professional component of multiple imaging services

In the case of the professional component of imaging services furnished on or after January 1, 2017, instead of the 25 percent reduction for multiple procedures specified in the final rule published by the Secretary in the Federal Register on November 28, 2011, as amended in the final rule published by the Secretary in the Federal Register on November 16, 2012, the reduction percentage shall be 5 percent.

(11) Special rule for certain radiation therapy services

The code definitions, the work relative value units under subsection (c)(2)(C)(i), and the direct inputs for the practice expense relative value units under subsection (c)(2)(C)(ii) for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016.

(c) Determination of relative values for physicians' services

(1) Division of physicians' services into components

In this section, with respect to a physicians' service:

(A) "Work component" defined

The term ''work component'' means the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. Such portion shall—

(i) include activities before and after direct patient contact, and

(ii) be defined, with respect to surgical procedures, to reflect a global definition including pre-operative and post-operative physicians' services.

(B) "Practice expense component" defined

The term ''practice expense component'' means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.

(C) "Malpractice component" defined

The term ''malpractice component'' means the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.

(2) Determination of relative values

(A) In general

(i) Combination of units for components

The Secretary shall develop a methodology for combining the work, practice expense, and malpractice relative value units, determined under subparagraph (C), for each service in a manner to produce a single relative value for that service. Such relative values are subject to adjustment under subparagraph (F)(i) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993.

(ii) Extrapolation

The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission and the results

of consultations with organizations representing physicians who provide such services.

(B) Periodic review and adjustments in relative values

(i) Periodic review

The Secretary, not less often than every 5 years, shall review the relative values established under this paragraph for all physicians' services.

(ii) Adjustments

(I) In general

The Secretary shall, to the extent the Secretary determines to be necessary and subject to subclause (II) and paragraph (7), adjust the number of such units to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. The Secretary shall publish an explanation of the basis for such adjustments.

(II) Limitation on annual adjustments

Subject to clauses (iv) and (v), the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part for the year to differ by more than $20,000,000 from the amount of expenditures under this part that would have been made if such adjustments had not been made.

(iii) Consultation

The Secretary, in making adjustments under clause (ii), shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.

(iv) Exemption of certain additional expenditures from budget neutrality

The additional expenditures attributable to—

(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II);

(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year; and

(IV) subsection (b)(6) shall not be taken into account in applying clause (ii)(II) for 2010, 2011, or the first 2 months of 2012.

(v) Exemption of certain reduced expenditures from budget-neutrality calculation

The following reduced expenditures, as estimated by the Secretary, shall not be taken into account in applying clause (ii)(II):

(I) Reduced payment for multiple imaging procedures

Effective for fee schedules established beginning with 2007, reduced expenditures attributable to the multiple procedure payment reduction for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (42 CFR 405, et al.) insofar as it relates to the physician fee schedules for 2006 and 2007.

(II) OPD payment cap for imaging services

Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

(III) Change in utilization rate for certain imaging services

Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the changes in the utilization rate applicable to 2011 and 2014, as described in the first and second sentence, respectively, of subsection (b)(4)(C).

(IV), (V) Repealed. Pub. L. 111–152, title I, § 1107(2), Mar. 30, 2010, 124 Stat. 1050

(VI) Additional reduced payment for multiple imaging procedures

Effective for fee schedules established beginning with 2010 (but not applied for services furnished prior to July 1, 2010), reduced expenditures attributable to the increase in the multiple procedure payment reduction from 25 to 50 percent (as described in subsection (b)(4)(D)).

(VII) Reduced expenditures for multiple therapy services

Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the multiple procedure payment reduction for therapy services (as described in subsection (b)(7)).

(VIII) Reduced expenditures attributable to application of quality incentives for computed tomography

Effective for fee schedules established beginning with 2016, reduced expenditures attributable to the application of the quality incentives for computed tomography under section 1395m(p) of this title[1]

(IX) Reductions for misvalued services if target not met

Effective for fee schedules beginning with 2016, reduced expenditures attributable to the application of the target recapture amount described in subparagraph (O)(iii).

(X) Reduced expenditures attributable to incentives to transition to digital radiography

Effective for fee schedules established beginning with 2017, reduced expendi-

[1] So in original. Probably should be followed by a period.

tures attributable to subparagraph (A) of subsection (b)(9) and effective for fee schedules established beginning with 2018, reduced expenditures attributable to subparagraph (B) of such subsection.

(XI) Discount in payment for professional component of imaging services

Effective for fee schedules established beginning with 2017, reduced expenditures attributable to subsection (b)(10).

(vi) Alternative application of budget-neutrality adjustment

Notwithstanding subsection (d)(9)(A), effective for fee schedules established beginning with 2009, with respect to the 5-year review of work relative value units used in fee schedules for 2007 and 2008, in lieu of continuing to apply budget-neutrality adjustments required under clause (ii) for 2007 and 2008 to work relative value units, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for years beginning with 2009.

(C) Computation of relative value units for components

For purposes of this section for each physicians' service—

(i) Work relative value units

The Secretary shall determine a number of work relative value units for the service or group of services based on the relative resources incorporating physician time and intensity required in furnishing the service or group of services.

(ii) Practice expense relative value units

The Secretary shall determine a number of practice expense relative value units for the service for years before 1999 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the practice expense percentage for the service (as determined under paragraph (3)(C)(ii)),

and for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service or group of services. For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For 2001, such number of units shall be determined based 25 percent on such product and based 75 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.

(iii) Malpractice relative value units

The Secretary shall determine a number of malpractice relative value units for the service or group of services for years before 2000 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service or group of services, and

(II) the malpractice percentage for the service or group of services (as determined under paragraph (3)(C)(iii)),

and for years beginning with 2000 based on the malpractice expense resources involved in furnishing the service or group of services.

(D) "Base allowed charges" defined

In this paragraph, the term ''base allowed charges'' means, with respect to a physician's service, the national average allowed charges for the service under this part for services furnished during 1991, as estimated by the Secretary using the most recent data available.

(E) Reduction in practice expense relative value units for certain services

(i) In general

Subject to clause (ii), the Secretary shall reduce the practice expense relative value units applied to services described in clause (iii) furnished in—

(I) 1994, by 25 percent of the number by which the number of practice expense relative value units (determined for 1994 without regard to this subparagraph) exceeds the number of work relative value units determined for 1994,

(II) 1995, by an additional 25 percent of such excess, and

(III) 1996, by an additional 25 percent of such excess.

(ii) Floor on reductions

The practice expense relative value units for a physician's service shall not be reduced under this subparagraph to a number less than 128 percent of the number of work relative value units.

(iii) Services covered

For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iv) and for which—

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1994) exceeds 128 percent of the number of work relative value units (determined for such year).

(iv) Excluded services

For purposes of clause (iii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this subchapter in an office setting.

(F) Budget neutrality adjustments

The Secretary—

(i) shall reduce the relative values for all services (other than anesthesia services) established under this paragraph (and, in

the case of anesthesia services, the conversion factor established by the Secretary for such services) by such percentage as the Secretary determines to be necessary so that, beginning in 1996, the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section that exceed the amount of such expenditures that would have been made if such amendment had not been made, and

(ii) shall reduce the amounts determined under subsection (a)(2)(B)(ii)(I) of this section by such percentage as the Secretary determines to be required to assure that, taking into account the reductions made under clause (i), the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section in 1994 that exceed the amount of such expenditures that would have been made if such amendment had not been made.

(G) Adjustments in relative value units for 1998

(i) In general

The Secretary shall—

(I) subject to clauses (iv) and (v), reduce the practice expense relative value units applied to any services described in clause (ii) furnished in 1998 to a number equal to 110 percent of the number of work relative value units, and

(II) increase the practice expense relative value units for office visit procedure codes during 1998 by a uniform percentage which the Secretary estimates will result in an aggregate increase in payments for such services equal to the aggregate decrease in payments by reason of subclause (I).

(ii) Services covered

For purposes of clause (i), the services described in this clause are physicians' services that are not described in clause (iii) and for which—

(I) there are work relative value units, and

(II) the number of practice expense relative value units (determined for 1998) exceeds 110 percent of the number of work relative value units (determined for such year).

(iii) Excluded services

For purposes of clause (ii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this subchapter in an office setting.

(iv) Limitation on aggregate reallocation

If the application of clause (i)(I) would result in an aggregate amount of reductions under such clause in excess of $390,000,000, such clause shall be applied by substituting for 110 percent such greater percentage as the Secretary estimates will result in the aggregate amount of such reductions equaling $390,000,000.

(v) No reduction for certain services

Practice expense relative value units for a procedure performed in an office or in a setting out of an office shall not be reduced under clause (i) if the in-office or out-of-office practice expense relative value, respectively, for the procedure would increase under the proposed rule on resource-based practice expenses issued by the Secretary on June 18, 1997 (62 Federal Register 33158 et seq.).

(H) Adjustments in practice expense relative value units for certain drug administration services beginning in 2004

(i) Use of survey data

In establishing the physician fee schedule under subsection (b) of this section with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey—

(I) covers practice expenses for oncology drug administration services; and

(II) meets criteria established by the Secretary for acceptance of such surveys.

(ii) Pricing of clinical oncology nurses in practice expense methodology

If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c) of this section.

(iii) Work relative value units for certain drug administration services

In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

(iv) Drug administration services described

The drug administration services described in this clause are physicians' services—

(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

(II) for which there are no work relative value units assigned under this subsection as of such date; and

(III) for which national relative value units have been assigned under this subsection as of such date.

(I) Adjustments in practice expense relative value units for certain drug administration services beginning with 2005

(i) In general

In establishing the physician fee schedule under subsection (b) of this section with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

(ii) Use of supplemental survey data

(I) In general

Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1395u(*o*) of this title, the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(II) Limitation on specialty

Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this subchapter in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

(III) Application

This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

(J) Provisions for appropriate reporting and billing for physicians' services associated with the administration of covered outpatient drugs and biologicals

(i) Evaluation of codes

The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

(ii) Use of existing processes

In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

(iii) Implementation

In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1395w–3a of this title or section 1395w–3b of this title, and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

(iv) Subsequent, budget neutral adjustments permitted

Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.

(K) Potentially misvalued codes

(i) In general

The Secretary shall—

(I) periodically identify services as being potentially misvalued using criteria specified in clause (ii); and

(II) review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued under subclause (I).

(ii) Identification of potentially misvalued codes

For purposes of identifying potentially misvalued codes pursuant to clause (i)(I), the Secretary shall examine codes (and families of codes as appropriate) based on any or all of the following criteria:

(I) Codes that have experienced the fastest growth.

(II) Codes that have experienced substantial changes in practice expenses.

(III) Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.

(IV) Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.

(V) Codes with low relative values, particularly those that are often billed multiple times for a single treatment.

(VI) Codes that have not been subject to review since implementation of the fee schedule.

(VII) Codes that account for the majority of spending under the physician fee schedule.

(VIII) Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.

(IX) Codes for which there may be a change in the typical site of service since the code was last valued.

(X) Codes for which there is a significant difference in payment for the same service between different sites of service.

(XI) Codes for which there may be anomalies in relative values within a family of codes.

(XII) Codes for services where there may be efficiencies when a service is furnished at the same time as other services.

(XIII) Codes with high intra-service work per unit of time.

(XIV) Codes with high practice expense relative value units.

(XV) Codes with high cost supplies.

(XVI) Codes as determined appropriate by the Secretary.

(iii) Review and adjustments

(I) The Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services described in clause (i)(II).

(II) The Secretary may conduct surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment described in clause (i)(II).

(III) The Secretary may use analytic contractors to identify and analyze services identified under clause (i)(I), conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of services described in clause (i)(II).

(IV) The Secretary may coordinate the review and appropriate adjustment described in clause (i)(II) with the periodic review described in subparagraph (B).

(V) As part of the review and adjustment described in clause (i)(II), including with respect to codes with low relative values described in clause (ii), the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the fee schedule under subsection (b).

(VI) The provisions of subparagraph (B)(ii)(II) and paragraph (7) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(I).

(iv) Treatment of certain radiation therapy services

Radiation treatment delivery and related imaging services identified under subsection (b)(11) shall not be considered as potentially misvalued services for purposes of this subparagraph and subparagraph (O) for 2017 and 2018.

(L) Validating relative value units

(i) In general

The Secretary shall establish a process to validate relative value units under the fee schedule under subsection (b).

(ii) Components and elements of work

The process described in clause (i) may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work.

(iii) Scope of codes

The validation of work relative value units shall include a sampling of codes for services that is the same as the codes listed under subparagraph (K)(ii).

(iv) Methods

The Secretary may conduct the validation under this subparagraph using methods described in subclauses (I) through (V) of subparagraph (K)(iii) as the Secretary determines to be appropriate.

(v) Adjustments

The Secretary shall make appropriate adjustments to the work relative value units under the fee schedule under subsection (b). The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

(M) Authority to collect and use information on physicians' services in the determination of relative values

(i) Collection of information

Notwithstanding any other provision of law, the Secretary may collect or obtain information on the resources directly or indirectly related to furnishing services for which payment is made under the fee schedule established under subsection (b). Such information may be collected or obtained from any eligible professional or any other source.

(ii) Use of information

Notwithstanding any other provision of law, subject to clause (v), the Secretary may (as the Secretary determines appropriate) use information collected or obtained pursuant to clause (i) in the determination of relative values for services under this section.

(iii) Types of information

The types of information described in clauses (i) and (ii) may, at the Secretary's discretion, include any or all of the following:

(I) Time involved in furnishing services.

(II) Amounts and types of practice expense inputs involved with furnishing services.

(III) Prices (net of any discounts) for practice expense inputs, which may include paid invoice prices or other documentation or records.

(IV) Overhead and accounting information for practices of physicians and other suppliers.

(V) Any other element that would improve the valuation of services under this section.

(iv) Information collection mechanisms

Information may be collected or obtained pursuant to this subparagraph from any or all of the following:

(I) Surveys of physicians, other suppliers, providers of services, manufacturers, and vendors.

(II) Surgical logs, billing systems, or other practice or facility records.

(III) Electronic health records.

(IV) Any other mechanism determined appropriate by the Secretary.

(v) Transparency of use of information

(I) In general

Subject to subclauses (II) and (III), if the Secretary uses information collected or obtained under this subparagraph in the determination of relative values under this subsection, the Secretary shall disclose the information source and discuss the use of such information in such determination of relative values through notice and comment rulemaking.

(II) Thresholds for use

The Secretary may establish thresholds in order to use such information, including the exclusion of information collected or obtained from eligible professionals who use very high resources (as determined by the Secretary) in furnishing a service.

(III) Disclosure of information

The Secretary shall make aggregate information available under this subparagraph but shall not disclose information in a form or manner that identifies an eligible professional or a group practice, or information collected or obtained pursuant to a nondisclosure agreement.

(vi) Incentive to participate

The Secretary may provide for such payments under this part to an eligible professional that submits such solicited information under this subparagraph as the Secretary determines appropriate in order to compensate such eligible professional for such submission. Such payments shall be provided in a form and manner specified by the Secretary.

(vii) Administration

Chapter 35 of title 44 shall not apply to information collected or obtained under this subparagraph.

(viii) Definition of eligible professional

In this subparagraph, the term ''eligible professional'' has the meaning given such term in subsection (k)(3)(B).

(ix) Funding

For purposes of carrying out this subparagraph, in addition to funds otherwise appropriated, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $2,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each fiscal year beginning with fiscal year 2014. Amounts transferred under the preceding sentence for a fiscal year shall be available until expended.

(N) Authority for alternative approaches to establishing practice expense relative values

The Secretary may establish or adjust practice expense relative values under this subsection using cost, charge, or other data from suppliers or providers of services, including information collected or obtained under subparagraph (M).

(O) Target for relative value adjustments for misvalued services

With respect to fee schedules established for each of 2016 through 2018, the following shall apply:

(i) Determination of net reduction in expenditures

For each year, the Secretary shall determine the estimated net reduction in expenditures under the fee schedule under this section with respect to the year as a result of adjustments to the relative values established under this paragraph for misvalued codes.

(ii) Budget neutral redistribution of funds if target met and counting overages towards the target for the succeeding year

If the estimated net reduction in expenditures determined under clause (i) for the year is equal to or greater than the target for the year—

(I) reduced expenditures attributable to such adjustments shall be redistributed for the year in a budget neutral manner in accordance with subparagraph (B)(ii)(II); and

(II) the amount by which such reduced expenditures exceeds the target for the year shall be treated as a reduction in expenditures described in clause (i) for the succeeding year, for purposes of determining whether the target has or has not been met under this subparagraph with respect to that year.

(iii) Exemption from budget neutrality if target not met

If the estimated net reduction in expenditures determined under clause (i) for the year is less than the target for the year, reduced expenditures in an amount equal to the target recapture amount shall not be taken into account in applying subparagraph (B)(ii)(II) with respect to fee schedules beginning with 2016.

(iv) Target recapture amount

For purposes of clause (iii), the target recapture amount is, with respect to a year, an amount equal to the difference between—

(I) the target for the year; and

(II) the estimated net reduction in expenditures determined under clause (i) for the year.

(v) Target

For purposes of this subparagraph, with respect to a year, the target is calculated as 0.5 percent (or, for 2016, 1.0 percent) of the estimated amount of expenditures under the fee schedule under this section for the year.

(3) Component percentages

For purposes of paragraph (2), the Secretary shall determine a work percentage, a practice

expense percentage, and a malpractice percentage for each physician's service as follows:

(A) Division of services by specialty

For each physician's service or class of physicians' services, the Secretary shall determine the average percentage of each such service or class of services that is performed, nationwide, under this part by physicians in each of the different physician specialties (as identified by the Secretary).

(B) Division of specialty by component

The Secretary shall determine the average percentage division of resources, among the work component, the practice expense component, and the malpractice component, used by physicians in each of such specialties in furnishing physicians' services. Such percentages shall be based on national data that describe the elements of physician practice costs and revenues, by physician specialty. The Secretary may use extrapolation and other techniques to determine practice costs and revenues for specialties for which adequate data are not available.

(C) Determination of component percentages

(i) Work percentage

The work percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the work component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(ii) Practice expense percentage

For years before 2002, the practice expense percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the practice expense component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(iii) Malpractice percentage

For years before 1999, the malpractice percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the malpractice component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(D) Periodic recomputation

The Secretary may, from time to time, provide for the recomputation of work percentages, practice expense percentages, and malpractice percentages determined under this paragraph.

(4) Ancillary policies

The Secretary may establish ancillary policies (with respect to the use of modifiers, local codes, and other matters) as may be necessary to implement this section.

(5) Coding

The Secretary shall establish a uniform procedure coding system for the coding of all physicians' services. The Secretary shall provide for an appropriate coding structure for visits and consultations. The Secretary may incorporate the use of time in the coding for visits and consultations. The Secretary, in establishing such coding system, shall consult with the Physician Payment Review Commission and other organizations representing physicians.

(6) No variation for specialists

The Secretary may not vary the conversion factor or the number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.

(7) Phase-in of significant relative value unit (RVU) reductions

Effective for fee schedules established beginning with 2016, for services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2-year period.

(8) Global surgical packages

(A) Prohibition of implementation of rule regarding global surgical packages

(i) In general

The Secretary shall not implement the policy established in the final rule published on November 13, 2014 (79 Fed. Reg. 67548 et seq.), that requires the transition of all 10-day and 90-day global surgery packages to 0-day global periods.

(ii) Construction

Nothing in clause (i) shall be construed to prevent the Secretary from revaluing misvalued codes for specific surgical services or assigning values to new or revised codes for surgical services.

(B) Collection of data on services included in global surgical packages

(i) In general

Subject to clause (ii), the Secretary shall through rulemaking develop and implement a process to gather, from a representative sample of physicians, beginning not later than January 1, 2017, information needed to value surgical services. Such information shall include the number and level of medical visits furnished dur-

ing the global period and other items and services related to the surgery and furnished during the global period, as appropriate. Such information shall be reported on claims at the end of the global period or in another manner specified by the Secretary. For purposes of carrying out this paragraph (other than clause (iii)), the Secretary shall transfer from the Federal Supplemental Medical Insurance Trust Fund under section 1395t of this title $2,000,000 to the Center for Medicare & Medicaid Services Program Management Account for fiscal year 2015. Amounts transferred under the previous sentence shall remain available until expended.

(ii) Reassessment and potential sunset

Every 4 years, the Secretary shall reassess the value of the information collected pursuant to clause (i). Based on such a reassessment and by regulation, the Secretary may discontinue the requirement for collection of information under such clause if the Secretary determines that the Secretary has adequate information from other sources, such as qualified clinical data registries, surgical logs, billing systems or other practice or facility records, and electronic health records, in order to accurately value global surgical services under this section.

(iii) Inspector general audit

The Inspector General of the Department of Health and Human Services shall audit a sample of the information reported under clause (i) to verify the accuracy of the information so reported.

(C) Improving accuracy of pricing for surgical services

For years beginning with 2019, the Secretary shall use the information reported under subparagraph (B)(i) as appropriate and other available data for the purpose of improving the accuracy of valuation of surgical services under the physician fee schedule under this section.

(d) Conversion factors

(1) Establishment

(A) In general

The conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001 and ending with 2025, multiplied by the update (established under paragraph (4) or a subsequent paragraph) for the year involved. There shall be two separate conversion factors for each year beginning with 2026, one for items and services furnished by a qualifying APM participant (as defined in section 1395*l*(z)(2)[2] of this title) (referred to in this subsection as the ''qualifying APM conversion factor'') and the other for other items and services (referred to in this subsection as the ''nonqualifying APM conversion factor''), equal to the respective conversion factor for the previous year (or, in the case of 2026, equal to the single conversion factor for 2025) multiplied by the update established under paragraph (20) for such respective conversion factor for such year.

(B) Special provision for 1992

For purposes of subparagraph (A), the conversion factor specified in this subparagraph is a conversion factor (determined by the Secretary) which, if this section were to apply during 1991 using such conversion factor, would result in the same aggregate amount of payments under this part for physicians' services as the estimated aggregate amount of the payments under this part for such services in 1991.

(C) Special rules for 1998

Except as provided in subparagraph (D), the single conversion factor for 1998 under this subsection shall be the conversion factor for primary care services for 1997, increased by the Secretary's estimate of the weighted average of the three separate updates that would otherwise occur were it not for the enactment of chapter 1 of subtitle F of title IV of the Balanced Budget Act of 1997.

(D) Special rules for anesthesia services

The separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor (or, beginning with 2026, applicable conversion factor) established for other physicians' services, except as adjusted for changes in work, practice expense, or malpractice relative value units.

(E) Publication and dissemination of information

The Secretary shall—

(i) cause to have published in the Federal Register not later than November 1 of each year (beginning with 2000) the conversion factor which will apply to physicians' services for the succeeding year, the update determined under paragraph (4) for such succeeding year, and the allowed expenditures under such paragraph for such succeeding year; and

(ii) make available to the Medicare Payment Advisory Commission and the public by March 1 of each year (beginning with 2000) an estimate of the sustainable growth rate and of the conversion factor which will apply to physicians' services for the succeeding year and data used in making such estimate.

(2) Repealed. Pub. L. 105–33, title IV, § 4502(b), Aug. 5, 1997, 111 Stat. 433

(3) Update for 1999 and 2000

(A) In general

Unless otherwise provided by law, subject to subparagraph (D) and the budget-neutrality factor determined by the Secretary

[2] See References in Text note below.

under subsection (c)(2)(B)(ii) of this section, the update to the single conversion factor established in paragraph (1)(C) for 1999 and 2000 is equal to the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year (divided by 100), and

(ii) 1 plus the Secretary's estimate of the update adjustment factor for the year (divided by 100),

minus 1 and multiplied by 100.

(B) Update adjustment factor

For purposes of subparagraph (A)(ii), the ''update adjustment factor'' for a year is equal (as estimated by the Secretary) to—

(i) the difference between (I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by

(ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) of this section for the fiscal year which begins during such 12-month period.

(C) Determination of allowed expenditures

For purposes of this paragraph and paragraph (4), the allowed expenditures for physicians' services for the 12-month period ending with March 31 of—

(i) 1997 is equal to the actual expenditures for physicians' services furnished during such 12-month period, as estimated by the Secretary; or

(ii) a subsequent year is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) of this section for the fiscal year which begins during such 12-month period.

(D) Restriction on variation from medicare economic index

Notwithstanding the amount of the update adjustment factor determined under subparagraph (B) for a year, the update in the conversion factor under this paragraph for the year may not be—

(i) greater than 100 times the following amount: (1.03 + (MEI percentage/100)) − 1; or

(ii) less than 100 times the following amount: (0.93 + (MEI percentage/100)) − 1,

where ''MEI percentage'' means the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved.

(4) Update for years beginning with 2001 and ending with 2014

(A) In general

Unless otherwise provided by law, subject to the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii) of this section and subject to adjustment under subparagraph (F), the update to the single conversion factor established in paragraph (1)(C) for a year beginning with 2001 and ending with 2014 is equal to the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under subparagraph (B) for the year.

(B) Update adjustment factor

For purposes of subparagraph (A)(ii), subject to subparagraph (D) and the succeeding paragraphs of this subsection, the ''update adjustment factor'' for a year is equal (as estimated by the Secretary) to the sum of the following:

(i) Prior year adjustment component

An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (as determined under subparagraph (C)) and the amount of the actual expenditures for such services for that year;

(II) dividing that difference by the amount of the actual expenditures for such services for that year; and

(III) multiplying that quotient by 0.75.

(ii) Cumulative adjustment component

An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services (as determined under subparagraph (C)) from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for such services during that period;

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable growth rate under subsection (f) of this section for the year for which the update adjustment factor is to be determined; and

(III) multiplying that quotient by 0.33.

(C) Determination of allowed expenditures

For purposes of this paragraph:

(i) Period up to April 1, 1999

The allowed expenditures for physicians' services for a period before April 1, 1999, shall be the amount of the allowed expenditures for such period as determined under paragraph (3)(C).

(ii) Transition to calendar year allowed expenditures

Subject to subparagraph (E), the allowed expenditures for—

(I) the 9-month period beginning April 1, 1999, shall be the Secretary's estimate

of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such period; and

(II) the year of 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such year.

(iii) Years beginning with 2000

The allowed expenditures for a year (beginning with 2000) is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) of this section for the year involved.

(D) Restriction on update adjustment factor

The update adjustment factor determined under subparagraph (B) for a year may not be less than −0.07 or greater than 0.03.

(E) Recalculation of allowed expenditures for updates beginning with 2001

For purposes of determining the update adjustment factor for a year beginning with 2001, the Secretary shall recompute the allowed expenditures for previous periods beginning on or after April 1, 1999, consistent with subsection (f)(3) of this section.

(F) Transitional adjustment designed to provide for budget neutrality

Under this subparagraph the Secretary shall provide for an adjustment to the update under subparagraph (A)—

(i) for each of 2001, 2002, 2003, and 2004, of −0.2 percent; and

(ii) for 2005 of +0.8 percent.

(5) Update for 2004 and 2005

The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.

(6) Update for 2006

The update to the single conversion factor established in paragraph (1)(C) for 2006 shall be 0 percent.

(7) Conversion factor for 2007

(A) In general

The conversion factor that would otherwise be applicable under this subsection for 2007 shall be the amount of such conversion factor divided by the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for 2007 (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under paragraph (4)(B) for 2007.

(B) No effect on computation of conversion factor for 2008

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2008 as if subparagraph (A) had never applied.

(8) Update for 2008

(A) In general

Subject to paragraph (7)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2008, the update to the single conversion factor shall be 0.5 percent.

(B) No effect on computation of conversion factor for 2009

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2009 and subsequent years as if subparagraph (A) had never applied.

(9) Update for 2009

(A) In general

Subject to paragraphs (7)(B) and (8)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2009, the update to the single conversion factor shall be 1.1 percent.

(B) No effect on computation of conversion factor for 2010 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2010 and subsequent years as if subparagraph (A) had never applied.

(10) Update for January through May of 2010

(A) In general

Subject to paragraphs (7)(B), (8)(B), and (9)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on January 1, 2010, and ending on May 31, 2010, the update to the single conversion factor shall be 0 percent for 2010.

(B) No effect on computation of conversion factor for remaining portion of 2010 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for the period beginning on June 1, 2010, and ending on December 31, 2010, and for 2011 and subsequent years as if subparagraph (A) had never applied.

(11) Update for June through December of 2010

(A) In general

Subject to paragraphs (7)(B), (8)(B), (9)(B), and (10)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on June 1, 2010, and ending on December 31, 2010, the update to the single conversion factor shall be 2.2 percent.

(B) No effect on computation of conversion factor for 2011 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2011 and subsequent years as if subparagraph (A) had never applied.

(12) Update for 2011

(A) In general

Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), and (11)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2011, the update to the single conversion factor shall be 0 percent.

(B) No effect on computation of conversion factor for 2012 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2012 and subsequent years as if subparagraph (A) had never applied.

(13) Update for 2012

(A) In general

Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), and (12)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2012, the update to the single conversion factor shall be zero percent.

(B) No effect on computation of conversion factor for 2013 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2013 and subsequent years as if subparagraph (A) had never applied.

(14) Update for 2013

(A) In general

Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), and (13)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2013, the update to the single conversion factor for such year shall be zero percent.

(B) No effect on computation of conversion factor for 2014 and subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2014 and subsequent years as if subparagraph (A) had never applied.

(15) Update for 2014

(A) In general

Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), (13)(B), and (14)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2014, the update to the single conversion factor shall be 0.5 percent.

(B) No effect on computation of conversion factor for subsequent years

The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2015 and subsequent years as if subparagraph (A) had never applied.

(16) Update for January through June of 2015

Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), (11)(B), (12)(B), (13)(B), (14)(B), and (15)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2015 for the period beginning on January 1, 2015, and ending on June 30, 2015, the update to the single conversion factor shall be 0.0 percent.

(17) Update for July through December of 2015

The update to the single conversion factor established in paragraph (1)(C) for the period beginning on July 1, 2015, and ending on December 31, 2015, shall be 0.5 percent.

(18) Update for 2016 through 2019

The update to the single conversion factor established in paragraph (1)(C) for 2016 and each subsequent year through 2019 shall be 0.5 percent.

(19) Update for 2020 through 2025

The update to the single conversion factor established in paragraph (1)(C) for 2020 and each subsequent year through 2025 shall be 0.0 percent.

(20) Update for 2026 and subsequent years

For 2026 and each subsequent year, the update to the qualifying APM conversion factor established under paragraph (1)(A) is 0.75 percent, and the update to the nonqualifying APM conversion factor established under such paragraph is 0.25 percent.

(e) Geographic adjustment factors

(1) Establishment of geographic indices

(A) In general

Subject to subparagraphs (B), (C), (E), (G), (H), and (I), the Secretary shall establish—

(i) an index which reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in the different fee schedule areas compared to the national average of such costs,

(ii) an index which reflects the relative costs of malpractice expenses in the different fee schedule areas compared to the national average of such costs, and

(iii) an index which reflects ¼ of the difference between the relative value of physicians' work effort in each of the different fee schedule areas and the national average of such work effort.

(B) Class-specific geographic cost-of-practice indices

The Secretary may establish more than one index under subparagraph (A)(i) in the case of classes of physicians' services, if, because of differences in the mix of goods and services comprising practice expenses for the different classes of services, the application of a single index under such clause to different classes of such services would be substantially inequitable.

(C) Periodic review and adjustments in geographic adjustment factors

The Secretary, not less often than every 3 years, shall, in consultation with appropriate representatives of physicians, review the indices established under subparagraph (A) and the geographic index values applied under this subsection for all fee schedule areas. Based on such review, the Secretary may revise such index and adjust such index values, except that, if more than 1 year has elasped[3] since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.

[3] So in original. Probably should be ''elapsed''.

(D) Use of recent data

In establishing indices and index values under this paragraph, the Secretary shall use the most recent data available relating to practice expenses, malpractice expenses, and physician work effort in different fee schedule areas.

(E) Floor at 1.0 on work geographic index

After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2018, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

(G)[4] Floor for practice expense, malpractice, and work geographic indices for services furnished in Alaska

For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67. For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5[1]

(H) Practice expense geographic adjustment for 2010 and subsequent years

(i) For 2010

Subject to clause (iii), for services furnished during 2010, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(ii) For 2011

Subject to clause (iii), for services furnished during 2011, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(iii) Hold harmless

The practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011 shall not, as a result of the application of clause (i) or (ii), be reduced below the practice expense portion of the geographic adjustment factor under subparagraph (A)(i) (as calculated prior to the application of such clause (i) or (ii), respectively) for such area for such year.

(iv) Analysis

The Secretary shall analyze current methods of establishing practice expense geographic adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the costs of operating a medical practice in the different fee schedule areas. Such analysis shall include an evaluation of the following:

(I) The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.

(II) The office expense portion of the practice expense geographic adjustment described in subparagraph (A)(i), including the extent to which types of office expenses are determined in local markets instead of national markets.

(III) The weights assigned to each of the categories within the practice expense geographic adjustment described in subparagraph (A)(i).

(v) Revision for 2012 and subsequent years

As a result of the analysis described in clause (iv), the Secretary shall, not later than January 1, 2012, make appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—

(I) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and

(II) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments.

Such adjustments shall be made without regard to adjustments made pursuant to clauses (i) and (ii) and shall be made in a budget neutral manner.

(I) Floor for practice expense index for services furnished in frontier States

(i) In general

Subject to clause (ii), for purposes of payment for services furnished in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) on or after January 1, 2011, after calculating the practice expense index in subparagraph (A)(i), the Secretary shall increase any such index to 1.00 if such index would otherwise be less that[5] 1.00. The preceding sentence shall not be applied in a budget neutral manner.

[4] So in original. No subpar. (F) has been enacted.

[5] So in original. Probably should be ''than''.

(ii) Limitation

This subparagraph shall not apply to services furnished in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(2) Computation of geographic adjustment factor

For purposes of subsection (b)(1)(C) of this section, for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) Geographic cost-of-practice adjustment factor

For purposes of paragraph (2), the ''geographic cost-of-practice adjustment factor'', for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) Geographic malpractice adjustment factor

For purposes of paragraph (2), the ''geographic malpractice adjustment factor'', for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) Geographic physician work adjustment factor

For purposes of paragraph (2), the ''geographic physician work adjustment factor'', for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(6) Use of MSAs as fee schedule areas in California

(A) In general

Subject to the succeeding provisions of this paragraph and notwithstanding the previous provisions of this subsection, for services furnished on or after January 1, 2017, the fee schedule areas used for payment under this section applicable to California shall be the following:

(i) Each Metropolitan Statistical Area (each in this paragraph referred to as an ''MSA''), as defined by the Director of the Office of Management and Budget as of December 31 of the previous year, shall be a fee schedule area.

(ii) All areas not included in an MSA shall be treated as a single rest-of-State fee schedule area.

(B) Transition for MSAs previously in rest-of-state payment locality or in locality 3

(i) In general

For services furnished in California during a year beginning with 2017 and ending with 2021 in an MSA in a transition area (as defined in subparagraph (D)), subject to subparagraph (C), the geographic index values to be applied under this subsection for such year shall be equal to the sum of the following:

(I) Current law component

The old weighting factor (described in clause (ii)) for such year multiplied by the geographic index values under this subsection for the fee schedule area that included such MSA that would have applied in such area (as estimated by the Secretary) if this paragraph did not apply.

(II) MSA-based component

The MSA-based weighting factor (described in clause (iii)) for such year multiplied by the geographic index values computed for the fee schedule area under subparagraph (A) for the year (determined without regard to this subparagraph).

(ii) Old weighting factor

The old weighting factor described in this clause—

(I) for 2017, is 5⁄6; and

(II) for each succeeding year, is the old weighting factor described in this clause for the previous year minus 1⁄6.

(iii) MSA-based weighting factor

The MSA-based weighting factor described in this clause for a year is 1 minus the old weighting factor under clause (ii) for that year.

(C) Hold harmless

For services furnished in a transition area in California during a year beginning with 2017, the geographic index values to be applied under this subsection for such year shall not be less than the corresponding geographic index values that would have applied in such transition area (as estimated by the Secretary) if this paragraph did not apply.

(D) Transition area defined

In this paragraph, the term ''transition area'' means each of the following fee schedule areas for 2013:

(i) The rest-of-State payment locality.

(ii) Payment locality 3.

(E) References to fee schedule areas

Effective for services furnished on or after January 1, 2017, for California, any reference

in this section to a fee schedule area shall be deemed a reference to a fee schedule area established in accordance with this paragraph.

(f) Sustainable growth rate

(1) Publication

The Secretary shall cause to have published in the Federal Register not later than—

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; and

(B) November 1 of each succeeding year through 2014 the sustainable growth rate for such succeeding year and each of the preceding 2 years.

(2) Specification of growth rate

The sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 and ending with 2014 shall be equal to the product of—

(A) 1 plus the Secretary's estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians' services in the applicable period involved,

(B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous applicable period to the applicable period involved,

(C) 1 plus the Secretary's estimate of the annual average percentage growth in real gross domestic product per capita (divided by 100) during the 10-year period ending with the applicable period involved, and

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) or (d)(4)(B) of this section, as the case may be,

minus 1 and multiplied by 100.

(3) Data to be used

For purposes of determining the update adjustment factor under subsection (d)(4)(B) of this section for a year beginning with 2001, the sustainable growth rates taken into consideration in the determination under paragraph (2) shall be determined as follows:

(A) For 2001

For purposes of such calculations for 2001, the sustainable growth rates for fiscal year 2000 and the years 2000 and 2001 shall be determined on the basis of the best data available to the Secretary as of September 1, 2000.

(B) For 2002

For purposes of such calculations for 2002, the sustainable growth rates for fiscal year 2000 and for years 2000, 2001, and 2002 shall be determined on the basis of the best data available to the Secretary as of September 1, 2001.

(C) For 2003 and succeeding years

For purposes of such calculations for a year after 2002—

(i) the sustainable growth rates for that year and the preceding 2 years shall be determined on the basis of the best data available to the Secretary as of September 1 of the year preceding the year for which the calculation is made; and

(ii) the sustainable growth rate for any year before a year described in clause (i) shall be the rate as most recently determined for that year under this subsection.

Nothing in this paragraph shall be construed as affecting the sustainable growth rates established for fiscal year 1998 or fiscal year 1999.

(4) Definitions

In this subsection:

(A) Services included in physicians' services

The term ''physicians' services'' includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee.

(B) Medicare+Choice plan enrollee

The term ''Medicare+Choice plan enrollee'' means, with respect to a fiscal year, an individual enrolled under this part who has elected to receive benefits under this subchapter for the fiscal year through a Medicare+Choice plan offered under part C of this subchapter, and also includes an individual who is receiving benefits under this part through enrollment with an eligible organization with a risk-sharing contract under section 1395mm of this title.

(C) Applicable period

The term ''applicable period'' means—

(i) a fiscal year, in the case of fiscal year 1998, fiscal year 1999, and fiscal year 2000; or

(ii) a calendar year with respect to a year beginning with 2000;

as the case may be.

(g) Limitation on beneficiary liability

(1) Limitation on actual charges

(A) In general

In the case of a nonparticipating physician or nonparticipating supplier or other person (as defined in section 1395u(i)(2) of this title) who does not accept payment on an assignment-related basis for a physician's service furnished with respect to an individual enrolled under this part, the following rules apply:

(i) Application of limiting charge

No person may bill or collect an actual charge for the service in excess of the limiting charge described in paragraph (2) for such service.

(ii) No liability for excess charges

No person is liable for payment of any amounts billed for the service in excess of such limiting charge.

(iii) Correction of excess charges

If such a physician, supplier, or other person bills, but does not collect, an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall reduce on a timely basis the actual charge billed for the service to an amount not to exceed the limiting charge for the service.

(iv) Refund of excess collections

If such a physician, supplier, or other person collects an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall provide on a timely basis a refund to the individual charged in the amount by which the amount collected exceeded the limiting charge for the service. The amount of such a refund shall be reduced to the extent the individual has an outstanding balance owed by the individual to the physician.

(B) Sanctions

If a physician, supplier, or other person—

(i) knowingly and willfully bills or collects for services in violation of subparagraph (A)(i) on a repeated basis, or

(ii) fails to comply with clause (iii) or (iv) of subparagraph (A) on a timely basis,

the Secretary may apply sanctions against the physician, supplier, or other person in accordance with paragraph (2) of section 1395u(j) of this title. In applying this subparagraph, paragraph (4) of such section applies in the same manner as such paragraph applies to such section and any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.

(C) Timely basis

For purposes of this paragraph, a correction of a bill for an excess charge or refund of an amount with respect to a violation of subparagraph (A)(i) in the case of a service is considered to be provided ''on a timely basis'', if the reduction or refund is made not later than 30 days after the date the physician, supplier, or other person is notified by the carrier under this part of such violation and of the requirements of subparagraph (A).

(2) "Limiting charge" defined

(A) For 1991

For physicians' services of a physician furnished during 1991, other than radiologist services subject to section 1395m(b) of this title, the ''limiting charge'' shall be the same percentage (or, if less, 25 percent) above the recognized payment amount under this part with respect to the physician (as a nonparticipating physician) as the percentage by which—

(i) the maximum allowable actual charge (as determined under section 1395u(j)(1)(C) of this title as of December 31, 1990, or, if less, the maximum actual charge otherwise permitted for the service under this part as of such date) for the service of the physician, exceeds

(ii) the recognized payment amount for the service of the physician (as a nonparticipating physician) as of such date.

In the case of evaluation and management services (as specified in section 1395u(b)(16)(B)(ii) of this title), the preceding sentence shall be applied by substituting ''40 percent'' for ''25 percent''.

(B) For 1992

For physicians' services furnished during 1992, other than radiologist services subject to section 1395m(b) of this title, the ''limiting charge'' shall be the same percentage (or, if less, 20 percent) above the recognized payment amount under this part for nonparticipating physicians as the percentage by which—

(i) the limiting charge (as determined under subparagraph (A) as of December 31, 1991) for the service, exceeds

(ii) the recognized payment amount for the service for nonparticipating physicians as of such date.

(C) After 1992

For physicians' services furnished in a year after 1992, the ''limiting charge'' shall be 115 percent of the recognized payment amount under this part for nonparticipating physicians or for nonparticipating suppliers or other persons.

(D) Recognized payment amount

In this section, the term ''recognized payment amount'' means, for services furnished on or after January 1, 1992, the fee schedule amount determined under subsection (a) of this section (or, if payment under this part is made on a basis other than the fee schedule under this section, 95 percent of the other payment basis), and, for services furnished during 1991, the applicable percentage (as defined in section 1395u(b)(4)(A)(iv) of this title) of the prevailing charge (or fee schedule amount) for nonparticipating physicians for that year.

(3) Limitation on charges for medicare beneficiaries eligible for medicaid benefits

(A) In general

Payment for physicians' services furnished on or after April 1, 1990, to an individual who is enrolled under this part and eligible for any medical assistance (including as a qualified medicare beneficiary, as defined in section 1396d(p)(1) of this title) with respect to such services under a State plan approved under subchapter XIX of this chapter may only be made on an assignment-related basis and the provisions of section 1396a(n)(3)(A) of this title apply to further limit permissible charges under this section.

(B) Penalty

A person may not bill for physicians' services subject to subparagraph (A) other than on an assignment-related basis. No person is

liable for payment of any amounts billed for such a service in violation of the previous sentence. If a person knowingly and willfully bills for physicians' services in violation of the first sentence, the Secretary may apply sanctions against the person in accordance with section 1395u(j)(2) of this title.

(4) Physician submission of claims

(A) In general

For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part on a reasonable charge or fee schedule basis, a physician, supplier, or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title)—

(i) shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and

(ii) may not impose any charge relating to completing and submitting such a form.

(B) Penalty

(i) With respect to an assigned claim wherever a physician, provider, supplier or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title) fails to submit such a claim as required in subparagraph (A), the Secretary shall reduce by 10 percent the amount that would otherwise be paid for such claim under this part.

(ii) If a physician, supplier, or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title) fails to submit a claim required to be submitted under subparagraph (A) or imposes a charge in violation of such subparagraph, the Secretary shall apply the sanction with respect to such a violation in the same manner as a sanction may be imposed under section 1395u(p)(3) of this title for a violation of section 1395u(p)(1) of this title.

(5) Electronic billing; direct deposit

The Secretary shall encourage and develop a system providing for expedited payment for claims submitted electronically. The Secretary shall also encourage and provide incentives allowing for direct deposit as payments for services furnished by participating physicians. The Secretary shall provide physicians with such technical information as necessary to enable such physicians to submit claims electronically. The Secretary shall submit a plan to Congress on this paragraph by May 1, 1990.

(6) Monitoring of charges

(A) In general

The Secretary shall monitor—

(i) the actual charges of nonparticipating physicians for physicians' services furnished on or after January 1, 1991, to individuals enrolled under this part, and

(ii) changes (by specialty, type of service, and geographic area) in (I) the proportion of expenditures for physicians' services provided under this part by participating physicians, (II) the proportion of expenditures for such services for which payment is made under this part on an assignment-related basis, and (III) the amounts charged above the recognized payment amounts under this part.

(B) Report

The Secretary shall, by not later than April 15 of each year (beginning in 1992), report to the Congress information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information regarding the changes described in subparagraph (A)(ii).

(C) Plan

If the Secretary finds that there has been a significant decrease in the proportions described in subclauses (I) and (II) of subparagraph (A)(ii) or an increase in the amounts described in subclause (III) of that subparagraph, the Secretary shall develop a plan to address such a problem and transmit to Congress recommendations regarding the plan. The Medicare Payment Advisory Commission shall review the Secretary's plan and recommendations and transmit to Congress its comments regarding such plan and recommendations.

(7) Monitoring of utilization and access

(A) In general

The Secretary shall monitor—

(i) changes in the utilization of and access to services furnished under this part within geographic, population, and service related categories,

(ii) possible sources of inappropriate utilization of services furnished under this part which contribute to the overall level of expenditures under this part, and

(iii) factors underlying these changes and their interrelationships.

(B) Report

The Secretary shall by not later than April 15,[6] of each year (beginning with 1991) report to the Congress on the changes described in subparagraph (A)(i) and shall include in the report an examination of the factors (including factors relating to different services and specific categories and groups of services and geographic and demographic variations in utilization) which may contribute to such changes.

(C) Recommendations

The Secretary shall include in each annual report under subparagraph (B) recommendations—

(i) addressing any identified patterns of inappropriate utilization,

(ii) on utilization review,

(iii) on physician education or patient education,

(iv) addressing any problems of beneficiary access to care made evident by the monitoring process, and

[6] So in original. The comma probably should not appear.

(v) on such other matters as the Secretary deems appropriate.

The Medicare Payment Advisory Commission shall comment on the Secretary's recommendations and in developing its comments, the Commission shall convene and consult a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care.

(h) Sending information to physicians

Before the beginning of each year (beginning with 1992), the Secretary shall send to each physician or nonparticipating supplier or other person furnishing physicians' services (as defined in subsection (j)(3) of this section) furnishing physicians' services under this part, for services commonly performed by the physician, supplier, or other person, information on fee schedule amounts that apply for the year in the fee schedule area for participating and non-participating physicians, and the maximum amount that may be charged consistent with subsection (g)(2) of this section. Such information shall be transmitted in conjunction with notices to physicians, suppliers, and other persons under section 1395u(h) of this title (relating to the participating physician program) for a year.

(i) Miscellaneous provisions

(1) Restriction on administrative and judicial review

There shall be no administrative or judicial review under section 1395ff of this title or otherwise of—

(A) the determination of the adjusted historical payment basis (as defined in subsection (a)(2)(D)(i) of this section),

(B) the determination of relative values and relative value units under subsection (c) of this section, including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993,

(C) the determination of conversion factors under subsection (d) of this section, including without limitation a prospective redetermination of the sustainable growth rates for any or all previous fiscal years,

(D) the establishment of geographic adjustment factors under subsection (e) of this section,

(E) the establishment of the system for the coding of physicians' services under this section, and

(F) the collection and use of information in the determination of relative values under subsection (c)(2)(M).

(2) Assistants-at-surgery

(A) In general

Subject to subparagraph (B), in the case of a surgical service furnished by a physician, if payment is made separately under this part for the services of a physician serving as an assistant-at-surgery, the fee schedule amount shall not exceed 16 percent of the fee schedule amount otherwise determined under this section for the global surgical service involved.

(B) Denial of payment in certain cases

If the Secretary determines, based on the most recent data available, that for a surgical procedure (or class of surgical procedures) the national average percentage of such procedure performed under this part which involve the use of a physician as an assistant at surgery is less than 5 percent, no payment may be made under this part for services of an assistant at surgery involved in the procedure.

(3) No comparability adjustment

For physicians' services for which payment under this part is determined under this section—

(A) a carrier may not make any adjustment in the payment amount under section 1395u(b)(3)(B) of this title on the basis that the payment amount is higher than the charge applicable, for comparable services and under comparable circumstances, to the policyholders and subscribers of the carrier,

(B) no payment adjustment may be made under section 1395u(b)(8) of this title, and

(C) section 1395u(b)(9) of this title shall not apply.

(j) Definitions

In this section:

(1) Category

For services furnished before January 1, 1998, the term ''category'' means, with respect to physicians' services, surgical services, and all physicians' services other than surgical services (as defined by the Secretary and including anesthesia services), primary care services (as defined in section 1395u(i)(4) of this title), and all other physicians' services. The Secretary shall define surgical services and publish such definition in the Federal Register no later than May 1, 1990, after consultation with organizations representing physicians.

(2) Fee schedule area

Except as provided in subsection (e)(6)(D), the term ''fee schedule area'' means a locality used under section 1395u(b) of this title for purposes of computing payment amounts for physicians' services.

(3) Physicians' services

The term ''physicians' services'' includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1395x(*oo*)(2) of this title), (2)(R) (with respect to services described in subparagraphs (B), (C), and (D) of section 1395x(pp)(1) of this title), (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE), (2)(FF) (including administration of the health risk assessment), (3), (4), (13), (14) (with respect to services described in section 1395x(nn)(2) of this title), and (15) of section 1395x(s) of this title (other than clinical diagnostic laboratory tests and, except for purposes of subsections (a)(3), (g), and (h) of this section[7] such other

[7] So in original. Probably should be followed by a comma.

items and services as the Secretary may specify).

(4) Practice expenses

The term ''practice expenses'' includes all expenses for furnishing physicians' services, excluding malpractice expenses, physician compensation, and other physician fringe benefits.

(k) Quality reporting system

(1) In general

The Secretary shall implement a system for the reporting by eligible professionals of data on quality measures specified under paragraph (2). Such data shall be submitted in a form and manner specified by the Secretary (by program instruction or otherwise), which may include submission of such data on claims under this part.

(2) Use of consensus-based quality measures

(A) For 2007

(i) In general

For purposes of applying this subsection for the reporting of data on quality measures for covered professional services furnished during the period beginning July 1, 2007, and ending December 31, 2007, the quality measures specified under this paragraph are the measures identified as 2007 physician quality measures under the Physician Voluntary Reporting Program as published on the public website of the Centers for Medicare & Medicaid Services as of December 20, 2006, except as may be changed by the Secretary based on the results of a consensus-based process in January of 2007, if such change is published on such website by not later than April 1, 2007.

(ii) Subsequent refinements in application permitted

The Secretary may, from time to time (but not later than July 1, 2007), publish on such website (without notice or opportunity for public comment) modifications or refinements (such as code additions, corrections, or revisions) for the application of quality measures previously published under clause (i), but may not, under this clause, change the quality measures under the reporting system.

(iii) Implementation

Notwithstanding any other provision of law, the Secretary may implement by program instruction or otherwise this subsection for 2007.

(B) For 2008 and 2009

(i) In general

For purposes of reporting data on quality measures for covered professional services furnished during 2008 and 2009, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of electronic health records and electronic prescribing technology.

(ii) Proposed set of measures

Not later than August 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable. The Secretary shall provide for a period of public comment on such set of measures.

(iii) Final set of measures

Not later than November 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a final set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable.

(C) For 2010 and subsequent years

(i) In general

Subject to clause (ii), for purposes of reporting data on quality measures for covered professional services furnished during 2010 and each subsequent year, subject to subsection (m)(3)(C), the quality measures (including electronic prescribing quality measures) specified under this paragraph shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title.

(ii) Exception

In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1395aaa(a) of this title, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance.

(D) Opportunity to provide input on measures for 2009 and subsequent years

For each quality measure (including an electronic prescribing quality measure) adopted by the Secretary under subparagraph (B) (with respect to 2009) or subparagraph (C), the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.

(3) Covered professional services and eligible professionals defined

For purposes of this subsection:

(A) Covered professional services

The term ''covered professional services'' means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.

(B) Eligible professional

The term ''eligible professional'' means any of the following:

(i) A physician.

(ii) A practitioner described in section 1395u(b)(18)(C) of this title.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) Beginning with 2009, a qualified audiologist (as defined in section 1395x(*ll*)(3)(B) of this title).

(4) Use of registry-based reporting

As part of the publication of proposed and final quality measures for 2008 under clauses (ii) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry (such as the Society of Thoracic Surgeons National Database) or through a Maintenance of Certification program operated by a specialty body of the American Board of Medical Specialties that meets the criteria for such a registry, as identified by the Secretary.

(5) Identification units

For purposes of applying this subsection, the Secretary may identify eligible professionals through billing units, which may include the use of the Provider Identification Number, the unique physician identification number (described in section 1395*l*(q)(1) of this title), the taxpayer identification number, or the National Provider Identifier. For purposes of applying this subsection for 2007, the Secretary shall use the taxpayer identification number as the billing unit.

(6) Education and outreach

The Secretary shall provide for education and outreach to eligible professionals on the operation of this subsection.

(7) Limitations on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of the development and implementation of the reporting system under paragraph (1), including identification of quality measures under paragraph (2) and the application of paragraphs (4) and (5).

(8) Implementation

The Secretary shall carry out this subsection acting through the Administrator of the Centers for Medicare & Medicaid Services.

(9) Continued application for purposes of MIPS and for certain professionals volunteering to report

The Secretary shall, in accordance with subsection (q)(1)(F), carry out the provisions of this subsection—

(A) for purposes of subsection (q); and

(B) for eligible professionals who are not MIPS eligible professionals (as defined in subsection (q)(1)(C)) for the year involved.

(*l*) Physician Assistance and Quality Initiative Fund

(1) Establishment

The Secretary shall establish under this subsection a Physician Assistance and Quality Initiative Fund (in this subsection referred to as the ''Fund'') which shall be available to the Secretary for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the conversion factor under subsection (d).

(2) Funding

(A) Amount available

(i) In general

Subject to clause (ii), there shall be available to the Fund the following amounts:

(I) For expenditures during 2008, an amount equal to $150,500,000.

(II) For expenditures during 2009, an amount equal to $24,500,000.

(ii) Limitations on expenditures

(I) 2008

The amount available for expenditures during 2008 shall be reduced as provided by subparagraph (A) of section 225(c)(1) and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008).

(II) 2009

The amount available for expenditures during 2009 shall be reduced as provided by subparagraph (B) of such section 225(c)(1).

(B) Timely obligation of all available funds for services

The Secretary shall provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire amount available for expenditures, after application of subparagraph (A)(ii), during—

(i) 2008 for payment with respect to physicians' services furnished during 2008; and

(ii) 2009 for payment with respect to physicians' services furnished during 2009.

(C) Payment from Trust Fund

The amount specified in subparagraph (A) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title.

(D) Funding limitation

Amounts in the Fund shall be available in advance of appropriations in accordance with subparagraph (B) but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under subparagraph (A). The Secretary may obligate funds from the Fund only if the

Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

(E) Construction

In the case that expenditures from the Fund are applied to, or otherwise affect, a conversion factor under subsection (d) for a year, the conversion factor under such subsection shall be computed for a subsequent year as if such application or effect had never occurred.

(m) Incentive payments for quality reporting

(1) Incentive payments

(A) In general

For 2007 through 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, if—

(i) there are any quality measures that have been established under the physician reporting system that are applicable to any such services furnished by such professional for such reporting period; and

(ii) the eligible professional satisfactorily submits (as determined under this subsection) to the Secretary data on such quality measures in accordance with such reporting system for such reporting period,

in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount equal to the applicable quality percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Applicable quality percent

For purposes of subparagraph (A), the term ''applicable quality percent'' means—

(i) for 2007 and 2008, 1.5 percent;

(ii) for 2009 and 2010, 2.0 percent;

(iii) for 2011, 1.0 percent; and

(iv) for 2012, 2013, and 2014, 0.5 percent.

(2) Incentive payments for electronic prescribing

(A) In general

Subject to subparagraph (D), for 2009 through 2013, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount equal to the applicable electronic prescribing percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Limitation with respect to electronic prescribing quality measures

The provisions of this paragraph and subsection (a)(5) shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year)—

(i) the allowed charges under this part for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing quality measure applies (as identified by the Secretary and published on the Internet website of the Centers for Medicare & Medicaid Services as of January 1, 2008, and as subsequently modified by the Secretary) are less than 10 percent of the total of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or the group, as applicable); or

(ii) if determined appropriate by the Secretary, the eligible professional does not submit (including both electronically and nonelectronically) a sufficient number (as determined by the Secretary) of prescriptions under part D.

If the Secretary makes the determination to apply clause (ii) for a period, then clause (i) shall not apply for such period.

(C) Applicable electronic prescribing percent

For purposes of subparagraph (A), the term ''applicable electronic prescribing percent'' means—

(i) for 2009 and 2010, 2.0 percent;

(ii) for 2011 and 2012, 1.0 percent; and

(iii) for 2013, 0.5 percent.

(D) Limitation with respect to EHR incentive payments

The provisions of this paragraph shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the EHR reporting period the eligible professional (or group practice) receives an incentive payment under subsection (*o*)(1)(A) with respect to a certified EHR technology (as defined in

subsection (*o*)(4)) that has the capability of electronic prescribing.

(3) Satisfactory reporting and successful electronic prescriber described

(A) In general

For purposes of paragraph (1), an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported as follows:

(i) Three or fewer quality measures applicable

If there are no more than 3 quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, each such quality measure has been reported under such system in at least 80 percent of the cases in which such measure is reportable under the system.

(ii) Four or more quality measures applicable

If there are 4 or more quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, at least 3 such quality measures have been reported under such system in at least 80 percent of the cases in which the respective measure is reportable under the system.

For years after 2008, quality measures for purposes of this subparagraph shall not include electronic prescribing quality measures.

(B) Successful electronic prescriber

(i) In general

For purposes of paragraph (2) and subsection (a)(5), an eligible professional shall be treated as a successful electronic prescriber for a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year) if the eligible professional meets the requirement described in clause (ii), or, if the Secretary determines appropriate, the requirement described in clause (iii). If the Secretary makes the determination under the preceding sentence to apply the requirement described in clause (iii) for a period, then the requirement described in clause (ii) shall not apply for such period.

(ii) Requirement for submitting data on electronic prescribing quality measures

The requirement described in this clause is that, with respect to covered professional services furnished by an eligible professional during a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year), if there are any electronic prescribing quality measures that have been established under the physician reporting system and are applicable to any such services furnished by such professional for the period, such professional reported each such measure under such system in at least 50 percent of the cases in which such measure is reportable by such professional under such system.

(iii) Requirement for electronically prescribing under part D

The requirement described in this clause is that the eligible professional electronically submitted a sufficient number (as determined by the Secretary) of prescriptions under part D during the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year).

(iv) Use of part D data

Notwithstanding sections 1395w–115(d)(2)(B) and 1395w–115(f)(2) of this title, the Secretary may use data regarding drug claims submitted for purposes of section 1395w–115 of this title that are necessary for purposes of clause (iii), paragraph (2)(B)(ii), and paragraph (5)(G).

(v) Standards for electronic prescribing

To the extent practicable, in determining whether eligible professionals meet the requirements under clauses (ii) and (iii) for purposes of clause (i), the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1395w–104(e) of this title.

(C) Satisfactory reporting measures for group practices

(i) In general

By January 1, 2010, the Secretary shall establish and have in place a process under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures under subparagraph (A) and as meeting the requirement described in subparagraph (B)(ii) for covered professional services for a reporting period (or, for purposes of subsection (a)(5), for a reporting period for a year), or, for purposes of subsection (a)(8), for a quality reporting period for the year if, in lieu of reporting measures under subsection (k)(2)(C), the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time, specified by the Secretary.

(ii) Statistical sampling model

The process under clause (i) shall provide and, for 2016 and subsequent years, may provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Physician Group Practice demonstration project under section 1395cc–1 of this title.

(iii) No double payments

Payments to a group practice under this subsection by reason of the process under

clause (i) shall be in lieu of the payments that would otherwise be made under this subsection to eligible professionals in the group practice for satisfactorily submitting data on quality measures.

(D) Satisfactory reporting measures through participation in a qualified clinical data registry

For 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures under subparagraph (A) and, for 2016 and subsequent years, subparagraph (A) or (C) if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as described in subparagraph (E)) for the year.

(E) Qualified clinical data registry

(i) In general

The Secretary shall establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection.

(ii) Considerations

In establishing the requirements under clause (i), the Secretary shall consider whether an entity—

(I) has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;

(II) requires the submission of data from participants with respect to multiple payers;

(III) provides timely performance reports to participants at the individual participant level; and

(IV) supports quality improvement initiatives for participants.

(iii) Measures

With respect to measures used by a qualified clinical data registry—

(I) sections 1395aaa(b)(7) and 1395aaa–1(a) of this title shall not apply; and

(II) measures endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title may be used.

(iv) Consultation

In carrying out this subparagraph, the Secretary shall consult with interested parties.

(v) Determination

The Secretary shall establish a process to determine whether or not an entity meets the requirements established under clause (i). Such process may involve one or both of the following:

(I) A determination by the Secretary.

(II) A designation by the Secretary of one or more independent organizations to make such determination.

(F) Authority to revise satisfactorily reporting data

For years after 2009, the Secretary, in consultation with stakeholders and experts, may revise the criteria under this subsection for satisfactorily submitting data on quality measures under subparagraph (A) and the criteria for submitting data on electronic prescribing quality measures under subparagraph (B)(ii).

(4) Form of payment

The payment under this subsection shall be in the form of a single consolidated payment.

(5) Application

(A) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) Coordination with other bonus payments

The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) of section 1395*l* of this title and any payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

(C) Implementation

Notwithstanding any other provision of law, for 2007, 2008, and 2009, the Secretary may implement by program instruction or otherwise this subsection.

(D) Validation

(i) In general

Subject to the succeeding provisions of this subparagraph, for purposes of determining whether a measure is applicable to the covered professional services of an eligible professional under this subsection for 2007 and 2008, the Secretary shall presume that if an eligible professional submits data for a measure, such measure is applicable to such professional.

(ii) Method

The Secretary may establish procedures to validate (by sampling or other means as the Secretary determines to be appropriate) whether measures applicable to covered professional services of an eligible professional have been reported.

(iii) Denial of payment authority

If the Secretary determines that an eligible professional (or, in the case of a group practice under paragraph (3)(C), the group practice) has not reported measures applicable to covered professional services of such professional, the Secretary shall not pay the incentive payment under this subsection. If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).

(E) Limitations on review

Except as provided in subparagraph (I), there shall be no administrative or judicial

review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of—

(i) the determination of measures applicable to services furnished by eligible professionals under this subsection;

(ii) the determination of satisfactory reporting under this subsection;

(iii) the determination of a successful electronic prescriber under paragraph (3), the limitation under paragraph (2)(B), and the exception under subsection (a)(5)(B); and

(iv) the determination of any incentive payment under this subsection and the payment adjustment under paragraphs (5)(A) and (8)(A) of subsection (a).

(F) Extension

For 2008 through reporting periods occurring in 2015, the Secretary shall establish and, for reporting periods occurring in 2016 and subsequent years, the Secretary may establish alternative criteria for satisfactorily reporting under this subsection and alternative reporting periods under paragraph (6)(C) for reporting groups of measures under subsection (k)(2)(B) and for reporting using the method specified in subsection (k)(4).

(G) Posting on website

The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the following:

(i) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who satisfactorily submitted data on quality measures under this subsection.

(ii) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who are successful electronic prescribers.

(H) Feedback

The Secretary shall provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under this subsection.

(I) Informal appeals process

The Secretary shall, by not later than January 1, 2011, establish and have in place an informal process for eligible professionals to seek a review of the determination that an eligible professional did not satisfactorily submit data on quality measures under this subsection.

(6) Definitions

For purposes of this subsection:

(A) Eligible professional; covered professional services

The terms ''eligible professional'' and ''covered professional services'' have the meanings given such terms in subsection (k)(3).

(B) Physician reporting system

The term ''physician reporting system'' means the system established under subsection (k).

(C) Reporting period

(i) In general

Subject to clauses (ii) and (iii), the term ''reporting period'' means—

(I) for 2007, the period beginning on July 1, 2007, and ending on December 31, 2007; and

(II) for 2008 and subsequent years, the entire year.

(ii) Authority to revise reporting period

For years after 2009, the Secretary may revise the reporting period under clause (i) if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing administrative burden. If the Secretary revises such period pursuant to the preceding sentence, the term ''reporting period'' shall mean such revised period.

(iii) Reference

Any reference in this subsection to a reporting period with respect to the application of subsection (a)(5) (a)(8)[8] shall be deemed a reference to the reporting period under subsection (a)(5)(D)(iii) or the quality reporting period under subsection (a)(8)(D)(iii),[9] respectively.

(7) Integration of physician quality reporting and EHR reporting

Not later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under this subsection with reporting requirements under subsection (*o*) relating to the meaningful use of electronic health records. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—

(i) meaningful use of an electronic health record for purposes of subsection (*o*); and

(ii) quality of care furnished to an individual.

(B) Such other activities as specified by the Secretary.

(8) Additional incentive payment

(A) In general

For 2011 through 2014, if an eligible professional meets the requirements described in subparagraph (B), the applicable quality percent for such year, as described in clauses (iii) and (iv) of paragraph (1)(B), shall be increased by 0.5 percentage points.

(B) Requirements described

In order to qualify for the additional incentive payment described in subparagraph (A), an eligible professional shall meet the following requirements:

(i) The eligible professional shall—

(I) satisfactorily submit data on quality measures for purposes of paragraph (1) for a year; and

[8] So in original.

[9] So in original. Probably should be ''(a)(8)(C)(iii),''.

(II) have such data submitted on their behalf through a Maintenance of Certification Program (as defined in subparagraph (C)(i)) that meets—

(aa) the criteria for a registry (as described in subsection (k)(4)); or

(bb) an alternative form and manner determined appropriate by the Secretary.

(ii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(I) participates in such a Maintenance of Certification program for a year; and

(II) successfully completes a qualified Maintenance of Certification Program practice assessment (as defined in subparagraph (C)(ii)) for such year.

(iii) A Maintenance of Certification program submits to the Secretary, on behalf of the eligible professional, information—

(I) in a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of clause (ii) (which may be in the form of a structural measure);

(II) if requested by the Secretary, on the survey of patient experience with care (as described in subparagraph (C)(ii)(II)); and

(III) as the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(C) Definitions

For purposes of this paragraph:

(i) The term ''Maintenance of Certification Program'' means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills and professionalism. Such a program shall include the following:

(I) The program requires the physician to maintain a valid, unrestricted medical license in the United States.

(II) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

(III) The program requires a physician to demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

(IV) The program requires successful completion of a qualified Maintenance of Certification Program practice assessment as described in clause (ii).

(ii) The term ''qualified Maintenance of Certification Program practice assessment'' means an assessment of a physician's practice that—

(I) includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;

(II) includes a survey of patient experience with care; and

(III) requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under subclause (I) and then to remeasure to assess performance improvement after such intervention.

(9) Continued application for purposes of MIPS and for certain professionals volunteering to report

The Secretary shall, in accordance with subsection (q)(1)(F), carry out the processes under this subsection—

(A) for purposes of subsection (q); and

(B) for eligible professionals who are not MIPS eligible professionals (as defined in subsection (q)(1)(C)) for the year involved.

(n) Physician Feedback Program

(1) Establishment

(A) In general

(i) Establishment

The Secretary shall establish a Physician Feedback Program (in this subsection referred to as the ''Program'').

(ii) Reports on resources

The Secretary shall use claims data under this subchapter (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this subchapter.

(iii) Inclusion of certain information

If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this subchapter by the physician (or group of physicians) in such reports.

(B) Resource use

The resources described in subparagraph (A)(ii) may be measured—

(i) on an episode basis;

(ii) on a per capita basis; or

(iii) on both an episode and a per capita basis.

(2) Implementation

The Secretary shall implement the Program by not later than January 1, 2009.

(3) Data for reports

To the extent practicable, reports under the Program shall be based on the most recent data available.

(4) Authority to focus initial application

The Secretary may focus the initial application of the Program as appropriate, such as focusing the Program on—

(A) physician specialties that account for a certain percentage of all spending for physicians' services under this subchapter;

(B) physicians who treat conditions that have a high cost or a high volume, or both, under this subchapter;

(C) physicians who use a high amount of resources compared to other physicians;

(D) physicians practicing in certain geographic areas; or

(E) physicians who treat a minimum number of individuals under this subchapter.

(5) Authority to exclude certain information if insufficient information

The Secretary may exclude certain information regarding a service from a report under the Program with respect to a physician (or group of physicians) if the Secretary determines that there is insufficient information relating to that service to provide a valid report on that service.

(6) Adjustment of data

To the extent practicable, the Secretary shall make appropriate adjustments to the data used in preparing reports under the Program, such as adjustments to take into account variations in health status and other patient characteristics. For adjustments for reports on utilization under paragraph (9), see subparagraph (D) of such paragraph.

(7) Education and outreach

The Secretary shall provide for education and outreach activities to physicians on the operation of, and methodologies employed under, the Program.

(8) Disclosure exemption

Reports under the Program shall be exempt from disclosure under section 552 of title 5.

(9) Reports on utilization

(A) Development of episode grouper

(i) In general

The Secretary shall develop an episode grouper that combines separate but clinically related items and services into an episode of care for an individual, as appropriate.

(ii) Timeline for development

The episode grouper described in subparagraph (A)[10] shall be developed by not later than January 1, 2012.

(iii) Public availability

The Secretary shall make the details of the episode grouper described in subparagraph (A)[10] available to the public.

(iv) Endorsement

The Secretary shall seek endorsement of the episode grouper described in subparagraph (A)[10] by the entity with a contract under section 1395aaa(a) of this title.

(B) Reports on utilization

Effective beginning with 2012, the Secretary shall provide reports to physicians that compare, as determined appropriate by the Secretary, patterns of resource use of the individual physician to such patterns of other physicians.

(C) Analysis of data

The Secretary shall, for purposes of preparing reports under this paragraph, establish methodologies as appropriate, such as to—

(i) attribute episodes of care, in whole or in part, to physicians;

(ii) identify appropriate physicians for purposes of comparison under subparagraph (B); and

(iii) aggregate episodes of care attributed to a physician under clause (i) into a composite measure per individual.

(D) Data adjustment

In preparing reports under this paragraph, the Secretary shall make appropriate adjustments, including adjustments—

(i) to account for differences in socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions); and

(ii) to eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)).

(E) Public availability of methodology

The Secretary shall make available to the public—

(i) the methodologies established under subparagraph (C);

(ii) information regarding any adjustments made to data under subparagraph (D); and

(iii) aggregate reports with respect to physicians.

(F) Definition of physician

In this paragraph:

(i) In general

The term ''physician'' has the meaning given that term in section 1395x(r)(1) of this title.

(ii) Treatment of groups

Such term includes, as the Secretary determines appropriate, a group of physicians.

(G) Limitations on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the establishment of the methodology under subparagraph (C), including the determination of an episode of care under such methodology.

(10) Coordination with other value-based purchasing reforms

The Secretary shall coordinate the Program with the value-based payment modifier established under subsection (p) and, as the Secretary determines appropriate, other similar provisions of this subchapter.

(11) Reports ending with 2017

Reports under the Program shall not be provided after December 31, 2017. See subsection

[10] So in original. Probably means cl. (i) of this subpar.

(q)(12) for reports under the eligible professionals Merit-based Incentive Payment System.

(*o*) Incentives for adoption and meaningful use of certified EHR technology

(1) Incentive payments

(A) In general

(i) In general

Subject to the succeeding subparagraphs of this paragraph, with respect to covered professional services furnished by an eligible professional during a payment year (as defined in subparagraph (E)), if the eligible professional is a meaningful EHR user (as determined under paragraph (2)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title), from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount equal to 75 percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the payment year) of the allowed charges under this part for all such covered professional services furnished by the eligible professional during such year.

(ii) No incentive payments with respect to years after 2016

No incentive payments may be made under this subsection with respect to a year after 2016.

(B) Limitations on amounts of incentive payments

(i) In general

In no case shall the amount of the incentive payment provided under this paragraph for an eligible professional for a payment year exceed the applicable amount specified under this subparagraph with respect to such eligible professional and such year.

(ii) Amount

Subject to clauses (iii) through (v), the applicable amount specified in this subparagraph for an eligible professional is as follows:

(I) For the first payment year for such professional, $15,000 (or, if the first payment year for such eligible professional is 2011 or 2012, $18,000).

(II) For the second payment year for such professional, $12,000.

(III) For the third payment year for such professional, $8,000.

(IV) For the fourth payment year for such professional, $4,000.

(V) For the fifth payment year for such professional, $2,000.

(VI) For any succeeding payment year for such professional, $0.

(iii) Phase down for eligible professionals first adopting EHR after 2013

If the first payment year for an eligible professional is after 2013, then the amount specified in this subparagraph for a payment year for such professional is the same as the amount specified in clause (ii) for such payment year for an eligible professional whose first payment year is 2013.

(iv) Increase for certain eligible professionals

In the case of an eligible professional who predominantly furnishes services under this part in an area that is designated by the Secretary (under section 254e(a)(1)(A) of this title) as a health professional shortage area, the amount that would otherwise apply for a payment year for such professional under subclauses (I) through (V) of clause (ii) shall be increased by 10 percent. In implementing the preceding sentence, the Secretary may, as determined appropriate, apply provisions of subsections (m) and (u) of section 1395*l* of this title in a similar manner as such provisions apply under such subsection.

(v) No incentive payment if first adopting after 2014

If the first payment year for an eligible professional is after 2014 then the applicable amount specified in this subparagraph for such professional for such year and any subsequent year shall be $0.

(C) Non-application to hospital-based eligible professionals

(i) In general

No incentive payment may be made under this paragraph in the case of a hospital-based eligible professional.

(ii) Hospital-based eligible professional

For purposes of clause (i), the term ''hospital-based eligible professional'' means, with respect to covered professional services furnished by an eligible professional during the EHR reporting period for a payment year, an eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of such services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(D) Payment

(i) Form of payment

The payment under this paragraph may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(ii) Coordination of application of limitation for professionals in different practices

In the case of an eligible professional furnishing covered professional services in

more than one practice (as specified by the Secretary), the Secretary shall establish rules to coordinate the incentive payments, including the application of the limitation on amounts of such incentive payments under this paragraph, among such practices.

(iii) Coordination with Medicaid

The Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this subchapter and subchapter XIX. The Secretary may also adjust the reporting periods under such subchapter and such subsections in order to carry out this clause.

(E) Payment year defined

(i) In general

For purposes of this subsection, the term ''payment year'' means a year beginning with 2011.

(ii) First, second, etc. payment year

The term ''first payment year'' means, with respect to covered professional services furnished by an eligible professional, the first year for which an incentive payment is made for such services under this subsection. The terms ''second payment year'', ''third payment year'', ''fourth payment year'', and ''fifth payment year'' mean, with respect to covered professional services furnished by such eligible professional, each successive year immediately following the first payment year for such professional.

(2) Meaningful EHR user

(A) In general

An eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year, or pursuant to subparagraph (D) for purposes of subsection (q), for a performance period under such subsection for a year) if each of the following requirements is met:

(i) Meaningful use of certified EHR technology

The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.

(ii) Information exchange

The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

(iii) Reporting on measures using EHR

Subject to subparagraph (B)(ii) and subsection (q)(5)(B)(ii)(II) and using such certified EHR technology, the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary may provide for the use of alternative means for meeting the requirements of clauses (i), (ii), and (iii) in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary). The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

(B) Reporting on measures

(i) Selection

The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title.

(II) Prior to any measure being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) Limitation

The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) Coordination of reporting of information

In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C).

(C) Demonstration of meaningful use of certified EHR technology and information exchange

(i) In general

A professional may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicat-

ing that a patient encounter was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) Use of part D data

Notwithstanding sections 1395w–115(d)(2)(B) and 1395w–115(f)(2) of this title, the Secretary may use data regarding drug claims submitted for purposes of section 1395w–115 of this title that are necessary for purposes of subparagraph (A).

(D) Continued application for purposes of MIPS

With respect to 2019 and each subsequent payment year, the Secretary shall, for purposes of subsection (q) and in accordance with paragraph (1)(F) of such subsection, determine whether an eligible professional who is a MIPS eligible professional (as defined in subsection (q)(1)(C)) for such year is a meaningful EHR user under this paragraph for the performance period under subsection (q) for such year.

(3) Application

(A) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) Coordination with other payments

The provisions of this subsection shall not be taken into account in applying the provisions of subsection (m) of this section and of section 1395*l*(m) of this title and any payment under such provisions shall not be taken into account in computing allowable charges under this subsection.

(C) Limitations on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (a)(7)(A), including the limitation under paragraph (1)(B) and coordination under clauses (ii) and (iii) of paragraph (1)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (2), including selection of measures under paragraph (2)(B), specification of the means of demonstrating meaningful EHR use under paragraph (2)(C), and the hardship exception under subsection (a)(7)(B);

(iii) the methodology and standards for determining a hospital-based eligible professional under paragraph (1)(C); and

(iv) the specification of reporting periods under paragraph (5) and the selection of the form of payment under paragraph (1)(D)(i).

(D) Posting on website

The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of the eligible professionals who are meaningful EHR users and, as determined appropriate by the Secretary, of group practices receiving incentive payments under paragraph (1).

(4) Certified EHR technology defined

For purposes of this section, the term ''certified EHR technology'' means a qualified electronic health record (as defined in section 300jj(13) of this title) that is certified pursuant to section 300jj–11(c)(5) of this title as meeting standards adopted under section 300jj–14 of this title that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(5) Definitions

For purposes of this subsection:

(A) Covered professional services

The term ''covered professional services'' has the meaning given such term in subsection (k)(3).

(B) EHR reporting period

The term ''EHR reporting period'' means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(C) Eligible professional

The term ''eligible professional'' means a physician, as defined in section 1395x(r) of this title.

(p) Establishment of value-based payment modifier

(1) In general

The Secretary shall establish a payment modifier that provides for differential payment to a physician or a group of physicians under the fee schedule established under subsection (b) based upon the quality of care furnished compared to cost (as determined under paragraphs (2) and (3), respectively) during a performance period. Such payment modifier shall be separate from the geographic adjustment factors established under subsection (e).

(2) Quality

(A) In general

For purposes of paragraph (1), quality of care shall be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished (as established by the Secretary under subparagraph (B)).

(B) Measures

(i) The Secretary shall establish appropriate measures of the quality of care furnished by a physician or group of physicians to individuals enrolled under this part, such as measures that reflect health outcomes. Such measures shall be risk adjusted as determined appropriate by the Secretary.

(ii) The Secretary shall seek endorsement of the measures established under this subparagraph by the entity with a contract under section 1395aaa(a) of this title.

(C) Continued application for purposes of MIPS

The Secretary shall, in accordance with subsection (q)(1)(F), carry out subparagraph (B) for purposes of subsection (q).

(3) Costs

For purposes of paragraph (1), costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under subsection (n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)), and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions)[11] and other factors determined appropriate by the Secretary. With respect to 2019 and each subsequent year, the Secretary shall, in accordance with subsection (q)(1)(F), carry out this paragraph for purposes of subsection (q).

(4) Implementation

(A) Publication of measures, dates of implementation, performance period

Not later than January 1, 2012, the Secretary shall publish the following:

(i) The measures of quality of care and costs established under paragraphs (2) and (3), respectively.

(ii) The dates for implementation of the payment modifier (as determined under subparagraph (B)).

(iii) The initial performance period (as specified under subparagraph (B)(ii)).

(B) Deadlines for implementation

(i) Initial implementation

Subject to the preceding provisions of this subparagraph, the Secretary shall begin implementing the payment modifier established under this subsection through the rulemaking process during 2013 for the physician fee schedule established under subsection (b).

(ii) Initial performance period

(I) In general

The Secretary shall specify an initial performance period for application of the payment modifier established under this subsection with respect to 2015.

(II) Provision of information during initial performance period

During the initial performance period, the Secretary shall, to the extent practicable, provide information to physicians and groups of physicians about the quality of care furnished by the physician or group of physicians to individuals enrolled under this part compared to cost (as determined under paragraphs (2) and (3), respectively) with respect to the performance period.

(iii) Application

The Secretary shall apply the payment modifier established under this subsection for items and services furnished on or after January 1, 2015, with respect to specific physicians and groups of physicians the Secretary determines appropriate, and for services furnished on or after January 1, 2017, with respect to all physicians and groups of physicians. Such payment modifier shall not be applied for items and services furnished on or after January 1, 2019.

(C) Budget neutrality

The payment modifier established under this subsection shall be implemented in a budget neutral manner.

(5) Systems-based care

The Secretary shall, as appropriate, apply the payment modifier established under this subsection in a manner that promotes systems-based care.

(6) Consideration of special circumstances of certain providers

In applying the payment modifier under this subsection, the Secretary shall, as appropriate, take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities.

(7) Application

For purposes of the initial application of the payment modifier established under this subsection during the period beginning on January 1, 2015, and ending on December 31, 2016, the term ''physician'' has the meaning given such term in section 1395x(r) of this title. On or after January 1, 2017, the Secretary may apply this subsection to eligible professionals (as defined in subsection (k)(3)(B)) as the Secretary determines appropriate.

(8) Definitions

For purposes of this subsection:

(A) Costs

The term ''costs'' means expenditures per individual as determined appropriate by the Secretary. In making the determination under the preceding sentence, the Secretary may take into account the amount of growth in expenditures per individual for a physician compared to the amount of such growth for other physicians.

(B) Performance period

The term ''performance period'' means a period specified by the Secretary.

(9) Coordination with other value-based purchasing reforms

The Secretary shall coordinate the value-based payment modifier established under this subsection with the Physician Feedback Program under subsection (n) and, as the Secretary determines appropriate, other similar provisions of this subchapter.

[11] So in original. Probably should be followed by a second closing parenthesis.

(10) Limitations on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of—

(A) the establishment of the value-based payment modifier under this subsection;

(B) the evaluation of quality of care under paragraph (2), including the establishment of appropriate measures of the quality of care under paragraph (2)(B);

(C) the evaluation of costs under paragraph (3), including the establishment of appropriate measures of costs under such paragraph;

(D) the dates for implementation of the value-based payment modifier;

(E) the specification of the initial performance period and any other performance period under paragraphs (4)(B)(ii) and (8)(B), respectively;

(F) the application of the value-based payment modifier under paragraph (7); and

(G) the determination of costs under paragraph (8)(A).

(q) Merit-based Incentive Payment System

(1) Establishment

(A) In general

Subject to the succeeding provisions of this subsection, the Secretary shall establish an eligible professional Merit-based Incentive Payment System (in this subsection referred to as the ''MIPS'') under which the Secretary shall—

(i) develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards under paragraph (3) for a performance period (as established under paragraph (4)) for a year;

(ii) using such methodology, provide for a composite performance score in accordance with paragraph (5) for each such professional for each performance period; and

(iii) use such composite performance score of the MIPS eligible professional for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) under paragraph (6) to the professional for the year.

Notwithstanding subparagraph (C)(ii), under the MIPS, the Secretary shall permit any eligible professional (as defined in subsection (k)(3)(B)) to report on applicable measures and activities described in paragraph (2)(B).

(B) Program implementation

The MIPS shall apply to payments for items and services furnished on or after January 1, 2019.

(C) MIPS eligible professional defined

(i) In general

For purposes of this subsection, subject to clauses (ii) and (iv), the term ''MIPS eligible professional'' means—

(I) for the first and second years for which the MIPS applies to payments (and for the performance period for such first and second year), a physician (as defined in section 1395x(r) of this title), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1395x(aa)(5) of this title), a certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title), and a group that includes such professionals; and

(II) for the third year for which the MIPS applies to payments (and for the performance period for such third year) and for each succeeding year (and for the performance period for each such year), the professionals described in subclause (I), such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary, and a group that includes such professionals.

(ii) Exclusions

For purposes of clause (i), the term ''MIPS eligible professional'' does not include, with respect to a year, an eligible professional (as defined in subsection (k)(3)(B)) who—

(I) is a qualifying APM participant (as defined in section 1395*l*(z)(2)[2] of this title);

(II) subject to clause (vii), is a partial qualifying APM participant (as defined in clause (iii)) for the most recent period for which data are available and who, for the performance period with respect to such year, does not report on applicable measures and activities described in paragraph (2)(B) that are required to be reported by such a professional under the MIPS; or

(III) for the performance period with respect to such year, does not exceed the low-volume threshold measurement selected under clause (iv).

(iii) Partial qualifying APM participant

For purposes of this subparagraph, the term ''partial qualifying APM participant'' means, with respect to a year, an eligible professional for whom the Secretary determines the minimum payment percentage (or percentages), as applicable, described in paragraph (2) of section 1395*l*(z)[2] of this title for such year have not been satisfied, but who would be considered a qualifying APM participant (as defined in such paragraph) for such year if—

(I) with respect to 2019 and 2020, the reference in subparagraph (A) of such paragraph to 25 percent was instead a reference to 20 percent;

(II) with respect to 2021 and 2022—

(aa) the reference in subparagraph (B)(i) of such paragraph to 50 percent was instead a reference to 40 percent; and

(bb) the references in subparagraph (B)(ii) of such paragraph to 50 percent and 25 percent of such paragraph[8] were instead references to 40 percent and 20 percent, respectively; and

(III) with respect to 2023 and subsequent years—

(aa) the reference in subparagraph (C)(i) of such paragraph to 75 percent was instead a reference to 50 percent; and

(bb) the references in subparagraph (C)(ii) of such paragraph to 75 percent and 25 percent of such paragraph[8] were instead references to 50 percent and 20 percent, respectively.

(iv) Selection of low-volume threshold measurement

The Secretary shall select a low-volume threshold to apply for purposes of clause (ii)(III), which may include one or more or a combination of the following:

(I) The minimum number (as determined by the Secretary) of individuals enrolled under this part who are treated by the eligible professional for the performance period involved.

(II) The minimum number (as determined by the Secretary) of items and services furnished to individuals enrolled under this part by such professional for such performance period.

(III) The minimum amount (as determined by the Secretary) of allowed charges billed by such professional under this part for such performance period.

(v) Treatment of new Medicare enrolled eligible professionals

In the case of a professional who first becomes a Medicare enrolled eligible professional during the performance period for a year (and had not previously submitted claims under this subchapter such as a person, an entity, or a part of a physician group or under a different billing number or tax identifier), such professional shall not be treated under this subsection as a MIPS eligible professional until the subsequent year and performance period for such subsequent year.

(vi) Clarification

In the case of items and services furnished during a year by an individual who is not a MIPS eligible professional (including pursuant to clauses (ii) and (v)) with respect to a year, in no case shall a MIPS adjustment factor (or additional MIPS adjustment factor) under paragraph (6) apply to such individual for such year.

(vii) Partial qualifying APM participant clarifications

(I) Treatment as MIPS eligible professional

In the case of an eligible professional who is a partial qualifying APM participant, with respect to a year, and who, for the performance period for such year, reports on applicable measures and activities described in paragraph (2)(B) that are required to be reported by such a professional under the MIPS, such eligible professional is considered to be a MIPS eligible professional with respect to such year.

(II) Not eligible for qualifying APM participant payments

In no case shall an eligible professional who is a partial qualifying APM participant, with respect to a year, be considered a qualifying APM participant (as defined in paragraph (2) of section 1395*l*(z)[2] of this title) for such year or be eligible for the additional payment under paragraph (1) of such section for such year.

(D) Application to group practices

(i) In general

Under the MIPS:

(I) Quality performance category

The Secretary shall establish and apply a process that includes features of the provisions of subsection (m)(3)(C) for MIPS eligible professionals in a group practice with respect to assessing performance of such group with respect to the performance category described in clause (i) of paragraph (2)(A).

(II) Other performance categories

The Secretary may establish and apply a process that includes features of the provisions of subsection (m)(3)(C) for MIPS eligible professionals in a group practice with respect to assessing the performance of such group with respect to the performance categories described in clauses (ii) through (iv) of such paragraph.

(ii) Ensuring comprehensiveness of group practice assessment

The process established under clause (i) shall to the extent practicable reflect the range of items and services furnished by the MIPS eligible professionals in the group practice involved.

(E) Use of registries

Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection.

(F) Application of certain provisions

In applying a provision of subsection (k), (m), (*o*), or (p) for purposes of this subsection, the Secretary shall—

(i) adjust the application of such provision to ensure the provision is consistent with the provisions of this subsection; and

(ii) not apply such provision to the extent that the provision is duplicative with a provision of this subsection.

(G) Accounting for risk factors

(i) Risk factors

Taking into account the relevant studies conducted and recommendations made in reports under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014, and, as appropriate, other information, including information collected before completion of such studies and recommendations, the Secretary, on an on-

going basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors—

(I) assess appropriate adjustments to quality measures, resource use measures, and other measures used under the MIPS; and

(II) assess and implement appropriate adjustments to payment adjustments, composite performance scores, scores for performance categories, or scores for measures or activities under the MIPS.

(2) Measures and activities under performance categories

(A) Performance categories

Under the MIPS, the Secretary shall use the following performance categories (each of which is referred to in this subsection as a performance category) in determining the composite performance score under paragraph (5):

(i) Quality.

(ii) Resource use.

(iii) Clinical practice improvement activities.

(iv) Meaningful use of certified EHR technology.

(B) Measures and activities specified for each category

For purposes of paragraph (3)(A) and subject to subparagraph (C), measures and activities specified for a performance period (as established under paragraph (4)) for a year are as follows:

(i) Quality

For the performance category described in subparagraph (A)(i), the quality measures included in the final measures list published under subparagraph (D)(i) for such year and the list of quality measures described in subparagraph (D)(vi) used by qualified clinical data registries under subsection (m)(3)(E).

(ii) Resource use

For the performance category described in subparagraph (A)(ii), the measurement of resource use for such period under subsection (p)(3), using the methodology under subsection (r) as appropriate, and, as feasible and applicable, accounting for the cost of drugs under part D.

(iii) Clinical practice improvement activities

For the performance category described in subparagraph (A)(iii), clinical practice improvement activities (as defined in subparagraph (C)(v)(III)) under subcategories specified by the Secretary for such period, which shall include at least the following:

(I) The subcategory of expanded practice access, such as same day appointments for urgent needs and after hours access to clinician advice.

(II) The subcategory of population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.

(III) The subcategory of care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.

(IV) The subcategory of beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

(V) The subcategory of patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.

(VI) The subcategory of participation in an alternative payment model (as defined in section 1395*l*(z)(3)(C)[2] of this title).

In establishing activities under this clause, the Secretary shall give consideration to the circumstances of small practices (consisting of 15 or fewer professionals) and practices located in rural areas and in health professional shortage areas (as designated under section 254e(a)(1)(A) of this title).

(iv) Meaningful EHR use

For the performance category described in subparagraph (A)(iv), the requirements established for such period under subsection (*o*)(2) for determining whether an eligible professional is a meaningful EHR user.

(C) Additional provisions

(i) Emphasizing outcome measures under the quality performance category

In applying subparagraph (B)(i), the Secretary shall, as feasible, emphasize the application of outcome measures.

(ii) Application of additional system measures

The Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the performance categories described in clauses (i) and (ii) of subparagraph (A). For purposes of the previous sentence, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

(iii) Global and population-based measures

The Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the performance category described in subparagraph (A)(i).

(iv) Application of measures and activities to non-patient-facing professionals

In carrying out this paragraph, with respect to measures and activities specified

in subparagraph (B) for performance categories described in subparagraph (A), the Secretary—

(I) shall give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient; and

(II) may, to the extent feasible and appropriate, take into account such circumstances and apply under this subsection with respect to MIPS eligible professionals of such professional types or subcategories, alternative measures or activities that fulfill the goals of the applicable performance category.

In carrying out the previous sentence, the Secretary shall consult with professionals of such professional types or subcategories.

(v) Clinical practice improvement activities

(I) Request for information

In initially applying subparagraph (B)(iii), the Secretary shall use a request for information to solicit recommendations from stakeholders to identify activities described in such subparagraph and specifying criteria for such activities.

(II) Contract authority for clinical practice improvement activities performance category

In applying subparagraph (B)(iii), the Secretary may contract with entities to assist the Secretary in—

(aa) identifying activities described in subparagraph (B)(iii);

(bb) specifying criteria for such activities; and

(cc) determining whether a MIPS eligible professional meets such criteria.

(III) Clinical practice improvement activities defined

For purposes of this subsection, the term ''clinical practice improvement activity'' means an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

(D) Annual list of quality measures available for MIPS assessment

(i) In general

Under the MIPS, the Secretary, through notice and comment rulemaking and subject to the succeeding clauses of this subparagraph, shall, with respect to the performance period for a year, establish an annual final list of quality measures from which MIPS eligible professionals may choose for purposes of assessment under this subsection for such performance period. Pursuant to the previous sentence, the Secretary shall—

(I) not later than November 1 of the year prior to the first day of the first performance period under the MIPS, establish and publish in the Federal Register a final list of quality measures; and

(II) not later than November 1 of the year prior to the first day of each subsequent performance period, update the final list of quality measures from the previous year (and publish such updated final list in the Federal Register), by—

(aa) removing from such list, as appropriate, quality measures, which may include the removal of measures that are no longer meaningful (such as measures that are topped out);

(bb) adding to such list, as appropriate, new quality measures; and

(cc) determining whether or not quality measures on such list that have undergone substantive changes should be included in the updated list.

(ii) Call for quality measures

(I) In general

Eligible professional organizations and other relevant stakeholders shall be requested to identify and submit quality measures to be considered for selection under this subparagraph in the annual list of quality measures published under clause (i) and to identify and submit updates to the measures on such list. For purposes of the previous sentence, measures may be submitted regardless of whether such measures were previously published in a proposed rule or endorsed by an entity with a contract under section 1395aaa(a) of this title.

(II) Eligible professional organization defined

In this subparagraph, the term ''eligible professional organization'' means a professional organization as defined by nationally recognized specialty boards of certification or equivalent certification boards.

(iii) Requirements

In selecting quality measures for inclusion in the annual final list under clause (i), the Secretary shall—

(I) provide that, to the extent practicable, all quality domains (as defined in subsection (s)(1)(B)) are addressed by such measures; and

(II) ensure that such selection is consistent with the process for selection of measures under subsections (k), (m), and (p)(2).

(iv) Peer review

Before including a new measure in the final list of measures published under clause (i) for a year, the Secretary shall submit for publication in applicable specialty-appropriate, peer-reviewed journals such measure and the method for developing and selecting such measure, including clinical and other data supporting such measure.

(v) Measures for inclusion

The final list of quality measures published under clause (i) shall include, as applicable, measures under subsections (k), (m), and (p)(2), including quality measures from among—

(I) measures endorsed by a consensus-based entity;

(II) measures developed under subsection (s); and

(III) measures submitted under clause (ii)(I).

Any measure selected for inclusion in such list that is not endorsed by a consensus-based entity shall have a focus that is evidence-based.

(vi) Exception for qualified clinical data registry measures

Measures used by a qualified clinical data registry under subsection (m)(3)(E) shall not be subject to the requirements under clauses (i), (iv), and (v). The Secretary shall publish the list of measures used by such qualified clinical data registries on the Internet website of the Centers for Medicare & Medicaid Services.

(vii) Exception for existing quality measures

Any quality measure specified by the Secretary under subsection (k) or (m), including under subsection (m)(3)(E), and any measure of quality of care established under subsection (p)(2) for the reporting period or performance period under the respective subsection beginning before the first performance period under the MIPS—

(I) shall not be subject to the requirements under clause (i) (except under items (aa) and (cc) of subclause (II) of such clause) or to the requirement under clause (iv); and

(II) shall be included in the final list of quality measures published under clause (i) unless removed under clause (i)(II)(aa).

(viii) Consultation with relevant eligible professional organizations and other relevant stakeholders

Relevant eligible professional organizations and other relevant stakeholders, including State and national medical societies, shall be consulted in carrying out this subparagraph.

(ix) Optional application

The process under section 1395aaa–1 of this title is not required to apply to the selection of measures under this subparagraph.

(3) Performance standards

(A) Establishment

Under the MIPS, the Secretary shall establish performance standards with respect to measures and activities specified under paragraph (2)(B) for a performance period (as established under paragraph (4)) for a year.

(B) Considerations in establishing standards

In establishing such performance standards with respect to measures and activities specified under paragraph (2)(B), the Secretary shall consider the following:

(i) Historical performance standards.

(ii) Improvement.

(iii) The opportunity for continued improvement.

(4) Performance period

The Secretary shall establish a performance period (or periods) for a year (beginning with 2019). Such performance period (or periods) shall begin and end prior to the beginning of such year and be as close as possible to such year. In this subsection, such performance period (or periods) for a year shall be referred to as the performance period for the year.

(5) Composite performance score

(A) In general

Subject to the succeeding provisions of this paragraph and taking into account, as available and applicable, paragraph (1)(G), the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards under paragraph (3) with respect to applicable measures and activities specified in paragraph (2)(B) with respect to each performance category applicable to such professional for a performance period (as established under paragraph (4)) for a year. Using such methodology, the Secretary shall provide for a composite assessment (using a scoring scale of 0 to 100) for each such professional for the performance period for such year. In this subsection such a composite assessment for such a professional with respect to a performance period shall be referred to as the ''composite performance score'' for such professional for such performance period.

(B) Incentive to report; encouraging use of certified EHR technology for reporting quality measures

(i) Incentive to report

Under the methodology established under subparagraph (A), the Secretary shall provide that in the case of a MIPS eligible professional who fails to report on an applicable measure or activity that is required to be reported by the professional, the professional shall be treated as achieving the lowest potential score applicable to such measure or activity.

(ii) Encouraging use of certified EHR technology and qualified clinical data registries for reporting quality measures

Under the methodology established under subparagraph (A), the Secretary shall—

(I) encourage MIPS eligible professionals to report on applicable measures with respect to the performance category described in paragraph (2)(A)(i) through the use of certified EHR technology and qualified clinical data registries; and

(II) with respect to a performance period, with respect to a year, for which a MIPS eligible professional reports such

measures through the use of such EHR technology, treat such professional as satisfying the clinical quality measures reporting requirement described in subsection (*o*)(2)(A)(iii) for such year.

(C) Clinical practice improvement activities performance score

(i) Rule for certification

A MIPS eligible professional who is in a practice that is certified as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, with respect to a performance period shall be given the highest potential score for the performance category described in paragraph (2)(A)(iii) for such period.

(ii) APM participation

Participation by a MIPS eligible professional in an alternative payment model (as defined in section 1395*l*(z)(3)(C)[2] of this title) with respect to a performance period shall earn such eligible professional a minimum score of one-half of the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period.

(iii) Subcategories

A MIPS eligible professional shall not be required to perform activities in each subcategory under paragraph (2)(B)(iii) or participate in an alternative payment model in order to achieve the highest potential score for the performance category described in paragraph (2)(A)(iii).

(D) Achievement and improvement

(i) Taking into account improvement

Beginning with the second year to which the MIPS applies, in addition to the achievement of a MIPS eligible professional, if data sufficient to measure improvement is available, the methodology developed under subparagraph (A)—

(I) in the case of the performance score for the performance category described in clauses (i) and (ii) of paragraph (2)(A), shall take into account the improvement of the professional; and

(II) in the case of performance scores for other performance categories, may take into account the improvement of the professional.

(ii) Assigning higher weight for achievement

Subject to clause (i), under the methodology developed under subparagraph (A), the Secretary may assign a higher scoring weight under subparagraph (F) with respect to the achievement of a MIPS eligible professional than with respect to any improvement of such professional applied under clause (i) with respect to a measure, activity, or category described in paragraph (2).

(E) Weights for the performance categories

(i) In general

Under the methodology developed under subparagraph (A), subject to subparagraph (F)(i) and clause (ii), the composite performance score shall be determined as follows:

(I) Quality

(aa) In general

Subject to item (bb), thirty percent of such score shall be based on performance with respect to the category described in clause (i) of paragraph (2)(A). In applying the previous sentence, the Secretary shall, as feasible, encourage the application of outcome measures within such category.

(bb) First 2 years

For the first and second years for which the MIPS applies to payments, the percentage applicable under item (aa) shall be increased in a manner such that the total percentage points of the increase under this item for the respective year equals the total number of percentage points by which the percentage applied under subclause (II)(bb) for the respective year is less than 30 percent.

(II) Resource use

(aa) In general

Subject to item (bb), thirty percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A).

(bb) First 2 years

For the first year for which the MIPS applies to payments, not more than 10 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A). For the second year for which the MIPS applies to payments, not more than 15 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A).

(III) Clinical practice improvement activities

Fifteen percent of such score shall be based on performance with respect to the category described in clause (iii) of paragraph (2)(A).

(IV) Meaningful use of certified EHR technology

Twenty-five percent of such score shall be based on performance with respect to the category described in clause (iv) of paragraph (2)(A).

(ii) Authority to adjust percentages in case of high EHR meaningful use adoption

In any year in which the Secretary estimates that the proportion of eligible professionals (as defined in subsection (*o*)(5)) who are meaningful EHR users (as determined under subsection (*o*)(2)) is 75 percent or greater, the Secretary may reduce the percent applicable under clause (i)(IV), but

not below 15 percent. If the Secretary makes such reduction for a year, subject to subclauses (I)(bb) and (II)(bb) of clause (i), the percentages applicable under one or more of subclauses (I), (II), and (III) of clause (i) for such year shall be increased in a manner such that the total percentage points of the increase under this clause for such year equals the total number of percentage points reduced under the preceding sentence for such year.

(F) Certain flexibility for weighting performance categories, measures, and activities

Under the methodology under subparagraph (A), if there are not sufficient measures and activities (described in paragraph (2)(B)) applicable and available to each type of eligible professional involved, the Secretary shall assign different scoring weights (including a weight of 0)—

(i) which may vary from the scoring weights specified in subparagraph (E), for each performance category based on the extent to which the category is applicable to the type of eligible professional involved; and

(ii) for each measure and activity specified under paragraph (2)(B) with respect to each such category based on the extent to which the measure or activity is applicable and available to the type of eligible professional involved.

(G) Resource use

Analysis of the performance category described in paragraph (2)(A)(ii) shall include results from the methodology described in subsection (r)(5), as appropriate.

(H) Inclusion of quality measure data from other payers

In applying subsections (k), (m), and (p) with respect to measures described in paragraph (2)(B)(i), analysis of the performance category described in paragraph (2)(A)(i) may include data submitted by MIPS eligible professionals with respect to items and services furnished to individuals who are not individuals entitled to benefits under part A or enrolled under part B.

(I) Use of voluntary virtual groups for certain assessment purposes

(i) In general

In the case of MIPS eligible professionals electing to be a virtual group under clause (ii) with respect to a performance period for a year, for purposes of applying the methodology under subparagraph (A) with respect to the performance categories described in clauses (i) and (ii) of paragraph (2)(A)—

(I) the assessment of performance provided under such methodology with respect to such performance categories that is to be applied to each such professional in such group for such performance period shall be with respect to the combined performance of all such professionals in such group for such period; and

(II) with respect to the composite performance score provided under this paragraph for such performance period for each such MIPS eligible professional in such virtual group, the components of the composite performance score that assess performance with respect to such performance categories shall be based on the assessment of the combined performance under subclause (I) for such performance categories and performance period.

(ii) Election of practices to be a virtual group

The Secretary shall, in accordance with the requirements under clause (iii), establish and have in place a process to allow an individual MIPS eligible professional or a group practice consisting of not more than 10 MIPS eligible professionals to elect, with respect to a performance period for a year to be a virtual group under this subparagraph with at least one other such individual MIPS eligible professional or group practice. Such a virtual group may be based on appropriate classifications of providers, such as by geographic areas or by provider specialties defined by nationally recognized specialty boards of certification or equivalent certification boards.

(iii) Requirements

The requirements for the process under clause (ii) shall—

(I) provide that an election under such clause, with respect to a performance period, shall be made before the beginning of such performance period and may not be changed during such performance period;

(II) provide that an individual MIPS eligible professional and a group practice described in clause (ii) may elect to be in no more than one virtual group for a performance period and that, in the case of such a group practice that elects to be in such virtual group for such performance period, such election applies to all MIPS eligible professionals in such group practice;

(III) provide that a virtual group be a combination of tax identification numbers;

(IV) provide for formal written agreements among MIPS eligible professionals electing to be a virtual group under this subparagraph; and

(V) include such other requirements as the Secretary determines appropriate.

(6) MIPS payments

(A) MIPS adjustment factor

Taking into account paragraph (1)(G), the Secretary shall specify a MIPS adjustment factor for each MIPS eligible professional for a year. Such MIPS adjustment factor for a MIPS eligible professional for a year shall be in the form of a percent and shall be determined—

(i) by comparing the composite performance score of the eligible professional for

such year to the performance threshold established under subparagraph (D)(i) for such year;

(ii) in a manner such that the adjustment factors specified under this subparagraph for a year result in differential payments under this paragraph reflecting that—

(I) MIPS eligible professionals with composite performance scores for such year at or above such performance threshold for such year receive zero or positive payment adjustment factors for such year in accordance with clause (iii), with such professionals having higher composite performance scores receiving higher adjustment factors; and

(II) MIPS eligible professionals with composite performance scores for such year below such performance threshold for such year receive negative payment adjustment factors for such year in accordance with clause (iv), with such professionals having lower composite performance scores receiving lower adjustment factors;

(iii) in a manner such that MIPS eligible professionals with composite scores described in clause (ii)(I) for such year, subject to clauses (i) and (ii) of subparagraph (F), receive a zero or positive adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a score at the performance threshold and an adjustment factor of the applicable percent specified in subparagraph (B) is assigned for a score of 100; and

(iv) in a manner such that—

(I) subject to subclause (II), MIPS eligible professionals with composite performance scores described in clause (ii)(II) for such year receive a negative payment adjustment factor on a linear sliding scale such that an adjustment factor of 0 percent is assigned for a score at the performance threshold and an adjustment factor of the negative of the applicable percent specified in subparagraph (B) is assigned for a score of 0; and

(II) MIPS eligible professionals with composite performance scores that are equal to or greater than 0, but not greater than ¼ of the performance threshold specified under subparagraph (D)(i) for such year, receive a negative payment adjustment factor that is equal to the negative of the applicable percent specified in subparagraph (B) for such year.

(B) Applicable percent defined

For purposes of this paragraph, the term ''applicable percent'' means—

(i) for 2019, 4 percent;

(ii) for 2020, 5 percent;

(iii) for 2021, 7 percent; and

(iv) for 2022 and subsequent years, 9 percent.

(C) Additional MIPS adjustment factors for exceptional performance

For 2019 and each subsequent year through 2024, in the case of a MIPS eligible professional with a composite performance score for a year at or above the additional performance threshold under subparagraph (D)(ii) for such year, in addition to the MIPS adjustment factor under subparagraph (A) for the eligible professional for such year, subject to subparagraph (F)(iv), the Secretary shall specify an additional positive MIPS adjustment factor for such professional and year. Such additional MIPS adjustment factors shall be in the form of a percent and determined by the Secretary in a manner such that professionals having higher composite performance scores above the additional performance threshold receive higher additional MIPS adjustment factors.

(D) Establishment of performance thresholds

(i) Performance threshold

For each year of the MIPS, the Secretary shall compute a performance threshold with respect to which the composite performance score of MIPS eligible professionals shall be compared for purposes of determining adjustment factors under subparagraph (A) that are positive, negative, and zero. Such performance threshold for a year shall be the mean or median (as selected by the Secretary) of the composite performance scores for all MIPS eligible professionals with respect to a prior period specified by the Secretary. The Secretary may reassess the selection of the mean or median under the previous sentence every 3 years.

(ii) Additional performance threshold for exceptional performance

In addition to the performance threshold under clause (i), for each year of the MIPS, the Secretary shall compute an additional performance threshold for purposes of determining the additional MIPS adjustment factors under subparagraph (C). For each such year, the Secretary shall apply either of the following methods for computing such additional performance threshold for such a year:

(I) The threshold shall be the score that is equal to the 25th percentile of the range of possible composite performance scores above the performance threshold determined under clause (i).

(II) The threshold shall be the score that is equal to the 25th percentile of the actual composite performance scores for MIPS eligible professionals with composite performance scores at or above the performance threshold with respect to the prior period described in clause (i).

(iii) Special rule for initial 2 years

With respect to each of the first two years to which the MIPS applies, the Secretary shall, prior to the performance period for such years, establish a performance threshold for purposes of determining MIPS adjustment factors under subparagraph (A) and a threshold for purposes of determining additional MIPS adjustment factors under subparagraph (C). Each such performance threshold shall—

(I) be based on a period prior to such performance periods; and

(II) take into account—

(aa) data available with respect to performance on measures and activities that may be used under the performance categories under subparagraph (2)(B); and

(bb) other factors determined appropriate by the Secretary.

(E) Application of MIPS adjustment factors

In the case of items and services furnished by a MIPS eligible professional during a year (beginning with 2019), the amount otherwise paid under this part with respect to such items and services and MIPS eligible professional for such year, shall be multiplied by—

(i) 1, plus

(ii) the sum of—

(I) the MIPS adjustment factor determined under subparagraph (A) divided by 100, and

(II) as applicable, the additional MIPS adjustment factor determined under subparagraph (C) divided by 100.

(F) Aggregate application of MIPS adjustment factors

(i) Application of scaling factor

(I) In general

With respect to positive MIPS adjustment factors under subparagraph (A)(ii)(I) for eligible professionals whose composite performance score is above the performance threshold under subparagraph (D)(i) for such year, subject to subclause (II), the Secretary shall increase or decrease such adjustment factors by a scaling factor in order to ensure that the budget neutrality requirement of clause (ii) is met.

(II) Scaling factor limit

In no case may the scaling factor applied under this clause exceed 3.0.

(ii) Budget neutrality requirement

(I) In general

Subject to clause (iii), the Secretary shall ensure that the estimated amount described in subclause (II) for a year is equal to the estimated amount described in subclause (III) for such year.

(II) Aggregate increases

The amount described in this subclause is the estimated increase in the aggregate allowed charges resulting from the application of positive MIPS adjustment factors under subparagraph (A) (after application of the scaling factor described in clause (i)) to MIPS eligible professionals whose composite performance score for a year is above the performance threshold under subparagraph (D)(i) for such year.

(III) Aggregate decreases

The amount described in this subclause is the estimated decrease in the aggregate allowed charges resulting from the application of negative MIPS adjustment factors under subparagraph (A) to MIPS eligible professionals whose composite performance score for a year is below the performance threshold under subparagraph (D)(i) for such year.

(iii) Exceptions

(I) In the case that all MIPS eligible professionals receive composite performance scores for a year that are below the performance threshold under subparagraph (D)(i) for such year, the negative MIPS adjustment factors under subparagraph (A) shall apply with respect to such MIPS eligible professionals and the budget neutrality requirement of clause (ii) and the additional adjustment factors under clause (iv) shall not apply for such year.

(II) In the case that, with respect to a year, the application of clause (i) results in a scaling factor equal to the maximum scaling factor specified in clause (i)(II), such scaling factor shall apply and the budget neutrality requirement of clause (ii) shall not apply for such year.

(iv) Additional incentive payment adjustments

(I) In general

Subject to subclause (II), in specifying the MIPS additional adjustment factors under subparagraph (C) for each applicable MIPS eligible professional for a year, the Secretary shall ensure that the estimated aggregate increase in payments under this part resulting from the application of such additional adjustment factors for MIPS eligible professionals in a year shall be equal (as estimated by the Secretary) to $500,000,000 for each year beginning with 2019 and ending with 2024.

(II) Limitation on additional incentive payment adjustments

The MIPS additional adjustment factor under subparagraph (C) for a year for an applicable MIPS eligible professional whose composite performance score is above the additional performance threshold under subparagraph (D)(ii) for such year shall not exceed 10 percent. The application of the previous sentence may result in an aggregate amount of additional incentive payments that are less than the amount specified in subclause (I).

(7) Announcement of result of adjustments

Under the MIPS, the Secretary shall, not later than 30 days prior to January 1 of the year involved, make available to MIPS eligible professionals the MIPS adjustment factor (and, as applicable, the additional MIPS adjustment factor) under paragraph (6) applicable to the eligible professional for items and services furnished by the professional for such year. The Secretary may include such information in the confidential feedback under paragraph (12).

(8) No effect in subsequent years

The MIPS adjustment factors and additional MIPS adjustment factors under paragraph (6) shall apply only with respect to the year involved, and the Secretary shall not take into account such adjustment factors in making payments to a MIPS eligible professional under this part in a subsequent year.

(9) Public reporting

(A) In general

The Secretary shall, in an easily understandable format, make available on the Physician Compare Internet website of the Centers for Medicare & Medicaid Services the following:

(i) Information regarding the performance of MIPS eligible professionals under the MIPS, which—

(I) shall include the composite score for each such MIPS eligible professional and the performance of each such MIPS eligible professional with respect to each performance category; and

(II) may include the performance of each such MIPS eligible professional with respect to each measure or activity specified in paragraph (2)(B).

(ii) The names of eligible professionals in eligible alternative payment models[12] (as defined in section 1395*l*(z)(3)(D)[2] of this title) and, to the extent feasible, the names of such eligible alternative payment models and performance of such models.

(B) Disclosure

The information made available under this paragraph shall indicate, where appropriate, that publicized information may not be representative of the eligible professional's entire patient population, the variety of services furnished by the eligible professional, or the health conditions of individuals treated.

(C) Opportunity to review and submit corrections

The Secretary shall provide for an opportunity for a professional described in subparagraph (A) to review, and submit corrections for, the information to be made public with respect to the professional under such subparagraph prior to such information being made public.

(D) Aggregate information

The Secretary shall periodically post on the Physician Compare Internet website aggregate information on the MIPS, including the range of composite scores for all MIPS eligible professionals and the range of the performance of all MIPS eligible professionals with respect to each performance category.

(10) Consultation

The Secretary shall consult with stakeholders in carrying out the MIPS, including for the identification of measures and activities under paragraph (2)(B) and the methodologies developed under paragraphs (5)(A) and (6) and regarding the use of qualified clinical data registries. Such consultation shall include the use of a request for information or other mechanisms determined appropriate.

(11) Technical assistance to small practices and practices in health professional shortage areas

(A) In general

The Secretary shall enter into contracts or agreements with appropriate entities (such as quality improvement organizations, regional extension centers (as described in section 300jj–32(c) of this title), or regional health collaboratives) to offer guidance and assistance to MIPS eligible professionals in practices of 15 or fewer professionals (with priority given to such practices located in rural areas, health professional shortage areas (as designated under in[8] section 254e(a)(1)(A) of this title), and medically underserved areas, and practices with low composite scores) with respect to—

(i) the performance categories described in clauses (i) through (iv) of paragraph (2)(A); or

(ii) how to transition to the implementation of and participation in an alternative payment model as described in section 1395*l*(z)(3)(C)[2] of this title.

(B) Funding for technical assistance

For purposes of implementing subparagraph (A), the Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title to the Centers for Medicare & Medicaid Services Program Management Account of $20,000,000 for each of fiscal years 2016 through 2020. Amounts transferred under this subparagraph for a fiscal year shall be available until expended.

(12) Feedback and information to improve performance

(A) Performance feedback

(i) In general

Beginning July 1, 2017, the Secretary—

(I) shall make available timely (such as quarterly) confidential feedback to MIPS eligible professionals on the performance of such professionals with respect to the performance categories under clauses (i) and (ii) of paragraph (2)(A); and

(II) may make available confidential feedback to such professionals on the performance of such professionals with respect to the performance categories under clauses (iii) and (iv) of such paragraph.

(ii) Mechanisms

The Secretary may use one or more mechanisms to make feedback available under clause (i), which may include use of a web-based portal or other mechanisms determined appropriate by the Secretary.

[12] So in original. Section 1395*l*(z)(3)(D) of this title defines the term ''eligible alternative payment entity''.

With respect to the performance category described in paragraph (2)(A)(i), feedback under this subparagraph shall, to the extent an eligible professional chooses to participate in a data registry for purposes of this subsection (including registries under subsections (k) and (m)), be provided based on performance on quality measures reported through the use of such registries. With respect to any other performance category described in paragraph (2)(A), the Secretary shall encourage provision of feedback through qualified clinical data registries as[13] described in subsection (m)(3)(E)).

(iii) Use of data

For purposes of clause (i), the Secretary may use data, with respect to a MIPS eligible professional, from periods prior to the current performance period and may use rolling periods in order to make illustrative calculations about the performance of such professional.

(iv) Disclosure exemption

Feedback made available under this subparagraph shall be exempt from disclosure under section 552 of title 5.

(v) Receipt of information

The Secretary may use the mechanisms established under clause (ii) to receive information from professionals, such as information with respect to this subsection.

(B) Additional information

(i) In general

Beginning July 1, 2018, the Secretary shall make available to MIPS eligible professionals information, with respect to individuals who are patients of such MIPS eligible professionals, about items and services for which payment is made under this subchapter that are furnished to such individuals by other suppliers and providers of services, which may include information described in clause (ii). Such information may be made available under the previous sentence to such MIPS eligible professionals by mechanisms determined appropriate by the Secretary, which may include use of a web-based portal. Such information may be made available in accordance with the same or similar terms as data are made available to accountable care organizations participating in the shared savings program under section 1395jjj of this title.

(ii) Type of information

For purposes of clause (i), the information described in this clause,[6] is the following:

(I) With respect to selected items and services (as determined appropriate by the Secretary) for which payment is made under this subchapter and that are furnished to individuals, who are patients of a MIPS eligible professional, by another supplier or provider of services during the most recent period for which data are available (such as the most recent three-month period), such as the name of such providers furnishing such items and services to such patients during such period, the types of such items and services so furnished, and the dates such items and services were so furnished.

(II) Historical data, such as averages and other measures of the distribution if appropriate, of the total, and components of, allowed charges (and other figures as determined appropriate by the Secretary).

(13) Review

(A) Targeted review

The Secretary shall establish a process under which a MIPS eligible professional may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to such eligible professional under this subsection for a year. The results of a review conducted pursuant to the previous sentence shall not be taken into account for purposes of paragraph (6) with respect to a year (other than with respect to the calculation of such eligible professional's MIPS adjustment factor for such year or additional MIPS adjustment factor for such year) after the factors determined in subparagraph (A) and subparagraph (C) of such paragraph have been determined for such year.

(B) Limitation

Except as provided for in subparagraph (A), there shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the following:

(i) The methodology used to determine the amount of the MIPS adjustment factor under paragraph (6)(A) and the amount of the additional MIPS adjustment factor under paragraph (6)(C) and the determination of such amounts.

(ii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iii) The identification of measures and activities specified under paragraph (2)(B) and information made public or posted on the Physician Compare Internet website of the Centers for Medicare & Medicaid Services under paragraph (9).

(iv) The methodology developed under paragraph (5) that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

(r) Collaborating with the physician, practitioner, and other stakeholder communities to improve resource use measurement

(1) In general

In order to involve the physician, practitioner, and other stakeholder communities in

[13] So in original. Probably should be preceded by an opening parenthesis.

enhancing the infrastructure for resource use measurement, including for purposes of the Merit-based Incentive Payment System under subsection (q) and alternative payment models under section 1395*l*(z)[2] of this title, the Secretary shall undertake the steps described in the succeeding provisions of this subsection.

(2) Development of care episode and patient condition groups and classification codes

(A) In general

In order to classify similar patients into care episode groups and patient condition groups, the Secretary shall undertake the steps described in the succeeding provisions of this paragraph.

(B) Public availability of existing efforts to design an episode grouper

Not later than 180 days after April 16, 2015, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the episode groups developed pursuant to subsection (n)(9)(A) and related descriptive information.

(C) Stakeholder input

The Secretary shall accept, through the date that is 120 days after the day the Secretary posts the list pursuant to subparagraph (B), suggestions from physician specialty societies, applicable practitioner organizations, and other stakeholders for episode groups in addition to those posted pursuant to such subparagraph, and specific clinical criteria and patient characteristics to classify patients into—

(i) care episode groups; and

(ii) patient condition groups.

(D) Development of proposed classification codes

(i) In general

Taking into account the information described in subparagraph (B) and the information received under subparagraph (C), the Secretary shall—

(I) establish care episode groups and patient condition groups, which account for a target of an estimated ½ of expenditures under parts A and B (with such target increasing over time as appropriate); and

(II) assign codes to such groups.

(ii) Care episode groups

In establishing the care episode groups under clause (i), the Secretary shall take into account—

(I) the patient's clinical problems at the time items and services are furnished during an episode of care, such as the clinical conditions or diagnoses, whether or not inpatient hospitalization occurs, and the principal procedures or services furnished; and

(II) other factors determined appropriate by the Secretary.

(iii) Patient condition groups

In establishing the patient condition groups under clause (i), the Secretary shall take into account—

(I) the patient's clinical history at the time of a medical visit, such as the patient's combination of chronic conditions, current health status, and recent significant history (such as hospitalization and major surgery during a previous period, such as 3 months); and

(II) other factors determined appropriate by the Secretary, such as eligibility status under this subchapter (including eligibility under section 426(a) of this title, section 426(b) of this title, or section 426–1 of this title, and dual eligibility under this subchapter and subchapter XIX).

(E) Draft care episode and patient condition groups and classification codes

Not later than 270 days after the end of the comment period described in subparagraph (C), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a draft list of the care episode and patient condition codes established under subparagraph (D) (and the criteria and characteristics assigned to such code).

(F) Solicitation of input

The Secretary shall seek, through the date that is 120 days after the Secretary posts the list pursuant to subparagraph (E), comments from physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part, regarding the care episode and patient condition groups (and codes) posted under subparagraph (E). In seeking such comments, the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include use of open door forums, town hall meetings, or other appropriate mechanisms.

(G) Operational list of care episode and patient condition groups and codes

Not later than 270 days after the end of the comment period described in subparagraph (F), taking into account the comments received under such subparagraph, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services an operational list of care episode and patient condition codes (and the criteria and characteristics assigned to such code).

(H) Subsequent revisions

Not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational lists of care episode and patient condition codes as the Secretary determines may be appropriate. Such revisions may be based on experience, new information developed pursuant to subsection (n)(9)(A), and input from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part.

(3) Attribution of patients to physicians or practitioners

(A) In general

In order to facilitate the attribution of patients and episodes (in whole or in part) to one or more physicians or applicable practitioners furnishing items and services, the Secretary shall undertake the steps described in the succeeding provisions of this paragraph.

(B) Development of patient relationship categories and codes

The Secretary shall develop patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. Such patient relationship categories shall include different relationships of the physician or applicable practitioner to the patient (and the codes may reflect combinations of such categories), such as a physician or applicable practitioner who—

(i) considers themself to have the primary responsibility for the general and ongoing care for the patient over extended periods of time;

(ii) considers themself to be the lead physician or practitioner and who furnishes items and services and coordinates care furnished by other physicians or practitioners for the patient during an acute episode;

(iii) furnishes items and services to the patient on a continuing basis during an acute episode of care, but in a supportive rather than a lead role;

(iv) furnishes items and services to the patient on an occasional basis, usually at the request of another physician or practitioner; or

(v) furnishes items and services only as ordered by another physician or practitioner.

(C) Draft list of patient relationship categories and codes

Not later than one year after April 16, 2015, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a draft list of the patient relationship categories and codes developed under subparagraph (B).

(D) Stakeholder input

The Secretary shall seek, through the date that is 120 days after the Secretary posts the list pursuant to subparagraph (C), comments from physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part, regarding the patient relationship categories and codes posted under subparagraph (C). In seeking such comments, the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include open door forums, town hall meetings, web-based forums, or other appropriate mechanisms.

(E) Operational list of patient relationship categories and codes

Not later than 240 days after the end of the comment period described in subparagraph (D), taking into account the comments received under such subparagraph, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services an operational list of patient relationship categories and codes.

(F) Subsequent revisions

Not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational list of patient relationship categories and codes as the Secretary determines appropriate. Such revisions may be based on experience, new information developed pursuant to subsection (n)(9)(A), and input from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part.

(4) Reporting of information for resource use measurement

Claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, as determined appropriate by the Secretary, include—

(A) applicable codes established under paragraphs (2) and (3); and

(B) the national provider identifier of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).

(5) Methodology for resource use analysis

(A) In general

In order to evaluate the resources used to treat patients (with respect to care episode and patient condition groups), the Secretary shall, as the Secretary determines appropriate—

(i) use the patient relationship codes reported on claims pursuant to paragraph (4) to attribute patients (in whole or in part) to one or more physicians and applicable practitioners;

(ii) use the care episode and patient condition codes reported on claims pursuant to paragraph (4) as a basis to compare similar patients and care episodes and patient condition groups; and

(iii) conduct an analysis of resource use (with respect to care episodes and patient condition groups of such patients).

(B) Analysis of patients of physicians and practitioners

In conducting the analysis described in subparagraph (A)(iii) with respect to patients attributed to physicians and applicable practitioners, the Secretary shall, as feasible—

(i) use the claims data experience of such patients by patient condition codes during a common period, such as 12 months; and

(ii) use the claims data experience of such patients by care episode codes—

(I) in the case of episodes without a hospitalization, during periods of time (such as the number of days) determined appropriate by the Secretary; and

(II) in the case of episodes with a hospitalization, during periods of time (such as the number of days) before, during, and after the hospitalization.

(C) Measurement of resource use

In measuring such resource use, the Secretary—

(i) shall use per patient total allowed charges for all services under part A and this part (and, if the Secretary determines appropriate, part D) for the analysis of patient resource use, by care episode codes and by patient condition codes; and

(ii) may, as determined appropriate, use other measures of allowed charges (such as subtotals for categories of items and services) and measures of utilization of items and services (such as frequency of specific items and services and the ratio of specific items and services among attributed patients or episodes).

(D) Stakeholder input

The Secretary shall seek comments from the physician specialty societies, applicable practitioner organizations, and other stakeholders, including representatives of individuals entitled to benefits under part A or enrolled under this part, regarding the resource use methodology established pursuant to this paragraph. In seeking comments the Secretary shall use one or more mechanisms (other than notice and comment rulemaking) that may include open door forums, town hall meetings, web-based forums, or other appropriate mechanisms.

(6) Implementation

To the extent that the Secretary contracts with an entity to carry out any part of the provisions of this subsection, the Secretary may not contract with an entity or an entity with a subcontract if the entity or subcontracting entity currently makes recommendations to the Secretary on relative values for services under the fee schedule for physicians' services under this section.

(7) Limitation

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of—

(A) care episode and patient condition groups and codes established under paragraph (2);

(B) patient relationship categories and codes established under paragraph (3); and

(C) measurement of, and analyses of resource use with respect to, care episode and patient condition codes and patient relationship codes pursuant to paragraph (5).

(8) Administration

Chapter 35 of title 44 shall not apply to this section.

(9) Definitions

In this subsection:

(A) Physician

The term ''physician'' has the meaning given such term in section 1395x(r)(1) of this title.

(B) Applicable practitioner

The term ''applicable practitioner'' means—

(i) a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1395x(aa)(5) of this title), and a certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title); and

(ii) beginning January 1, 2019, such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary.

(10) Clarification

The provisions of sections 1395aaa(b)(7) of this title and 1395aaa–1 of this title shall not apply to this subsection.

(s) Priorities and funding for measure development

(1) Plan identifying measure development priorities and timelines

(A) Draft measure development plan

Not later than January 1, 2016, the Secretary shall develop, and post on the Internet website of the Centers for Medicare & Medicaid Services, a draft plan for the development of quality measures for application under the applicable provisions (as defined in paragraph (5)). Under such plan the Secretary shall—

(i) address how measures used by private payers and integrated delivery systems could be incorporated under subchapter XVIII;

(ii) describe how coordination, to the extent possible, will occur across organizations developing such measures; and

(iii) take into account how clinical best practices and clinical practice guidelines should be used in the development of quality measures.

(B) Quality domains

For purposes of this subsection, the term ''quality domains'' means at least the following domains:

(i) Clinical care.

(ii) Safety.

(iii) Care coordination.

(iv) Patient and caregiver experience.

(v) Population health and prevention.

(C) Consideration

In developing the draft plan under this paragraph, the Secretary shall consider—

(i) gap analyses conducted by the entity with a contract under section 1395aaa(a) of this title or other contractors or entities;

(ii) whether measures are applicable across health care settings;

(iii) clinical practice improvement activities submitted under subsection (q)(2)(C)(iv) for identifying possible areas for future measure development and identifying existing gaps with respect to such measures; and

(iv) the quality domains applied under this subsection.

(D) Priorities

In developing the draft plan under this paragraph, the Secretary shall give priority to the following types of measures:

(i) Outcome measures, including patient reported outcome and functional status measures.

(ii) Patient experience measures.

(iii) Care coordination measures.

(iv) Measures of appropriate use of services, including measures of over use.

(E) Stakeholder input

The Secretary shall accept through March 1, 2016, comments on the draft plan posted under paragraph (1)(A) from the public, including health care providers, payers, consumers, and other stakeholders.

(F) Final measure development plan

Not later than May 1, 2016, taking into account the comments received under this subparagraph, the Secretary shall finalize the plan and post on the Internet website of the Centers for Medicare & Medicaid Services an operational plan for the development of quality measures for use under the applicable provisions. Such plan shall be updated as appropriate.

(2) Contracts and other arrangements for quality measure development

(A) In general

The Secretary shall enter into contracts or other arrangements with entities for the purpose of developing, improving, updating, or expanding in accordance with the plan under paragraph (1) quality measures for application under the applicable provisions. Such entities shall include organizations with quality measure development expertise.

(B) Prioritization

(i) In general

In entering into contracts or other arrangements under subparagraph (A), the Secretary shall give priority to the development of the types of measures described in paragraph (1)(D).

(ii) Consideration

In selecting measures for development under this subsection, the Secretary shall consider—

(I) whether such measures would be electronically specified; and

(II) clinical practice guidelines to the extent that such guidelines exist.

(3) Annual report by the Secretary

(A) In general

Not later than May 1, 2017, and annually thereafter, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a report on the progress made in developing quality measures for application under the applicable provisions.

(B) Requirements

Each report submitted pursuant to subparagraph (A) shall include the following:

(i) A description of the Secretary's efforts to implement this paragraph.

(ii) With respect to the measures developed during the previous year—

(I) a description of the total number of quality measures developed and the types of such measures, such as an outcome or patient experience measure;

(II) the name of each measure developed;

(III) the name of the developer and steward of each measure;

(IV) with respect to each type of measure, an estimate of the total amount expended under this subchapter to develop all measures of such type; and

(V) whether the measure would be electronically specified.

(iii) With respect to measures in development at the time of the report—

(I) the information described in clause (ii), if available; and

(II) a timeline for completion of the development of such measures.

(iv) A description of any updates to the plan under paragraph (1) (including newly identified gaps and the status of previously identified gaps) and the inventory of measures applicable under the applicable provisions.

(v) Other information the Secretary determines to be appropriate.

(4) Stakeholder input

With respect to paragraph (1), the Secretary shall seek stakeholder input with respect to—

(A) the identification of gaps where no quality measures exist, particularly with respect to the types of measures described in paragraph (1)(D);

(B) prioritizing quality measure development to address such gaps; and

(C) other areas related to quality measure development determined appropriate by the Secretary.

(5) Definition of applicable provisions

In this subsection, the term ''applicable provisions'' means the following provisions:

(A) Subsection (q)(2)(B)(i).

(B) Section 1395*l*(z)(2)(C)[2] of this title.

(6) Funding

For purposes of carrying out this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2015 through 2019. Amounts transferred under this paragraph shall remain available through the end of fiscal year 2022.

(7) Administration

Chapter 35 of title 44 shall not apply to the collection of information for the development of quality measures.

(Aug. 14, 1935, ch. 531, title XVIII, §1848, as added Pub. L. 101–239, title VI, §6102(a), Dec. 19, 1989, 103 Stat. 2169; amended Pub. L. 101–508, title IV,

§§ 4102(b), (g)(2), 4104(b)(2), 4105(a)(3), (c), 4106(b)(1), 4107(a)(1), 4109(a), 4116, 4118(b)–(f)(1), (k), Nov. 5, 1990, 104 Stat. 1388–56, 1388–57, 1388–59 to 1388–63, 1388–65, 1388–67, 1388–68, 1388–71; Pub. L. 103–66, title XIII, §§ 13511(a), 13512–13514(c), 13515(a)(1), (c), 13516(a)(1), 13517(a), 13518(a), Aug. 10, 1993, 107 Stat. 580–583, 585, 586; Pub. L. 103–432, title I, §§ 121(b)(1), (2), 122(a), (b), 123(a), (d), 126(b)(6), (g)(2)(B), (5)–(7), (10)(A), Oct. 31, 1994, 108 Stat. 4409, 4410, 4412, 4415, 4416; Pub. L. 105–33, title IV, §§ 4022(b)(2)(B), (C), 4102(d), 4103(d), 4104(d), 4105(a)(2), 4106(b), 4501, 4502(a)(1), (b), 4503, 4504(a), 4505(a), (b), (e), (f)(1), 4644(d), 4714(b)(2), Aug. 5, 1997, 111 Stat. 354, 355, 361, 362, 365, 366, 368, 432–437, 488, 510; Pub. L. 106–113, div. B, § 1000(a)(6) [title II, § 211(a)(1), (2)(A), (3)(A), (b), title III, § 321(k)(5)], Nov. 29, 1999, 113 Stat. 1536, 1501A–345 to 1501A–348, 1501A–366; Pub. L. 106–554, § 1(a)(6) [title I, § 104(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–469; Pub. L. 108–7, div. N, title IV, § 402(a), Feb. 20, 2003, 117 Stat. 548; Pub. L. 108–173, title III, § 303(a)(1), (g)(2), title IV, § 412, title VI, §§ 601(a)(1), (2), (b)(1), 602, 611(c), title VII, § 736(b)(10), Dec. 8, 2003, 117 Stat. 2233, 2253, 2274, 2300, 2301, 2304, 2356; Pub. L. 109–171, title V, §§ 5102, 5104(a), 5112(c), Feb. 8, 2006, 120 Stat. 39, 40, 44; Pub. L. 109–432, div. B, title I, §§ 101(a), (b), (d), 102, Dec. 20, 2006, 120 Stat. 2975, 2980, 2981; Pub. L. 110–90, § 6, Sept. 29, 2007, 121 Stat. 985; Pub. L. 110–161, div. G, title II, § 225(c)(2), title V, § 524, Dec. 26, 2007, 121 Stat. 2190, 2212; Pub. L. 110–173, title I, §§ 101(a)(1), (2)(A), (b)(1), 103, Dec. 29, 2007, 121 Stat. 2493–2495; Pub. L. 110–252, title VII, § 7002(c), June 30, 2008, 122 Stat. 2395; Pub. L. 110–275, title I, §§ 131(a)(1), (3)(C), (b)(1)–(4)(A), (5), (c)(1), 132(a), (b), 133(b), 134, 139(a), 144(a)(2), 152(b)(1)(C), July 15, 2008, 122 Stat. 2520–2522, 2525–2527, 2529, 2532, 2541, 2546, 2552; Pub. L. 111–5, div. B, title IV, § 4101(a), (b), (f), Feb. 17, 2009, 123 Stat. 467, 472, 476; Pub. L. 111–118, div. B, § 1011(a), Dec. 19, 2009, 123 Stat. 3473; Pub. L. 111–144, § 5, Mar. 2, 2010, 124 Stat. 46; Pub. L. 111–148, title III, §§ 3002(a)–(c)(1), (d)–(f), 3003(a), 3007, 3101, 3102, 3111(a)(1), 3134(a), 3135(a), (b), title IV, § 4103(c)(2), title V, § 5501(c), title X, §§ 10310, 10324(c), 10327(a), 10501(h), Mar. 23, 2010, 124 Stat. 363–366, 373, 415, 416, 421, 434, 436, 437, 556, 654, 942, 960, 962, 997; Pub. L. 111–152, title I, §§ 1107, 1108, Mar. 30, 2010, 124 Stat. 1050; Pub. L. 111–157, §§ 4, 5(a)(1), Apr. 15, 2010, 124 Stat. 1117; Pub. L. 111–192, title I, § 101(a), June 25, 2010, 124 Stat. 1280; Pub. L. 111–286, §§ 2, 3, Nov. 30, 2010, 124 Stat. 3056; Pub. L. 111–309, title I, §§ 101, 103, Dec. 15, 2010, 124 Stat. 3285, 3287; Pub. L. 112–78, title III, §§ 301, 303, 309, Dec. 23, 2011, 125 Stat. 1283, 1284, 1286; Pub. L. 112–96, title III, §§ 3003(a), 3004(a), Feb. 22, 2012, 126 Stat. 186, 187; Pub. L. 112–240, title VI, §§ 601(a), (b)(1), 602, 633(a), 635, Jan. 2, 2013, 126 Stat. 2345, 2347, 2355, 2356; Pub. L. 113–67, div. B, title I, §§ 1101, 1102, Dec. 26, 2013, 127 Stat. 1196; Pub. L. 113–93, title I, §§ 101, 102, title II, §§ 218(a)(2)(B), 220(a)–(f), (h), Apr. 1, 2014, 128 Stat. 1041, 1064, 1070–1074; Pub. L. 113–295, div. B, title II, § 202, Dec. 19, 2014, 128 Stat. 4065; Pub. L. 114–10, title I, §§ 101(a)(1), (2), (b), (c)(1), (d), (f), 102, 103(a), 106(b)(2)(A), title II, § 201, title V, § 523, Apr. 16, 2015, 129 Stat. 89, 91, 92, 115, 123–131, 139, 143, 177; Pub. L. 114–113, div. O, title V, § 502(a)(1)–(2)(B), Dec. 18, 2015, 129 Stat. 3018, 3019; Pub. L. 114–115, §§ 3(a), 4(a), Dec. 28, 2015, 129 Stat. 3132, 3133.)

AMENDMENT OF SUBSECTION (*o*)(2)(A)(ii)

Pub. L. 114–10, title I, § 101(b)(2)(A), (C), Apr. 16, 2015, 129 Stat. 139, 140, provided that, applicable to meaningful EHR users as of the date that is one year after Apr. 16, 2015, subsection (o)(2)(A)(ii) of this section is amended by inserting before the period at the end the following: '', and the professional demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the professional has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology''. See 2015 Amendment note below.

REFERENCES IN TEXT

Section 13515(b) of the Omnibus Budget Reconciliation Act of 1993, referred to in subsecs. (a)(2)(B)(ii)(I), (c)(2)(A)(i), and (i)(1)(B), is section 13515(b) of Pub. L. 103–66, which is set out as a note under section 1395u of this title.

Section 6105(b) of the Omnibus Budget Reconciliation Act of 1989, referred to in subsec. (a)(2)(D)(ii), (iii), is section 6105(b) of Pub. L. 101–239, which is set out as a note under section 1395m of this title.

Section 4048(b) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (b)(2)(B), is section 4048(b) of Pub. L. 100–203, which is set out as a note under section 1395u of this title.

Section 13514(a) of the Omnibus Budget Reconciliation Act of 1993, referred to in subsec. (c)(2)(F), is section 13514(a) of Pub. L. 103–66, which amended subsec. (b)(3) of this section. See 1993 Amendment note below.

Section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, referred to in subsec. (c)(2)(H)(i), (I)(ii)(I), is section 1000(a)(6) [title II, § 212] of Pub. L. 106–113, which is set out as a note under this section.

Section 1395*l*(z) of this title, referred to in subsecs. (d)(1)(A), (q), (r)(1), and (s)(5)(B), probably means the subsec. (z) of section 1395*l* of this title which relates to alternative payment models and qualifying APM participants and was added by Pub. L. 114–10, title I, § 101(e)(2), Apr. 16, 2015, 129 Stat. 117.

The Balanced Budget Act of 1997, referred to in subsec. (d)(1)(C), is Pub. L. 105–33, Aug. 5, 1997, 111 Stat. 251. Chapter 1 of subtitle F of title IV of the Act is chapter 1 (§§ 4501–4513) of subtitle F of title IV of Pub. L. 105–33, which amended this section and sections 1395a, 1395k, 1395*l*, 1395u, 1395x, 1395y, 1395cc, and 1395yy of this title and enacted provisions set out as notes under this section and sections 1395a, 1395k, 1395*l*, 1395x, and 1395ww of this title. For complete classification of this Act to the Code, see Tables.

Section 225(c)(1) and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, referred to in subsec. (*l*)(2)(A)(ii)(I), (II), are sections 225(c)(1) of title II and 524 of title V of div. G of Pub. L. 110–161, Dec. 26, 2007, 121 Stat. 2190, 2212. Section 225(c)(1) is not classified to the Code and section 524 amended this section.

Section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014, referred to in subsec. (q)(1)(G)(i), is section 2(d) of Pub. L. 113–185, which is set out as a note under section 1395*lll* of this title.

CODIFICATION

The text of section 101(c) of Pub. L. 109–432, div. B, title I, Dec. 20, 2006, 120 Stat. 2977, as amended by Pub. L. 110–173, title I, § 101(b)(2), Dec. 29, 2007, 121 Stat. 2494, which was formerly set out as a note under this section, was transferred to subsec. (m) of this section and amended by Pub. L. 110–275.

AMENDMENTS

2015—Subsec. (a)(7)(A)(i). Pub. L. 114–10, §101(b)(1)(A)(i), substituted ''each of 2015 through 2018'' for ''2015 or any subsequent payment year''.

Subsec. (a)(7)(A)(ii)(III). Pub. L. 114–10, §101(b)(1)(A)(ii), substituted ''2018'' for ''each subsequent year''.

Subsec. (a)(7)(A)(iii). Pub. L. 114–10, §101(b)(1)(A)(iii), struck out ''and subsequent years'' after ''for 2018'' in heading and ''and each subsequent year'' after ''For 2018'' and '', but in no case shall the applicable percent be less than 95 percent'' after ''in the preceding year'' in text.

Subsec. (a)(7)(B). Pub. L. 114–115, §4(a), inserted ''(and, with respect to the payment adjustment under subparagraph (A) for 2017, for categories of eligible professionals, as established by the Secretary and posted on the Internet website of the Centers for Medicare & Medicaid Services prior to December 15, 2015, an application for which must be submitted to the Secretary by not later than March 15, 2016)'' after ''case-by-case basis''.

Subsec. (a)(8)(A)(i). Pub. L. 114–10, §101(b)(2)(A)(i), substituted ''each of 2015 through 2018'' for ''2015 or any subsequent year''.

Subsec. (a)(8)(A)(ii)(II). Pub. L. 114–10, §101(b)(2)(A)(ii), substituted '', 2017, and 2018'' for ''and each subsequent year''.

Subsec. (a)(9). Pub. L. 114–10, §523(b), added par. (9).

Subsec. (b)(8). Pub. L. 114–10, §103(a), added par. (8).

Subsec. (b)(9). Pub. L. 114–113, §502(a)(1)(A), added par. (9).

Subsec. (b)(10). Pub. L. 114–113, §502(a)(2)(A), added par. (10).

Subsec. (b)(11). Pub. L. 114–115, §3(a)(1), added par. (11).

Subsec. (c)(2)(B)(v)(X). Pub. L. 114–113, §502(a)(1)(B), added subcl. (X).

Subsec. (c)(2)(B)(v)(XI). Pub. L. 114–113, §502(a)(2)(B), added subcl. (XI).

Subsec. (c)(2)(K)(iv). Pub. L. 114–115, §3(a)(2), added cl. (iv).

Subsec. (c)(8). Pub. L. 114–10, §523(a), added par. (8).

Subsec. (d)(1)(A). Pub. L. 114–10, §101(a)(1)(A)(i), (2)(A), inserted ''and ending with 2025'' after ''beginning with 2001'', ''or a subsequent paragraph'' after ''paragraph (4)'', and ''There shall be two separate conversion factors for each year beginning with 2026, one for items and services furnished by a qualifying APM participant (as defined in section 1395*l*(z)(2) of this title) (referred to in this subsection as the 'qualifying APM conversion factor') and the other for other items and services (referred to in this subsection as the 'nonqualifying APM conversion factor'), equal to the respective conversion factor for the previous year (or, in the case of 2026, equal to the single conversion factor for 2025) multiplied by the update established under paragraph (20) for such respective conversion factor for such year.'' at end.

Subsec. (d)(1)(D). Pub. L. 114–10, §101(a)(2)(B), inserted ''(or, beginning with 2026, applicable conversion factor)'' after ''single conversion factor''.

Subsec. (d)(4). Pub. L. 114–10, §101(a)(1)(A)(ii)(I), inserted ''and ending with 2014'' after ''years beginning with 2001'' in heading.

Subsec. (d)(4)(A). Pub. L. 114–10, §101(a)(1)(A)(ii)(II), inserted ''and ending with 2014'' after ''a year beginning with 2001'' in introductory provisions.

Subsec. (d)(16) to (20). Pub. L. 114–10, §101(a)(2)(C), added pars. (16) to (20) and struck out former par. (16) which related to update for January through March of 2015.

Subsec. (e)(1)(E). Pub. L. 114–10, §201, substituted ''January 1, 2018'' for ''April 1, 2015''.

Subsec. (f)(1)(B). Pub. L. 114–10, §101(a)(1)(B)(i), inserted ''through 2014'' after ''of each succeeding year''.

Subsec. (f)(2). Pub. L. 114–10, §101(a)(1)(B)(ii), inserted ''and ending with 2014'' after ''beginning with 2000'' in introductory provisions.

Subsec. (k)(9). Pub. L. 114–10, §101(b)(2)(B)(i), added par. (9).

Subsec. (m)(3)(C)(ii). Pub. L. 114–10, §101(d)(1)(A), inserted ''and, for 2016 and subsequent years, may provide'' after ''shall provide''.

Subsec. (m)(3)(D). Pub. L. 114–10, §101(d)(1)(B), inserted ''and, for 2016 and subsequent years, subparagraph (A) or (C)'' after ''subparagraph (A)''.

Subsec. (m)(5)(F). Pub. L. 114–10, §101(d)(2), substituted ''through reporting periods occurring in 2015'' for ''and subsequent years'' and inserted ''and, for reporting periods occurring in 2016 and subsequent years, the Secretary may establish'' after ''shall establish''.

Subsec. (m)(7) to (9). Pub. L. 114–10, §101(b)(2)(B)(ii), redesignated par. (7) relating to additional incentive payment as (8) and added par. (9).

Subsec. (n)(11). Pub. L. 114–10, §101(d)(3), added par. (11).

Subsec. (*o*)(2)(A). Pub. L. 114–10, §101(b)(1)(B)(i), in introductory provisions, substituted ''An'' for ''For purposes of paragraph (1), an'' and inserted '', or pursuant to subparagraph (D) for purposes of subsection (q), for a performance period under such subsection for a year'' after ''under such subsection for a year''.

Subsec. (*o*)(2)(A)(ii). Pub. L. 114–10, §106(b)(2)(A), inserted '', and the professional demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the professional has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology'' before period at end.

Subsec. (*o*)(2)(A)(iii). Pub. L. 114–10, §101(d)(4), inserted ''and subsection (q)(5)(B)(ii)(II)'' after ''Subject to subparagraph (B)(ii)''.

Subsec. (*o*)(2)(D). Pub. L. 114–10, §101(b)(1)(B)(ii), added subpar. (D).

Subsec. (p)(2)(C). Pub. L. 114–10, §101(b)(3)(B)(i), added subpar. (C).

Subsec. (p)(3). Pub. L. 114–10, §101(b)(3)(B)(ii), inserted at end ''With respect to 2019 and each subsequent year, the Secretary shall, in accordance with subsection (q)(1)(F), carry out this paragraph for purposes of subsection (q).''

Subsec. (p)(4)(B)(iii). Pub. L. 114–10, §101(b)(3)(A), amended cl. (iii) generally. Prior to amendment, text read as follows: ''The Secretary shall apply the payment modifier established under this subsection for items and services furnished—

''(I) beginning on January 1, 2015, with respect to specific physicians and groups of physicians the Secretary determines appropriate; and

''(II) beginning not later than January 1, 2017, with respect to all physicians and groups of physicians.''

Subsec. (q). Pub. L. 114–10, §101(c)(1), added subsec. (q).

Subsec. (r). Pub. L. 114–10, §101(f), added subsec. (r).

Subsec. (s). Pub. L. 114–10, §102, added subsec. (s).

2014—Subsec. (c)(2)(B)(ii)(I). Pub. L. 113–93, §220(e)(2)(A), substituted ''subclause (II) and paragraph (7)'' for ''subclause (II)''.

Subsec. (c)(2)(B)(v)(VIII). Pub. L. 113–295, §202(1)(A), substituted ''2016'' for ''2017'' in subcl. (VIII) relating to reductions for misvalued services if target not met.

Pub. L. 113–93, §220(d)(2), added subcl. (VIII) relating to reductions for misvalued services if target not met.

Pub. L. 113–93, §218(a)(2)(B), added subcl. (VIII) relating to reduced expenditures attributable to application of quality incentives for computed tomography.

Subsec. (c)(2)(B)(v)(IX). Pub. L. 113–295, §202(1)(B), redesignated subcl. (VIII) relating to reductions for misvalued services if target not met as (IX).

Subsec. (c)(2)(C)(i). Pub. L. 113–93, §220(f)(1), substituted ''the service or group of services'' for ''the service'' in two places.

Subsec. (c)(2)(C)(ii). Pub. L. 113–93, §220(f)(2), inserted ''or group of services'' after ''furnishing the service'' the first time appearing in concluding provisions.

Subsec. (c)(2)(C)(iii). Pub. L. 113–93, §220(f)(1), substituted ''the service or group of services'' for ''the service'' wherever appearing.

Subsec. (c)(2)(K)(ii). Pub. L. 113–93, § 220(c), amended cl. (ii) generally. Prior to amendment, text read as follows: ''For purposes of identifying potentially misvalued services pursuant to clause (i)(I), the Secretary shall examine (as the Secretary determines to be appropriate) codes (and families of codes as appropriate) for which there has been the fastest growth; codes (and families of codes as appropriate) that have experienced substantial changes in practice expenses; codes for new technologies or services within an appropriate period (such as 3 years) after the relative values are initially established for such codes; multiple codes that are frequently billed in conjunction with furnishing a single service; codes with low relative values, particularly those that are often billed multiple times for a single treatment; codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes'); and such other codes determined to be appropriate by the Secretary.''

Subsec. (c)(2)(K)(iii)(VI). Pub. L. 113–93, § 220(e)(2)(B), substituted ''provisions of subparagraph (B)(ii)(II) and paragraph (7)'' for ''provisions of subparagraph (B)(ii)(II)'' and ''under subparagraph (B)(ii)(I)'' for ''under subparagraph (B)(ii)(II)''.

Subsec. (c)(2)(M). Pub. L. 113–93, § 220(a)(1), added subpar. (M).

Subsec. (c)(2)(N). Pub. L. 113–93, § 220(b), added subpar. (N).

Subsec. (c)(2)(O). Pub. L. 113–295, § 202(2)(A), substituted ''2016 through 2018'' for ''2017 through 2020'' in introductory provisions.

Pub. L. 113–93, § 220(d)(1), added subpar. (O).

Subsec. (c)(2)(O)(iii). Pub. L. 113–295, § 202(2)(B), substituted ''2016'' for ''2017''.

Subsec. (c)(2)(O)(v). Pub. L. 113–295, § 202(2)(C), inserted ''(or, for 2016, 1.0 percent)'' after ''0.5 percent''.

Subsec. (c)(7). Pub. L. 113–295, § 202(3), substituted ''2016'' for ''2017''.

Pub. L. 113–93, § 220(e)(1), added par. (7).

Subsec. (d)(15). Pub. L. 113–93, § 101(1)(A), struck out ''January through March of'' before ''2014'' in heading.

Subsec. (d)(15)(A). Pub. L. 113–93, § 101(1)(B), struck out ''for the period beginning on January 1, 2014, and ending on March 31, 2014'' after ''2014''.

Subsec. (d)(15)(B). Pub. L. 113–93, § 101(1)(C), struck out ''remaining portion of 2014 and'' before ''subsequent years'' in heading and ''the period beginning on April 1, 2014, and ending on December 31, 2014, and for'' before ''2015'' in text.

Subsec. (d)(16). Pub. L. 113–93, § 101(2), added par. (16).

Subsec. (e)(1)(E). Pub. L. 113–93, § 102, substituted ''April 1, 2015'' for ''April 1, 2014''.

Subsec. (e)(6). Pub. L. 113–93, § 220(h)(1), added par. (6).

Subsec. (i)(1)(F). Pub. L. 113–93, § 220(a)(2), added subpar. (F).

Subsec. (j)(2). Pub. L. 113–93, § 220(h)(2), substituted ''Except as provided in subsection (e)(6)(D), the term'' for ''The term''.

2013—Subsec. (b)(4)(C). Pub. L. 112–240, § 635(1), substituted '', 2012, and 2013'' for ''and subsequent years'' and inserted at end ''With respect to fee schedules established for 2014 and subsequent years, in such methodology, the Secretary shall use a 90 percent utilization rate.''

Subsec. (b)(7). Pub. L. 112–240, § 633(a), substituted ''2011, and before April 1, 2013,'' for ''2011,'' and inserted at end ''In the case of such services furnished on or after April 1, 2013, and for which payment is made under such fee schedules, instead of the 25 percent multiple procedure payment reduction specified in such final rule, the reduction percentage shall be 50 percent.''

Subsec. (c)(2)(B)(v)(III). Pub. L. 112–240, § 635(2), substituted ''changes in the utilization rate applicable to 2011 and 2014, as described in the first and second sentence, respectively, of'' for ''change in the utilization rate applicable to 2011, as described in''.

Subsec. (d)(14). Pub. L. 112–240, § 601(a), added par. (14).

Subsec. (d)(15). Pub. L. 113–67, § 1101, added par. (15).

Subsec. (e)(1)(E). Pub. L. 113–67, § 1102, substituted ''April 1, 2014'' for ''January 1, 2014''.

Pub. L. 112–240, § 602, substituted ''before January 1, 2014'' for ''before January 1, 2013''.

Subsec. (m)(3)(D) to (F). Pub. L. 112–240, § 601(b)(1), added subpars. (D) and (E) and redesignated former subpar. (D) as (F).

2012—Subsec. (d)(13). Pub. L. 112–96, § 3003(a)(1), substituted ''2012'' for ''first two months of 2012'' in heading.

Subsec. (d)(13)(A). Pub. L. 112–96, § 3003(a)(2), substituted ''2012'' for ''the period beginning on January 1, 2012, and ending on February 29, 2012''.

Subsec. (d)(13)(B). Pub. L. 112–96, § 3003(a)(3), (4), substituted ''2013'' for ''remaining portion of 2012'' in heading and ''for 2013'' for ''for the period beginning on March 1, 2012, and ending on December 31, 2012, and for 2013'' in text.

Subsec. (e)(1)(E). Pub. L. 112–96, § 3004(a), substituted ''before January 1, 2013'' for ''before March 1, 2012''.

2011—Subsec. (b)(4)(B), (6). Pub. L. 112–78, § 309(1), substituted '', 2011, and the first 2 months of 2012'' for ''and 2011'' wherever appearing.

Subsec. (c)(2)(B)(iv)(IV). Pub. L. 112–78, § 309(2), substituted '', 2011, or the first 2 months of 2012'' for ''or 2011''.

Subsec. (d)(13). Pub. L. 112–78, § 301, added par. (13).

Subsec. (e)(1)(E). Pub. L. 112–78, § 303, substituted ''before March 1, 2012'' for ''before January 1, 2012''.

2010—Subsec. (a)(8). Pub. L. 111–148, § 3002(b), added par. (8).

Subsec. (b)(1). Pub. L. 111–148, § 3007(1), inserted ''subject to subsection (p),'' after ''1998,'' in introductory provisions.

Subsec. (b)(4)(B). Pub. L. 111–152, § 1107(1)(A), substituted ''subparagraph (A)'' for ''this paragraph''.

Pub. L. 111–148, § 3135(a)(1)(A), substituted ''this paragraph'' for ''subparagraph (A)''.

Pub. L. 111–148, § 3111(a)(1)(A)(i), inserted '', and for 2010 and 2011, dual-energy x-ray absorptiometry services (as described in paragraph (6))'' before the period.

Subsec. (b)(4)(C). Pub. L. 111–152, § 1107(1)(B), amended subpar. (C) generally. Prior to amendment, text read as follows: ''Consistent with the methodology for computing the number of practice expense relative value units under subsection (c)(2)(C)(ii) with respect to advanced diagnostic imaging services (as defined in section 1395m(e)(1)(B) of this title) furnished on or after January 1, 2010, the Secretary shall adjust such number of units so it reflects—

''(i) in the case of services furnished on or after January 1, 2010, and before January 1, 2013, a 65 percent (rather than 50 percent) presumed rate of utilization of imaging equipment;

''(ii) in the case of services furnished on or after January 1, 2013, and before January 1, 2014, a 70 percent (rather than 50 percent) presumed rate of utilization of imaging equipment; and

''(iii) in the case of services furnished on or after January 1, 2014, a 75 percent (rather than 50 percent) presumed rate of utilization of imaging equipment.''

Pub. L. 111–148, § 3135(a)(1)(B), added subpar. (C).

Subsec. (b)(4)(D). Pub. L. 111–148, § 3135(b)(1), added subpar. (D).

Subsec. (b)(6). Pub. L. 111–148, § 3111(a)(1)(A)(ii), added par. (6).

Subsec. (b)(7). Pub. L. 111–286, § 3(a), added par. (7).

Subsec. (c)(2)(B)(iv)(IV). Pub. L. 111–148, § 3111(a)(1)(B), added subcl. (IV).

Subsec. (c)(2)(B)(v)(III) to (V). Pub. L. 111–152, § 1107(2), added subcl. (III) and struck out former subcls. (III) to (V), which read as follows:

''(III) CHANGE IN PRESUMED UTILIZATION LEVEL OF CERTAIN ADVANCED DIAGNOSTIC IMAGING SERVICES FOR 2010 THROUGH 2012.—Effective for fee schedules established beginning with 2010 and ending with 2012, reduced expenditures attributable to the presumed rate of utilization of imaging equipment of 65 percent under subsection (b)(4)(C)(i) instead of a presumed rate of utilization of such equipment of 50 percent.

''(IV) CHANGE IN PRESUMED UTILIZATION LEVEL OF CERTAIN ADVANCED DIAGNOSTIC IMAGING SERVICES FOR 2013.—

Effective for fee schedules established for 2013, reduced expenditures attributable to the presumed rate of utilization of imaging equipment of 70 percent under subsection (b)(4)(C)(ii) instead of a presumed rate of utilization of such equipment of 50 percent.

''(V) CHANGE IN PRESUMED UTILIZATION LEVEL OF CERTAIN ADVANCED DIAGNOSTIC IMAGING SERVICES FOR 2014 AND SUBSEQUENT YEARS.—Effective for fee schedules established beginning with 2014, reduced expenditures attributable to the presumed rate of utilization of imaging equipment of 75 percent under subsection (b)(4)(C)(iii) instead of a presumed rate of utilization of such equipment of 50 percent.''

Pub. L. 111–148, §3135(a)(2), added subcls. (III) to (V).

Subsec. (c)(2)(B)(v)(VI). Pub. L. 111–148, §3135(b)(2), added subcl. (VI).

Subsec. (c)(2)(B)(v)(VII). Pub. L. 111–286, §3(b), added subcl. (VII).

Subsec. (c)(2)(B)(vii). Pub. L. 111–148, §5501(c), which directed the addition of cl. (vii), was repealed by Pub. L. 111–148, §10501(h). As enacted, text read as follows: ''Fifty percent of the additional expenditures under this part attributable to subsections (x) and (y) of section 1395*l* of this title for a year (as estimated by the Secretary) shall be taken into account in applying clause (ii)(II) for 2011 and subsequent years. In lieu of applying the budget-neutrality adjustments required under clause (ii)(II) to relative value units to account for such costs for the year, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for the year. For 2011 and subsequent years, the Secretary shall increase the incentive payment otherwise applicable under section 1395*l*(m) of this title by a percent estimated to be equal to the additional expenditures estimated under the first sentence of this clause for such year that is applicable to physicians who primarily furnish services in areas designated (under section 254e(a)(1)(A) of this title) as health professional shortage areas.''

Subsec. (c)(2)(K), (L). Pub. L. 111–148, §3134(a), added subpars. (K) and (L).

Subsec. (d)(10). Pub. L. 111–192, §101(a)(1), substituted ''January through May'' for ''portion'' in heading.

Pub. L. 111–148, §3101, which directed the addition of par. (10) relating to update for 2010, was repealed by Pub. L. 111–148, §10310. As enacted, text read as follows:

''(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), and (9)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010, the update to the single conversion factor shall be 0.5 percent.

''(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2011 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2011 and subsequent years as if subparagraph (A) had never applied.''

Subsec. (d)(10)(A). Pub. L. 111–157, §4(1), substituted ''May 31, 2010'' for ''March 31, 2010''.

Pub. L. 111–144, §5(1), substituted ''March 31, 2010'' for ''February 28, 2010''.

Subsec. (d)(10)(B). Pub. L. 111–157, §4(2), substituted ''June 1, 2010'' for ''April 1, 2010''.

Pub. L. 111–144, §5(2), substituted ''April 1, 2010'' for ''March 1, 2010''.

Subsec. (d)(11). Pub. L. 111–286, §2(1), substituted ''December'' for ''November'' in heading.

Pub. L. 111–192, §101(a)(2), added par. (11).

Subsec. (d)(11)(A). Pub. L. 111–286, §2(2), substituted ''December 31'' for ''November 30''.

Subsec. (d)(11)(B). Pub. L. 111–286, §2(3), substituted ''2011'' for ''remaining portion of 2010'' in heading and struck out ''the period beginning on December 1, 2010, and ending on December 31, 2010, and for'' before ''2011 and subsequent years'' in text.

Subsec. (d)(12). Pub. L. 111–309, §101, added par. (12).

Subsec. (e)(1)(A). Pub. L. 111–148, §10324(c)(1), substituted ''(H), and (I)'' for ''and (H)'' in introductory provisions.

Pub. L. 111–148, §3102(b)(1), substituted ''(G), and (H)'' for ''and (G)'' in introductory provisions.

Subsec. (e)(1)(E). Pub. L. 111–309, §103, substituted ''before January 1, 2012'' for ''before January 1, 2011''.

Pub. L. 111–148, §3102(a), substituted ''before January 1, 2011'' for ''before January 1, 2010''.

Subsec. (e)(1)(H). Pub. L. 111–148, §3102(b)(2), added subpar. (H).

Subsec. (e)(1)(H)(i). Pub. L. 111–152, §1108, substituted ''½'' for ''¾''.

Subsec. (e)(1)(I). Pub. L. 111–148, §10324(c)(2), added subpar. (I).

Subsec. (j)(3). Pub. L. 111–148, §4103(c)(2), inserted ''(2)(FF) (including administration of the health risk assessment),'' after ''(2)(EE),''.

Subsec. (k)(4). Pub. L. 111–148, §3002(c)(1), inserted ''or through a Maintenance of Certification program operated by a specialty body of the American Board of Medical Specialties that meets the criteria for such a registry'' after ''Database)''.

Subsec. (m)(1)(A). Pub. L. 111–148, §3002(a)(1)(A), substituted ''2014'' for ''2010'' in introductory provisions.

Subsec. (m)(1)(B)(iii), (iv). Pub. L. 111–148, §3002(a)(1)(B), added cls. (iii) and (iv).

Subsec. (m)(3)(A). Pub. L. 111–148, §3002(a)(2)(A), inserted ''(or, for purposes of subsection (a)(8), for the quality reporting period for the year)'' after ''reporting period'' in introductory provisions.

Subsec. (m)(3)(C)(i). Pub. L. 111–148, §3002(a)(2)(B), inserted '', or, for purposes of subsection (a)(8), for a quality reporting period for the year'' after ''(a)(5), for a reporting period for a year''.

Subsec. (m)(5)(E). Pub. L. 111–148, §3002(f)(1), substituted ''Except as provided in subparagraph (I), there shall'' for ''There shall'' in introductory provisions.

Subsec. (m)(5)(E)(iv). Pub. L. 111–148, §3002(a)(3), substituted ''paragraphs (5)(A) and (8)(A) of subsection (a)'' for ''subsection (a)(5)(A)''.

Subsec. (m)(5)(H), (I). Pub. L. 111–148, §3002(e), (f)(2), added subpars. (H) and (I).

Subsec. (m)(6)(C)(i)(II). Pub. L. 111–148, §3002(a)(4)(A), substituted ''and subsequent years'' for '', 2009, 2010, and 2011''.

Subsec. (m)(6)(C)(iii). Pub. L. 111–148, §3002(a)(4)(B), inserted ''(a)(8)'' after ''(a)(5)'' and substituted ''under subsection (a)(5)(D)(iii) or the quality reporting period under subsection (a)(8)(D)(iii), respectively'' for ''under subparagraph (D)(iii) of such subsection''.

Subsec. (m)(7). Pub. L. 111–148, §10327(a), added par. (7) relating to additional incentive payment.

Pub. L. 111–148, §3002(d), added par. (7) relating to integration of physician quality reporting and EHR reporting.

Subsec. (n)(1)(A). Pub. L. 111–148, §3003(a)(1)(A), designated existing provisions as cl. (i), inserted heading, substituted ''the 'Program').'' for ''the 'Program') under which the Secretary shall use claims data under this subchapter (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this subchapter. If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this subchapter by the physician (or group of physicians) in such reports.'', and added cls. (ii) and (iii).

Subsec. (n)(1)(B). Pub. L. 111–148, §3003(a)(1)(B), substituted ''subparagraph (A)(ii)'' for ''subparagraph (A)'' in introductory provisions.

Subsec. (n)(4). Pub. L. 111–148, §3003(a)(2)(B), inserted ''initial'' after ''focus the'' in introductory provisions.

Pub. L. 111–148, §3003(a)(2)(A), inserted ''initial'' after ''focus'' in heading.

Subsec. (n)(6). Pub. L. 111–148, §3003(a)(3), inserted at end ''For adjustments for reports on utilization under paragraph (9), see subparagraph (D) of such paragraph.''

Subsec. (n)(9), (10). Pub. L. 111–148, §3003(a)(4), added pars. (9) and (10).

Subsec. (*o*)(1)(C)(ii). Pub. L. 111–157, §5(a)(1), substituted ''inpatient or emergency room setting'' for ''setting (whether inpatient or outpatient)''.

Subsec. (p). Pub. L. 111–148, § 3007(2), added subsec. (p).

2009—Subsec. (a)(5)(A)(i). Pub. L. 111–5, § 4101(f)(1)(A), substituted '', 2013 or 2014'' for ''or any subsequent year''.

Subsec. (a)(5)(A)(ii)(III). Pub. L. 111–5, § 4101(f)(1)(B), struck out ''and each subsequent year'' after ''2014''.

Subsec. (a)(7). Pub. L. 111–5, § 4101(b), added par. (7).

Subsec. (d)(10). Pub. L. 111–118 added par. (10).

Subsec. (m)(2)(A). Pub. L. 111–5, § 4101(f)(2)(A), substituted ''Subject to subparagraph (D), for 2009'' for ''For 2009''.

Subsec. (m)(2)(D). Pub. L. 111–5, § 4101(f)(2)(B), added subpar. (D).

Subsec. (*o*). Pub. L. 111–5, § 4101(a), added subsec. (*o*).

2008—Subsec. (a)(4)(A). Pub. L. 110–275, § 139(a)(1), inserted ''except as provided in paragraph (5),'' after ''anesthesia cases,''.

Subsec. (a)(5). Pub. L. 110–275, § 132(b), added par. (5).

Subsec. (a)(6). Pub. L. 110–275, § 139(a)(2), added par. (6).

Subsec. (b)(5). Pub. L. 110–275, § 144(a)(2)(B), added par. (5).

Subsec. (c)(2)(B)(vi). Pub. L. 110–275, § 133(b), added cl. (vi).

Subsec. (d)(8). Pub. L. 110–275, § 131(a)(1)(A)(i), struck out ''a portion of'' before ''2008'' in heading.

Subsec. (d)(8)(A). Pub. L. 110–275, § 131(a)(1)(A)(ii), struck out ''for the period beginning on January 1, 2008, and ending on June 30, 2008,'' after ''for 2008,''.

Subsec. (d)(8)(B). Pub. L. 110–275, § 131(a)(1)(A)(iii), struck out ''the remaining portion of 2008 and'' before ''2009'' in heading and ''for the period beginning on July 1, 2008, and ending on December 31, 2008, and'' before ''for 2009'' in text.

Subsec. (d)(9). Pub. L. 110–275, § 131(a)(1)(B), added par. (9).

Subsec. (e)(1)(A). Pub. L. 110–275, § 134(c), amended Pub. L. 108–173, § 602(1). See 2003 Amendment note below.

Subsec. (e)(1)(E). Pub. L. 110–275, § 134(a), substituted ''before January 1, 2010'' for ''before July 1, 2008''.

Subsec. (e)(1)(G). Pub. L. 110–275, § 134(b), inserted at end ''For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5''.

Subsec. (j)(3). Pub. L. 110–275, § 152(b)(1)(C), inserted ''(2)(EE),'' after ''(2)(DD),''.

Pub. L. 110–275, § 144(a)(2)(A), inserted ''(2)(DD),'' after ''(2)(AA),''.

Subsec. (k)(2)(C), (D). Pub. L. 110–275, § 131(b)(1), added subpars. (C) and (D).

Subsec. (k)(3)(B)(iv). Pub. L. 110–275, § 131(b)(4)(A), added cl. (iv).

Subsec. (*l*)(2)(A)(i)(III). Pub. L. 110–275, § 131(a)(3)(C)(i)(I), struck out subcl. (III) which read as follows: ''For expenditures during 2013, an amount equal to $4,670,000,000.''

Pub. L. 110–252, § 7002(c)(1)(A), substituted ''$4,670,000,000'' for ''$4,960,000,000''.

Subsec. (*l*)(2)(A)(i)(IV). Pub. L. 110–275, § 131(a)(3)(C)(i)(I), struck out subcl. (IV) which read as follows: ''For expenditures during 2014, an amount equal to $290,000,000.''

Pub. L. 110–252, § 7002(c)(1)(B), added subcl. (IV).

Subsec. (*l*)(2)(A)(ii)(III). Pub. L. 110–275, § 131(a)(3)(C)(i)(II), struck out subcl. (III). Text read as follows: ''The amount available for expenditures during 2013 shall only be available for an adjustment to the update of the conversion factor under subsection (d) for that year.''

Subsec. (*l*)(2)(A)(ii)(IV). Pub. L. 110–275, § 131(a)(3)(C)(i)(II), struck out subcl. (IV). Text read as follows: ''The amount available for expenditures during 2014 shall only be available for an adjustment to the update of the conversion factor under subsection (d) for that year.''

Pub. L. 110–252, § 7002(c)(2), added subcl. (IV).

Subsec. (*l*)(2)(B). Pub. L. 110–275, § 131(a)(3)(C)(ii), inserted ''and'' at end of cl. (i), substituted period for semicolon at end of cl. (ii), and struck out cls. (iii) and (iv) which read as follows:

''(iii) 2013 for payment with respect to physicians' services furnished during 2013; and

''(iv) 2014 for payment with respect to physicians' services furnished during 2014.''

Subsec. (*l*)(2)(B)(iv). Pub. L. 110–252, § 7002(c)(3), added cl. (iv).

Subsec. (m). Pub. L. 110–275, § 131(b)(2), (3)(A), transferred subsec. (c) of section 101 of title I of div. B of Pub. L. 109–432 to subsec. (m) of this section and amended heading generally. Prior to amendment, heading read ''Transitional Bonus Incentive Payments for Quality Reporting in 2007 and 2008''. See Codification note above.

Subsec. (m)(1). Pub. L. 110–275, § 131(b)(3)(B), added par. (1) and struck out former par. (1) which provided for an additional payment for certain covered professional services furnished by an eligible professional.

Subsec. (m)(2). Pub. L. 110–275, § 132(a)(1), added par. (2). Former par. (2) redesignated (3).

Subsec. (m)(3). Pub. L. 110–275, § 132(a)(2)(A), inserted ''and successful electronic prescriber'' after ''reporting'' in heading.

Pub. L. 110–275, § 131(b)(3)(D)(i), (ii), designated existing provisions as subpar. (A) and inserted heading, redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A), and realigned margins.

Pub. L. 110–275, § 131(b)(3)(C), redesignated par. (2) as (3) and struck out former par. (3) which provided for payment limitation.

Subsec. (m)(3)(A). Pub. L. 110–275, § 131(b)(3)(D)(iii), inserted concluding provisions.

Subsec. (m)(3)(B). Pub. L. 110–275, § 132(a)(2)(B), added subpar. (B). Former subpar. (B) redesignated cl. (i) of subpar. (A).

Subsec. (m)(3)(C), (D). Pub. L. 110–275, § 131(b)(3)(D)(iv), added subpars. (C) and (D).

Subsec. (m)(5)(A). Pub. L. 110–275, § 131(b)(5)(A)(i), substituted ''subsection (k)'' for ''section 1848(k) of the Social Security Act, as added by subsection (b),'' and ''such subsection'' for ''such section''.

Subsec. (m)(5)(B). Pub. L. 110–275, § 131(b)(5)(A)(ii), struck out ''of the Social Security Act (42 U.S.C. 1395*l*)'' before ''and any payment''.

Subsec. (m)(5)(C). Pub. L. 110–275, § 131(b)(3)(E)(i), inserted ''for 2007, 2008, and 2009,'' after ''provision of law,''.

Subsec. (m)(5)(D)(i). Pub. L. 110–275, § 131(b)(3)(E)(ii)(I), which directed amendment of cl. (i) by inserting ''for 2007 and 2008'' after ''under this subsection'' and then substituting ''this subsection'' for ''paragraph (2)'', was executed by substituting ''under this subsection for 2007 and 2008'' for ''under paragraph (2)'' to reflect the probable intent of Congress.

Subsec. (m)(5)(D)(ii). Pub. L. 110–275, § 131(b)(3)(E)(ii)(II), substituted ''may establish procedures to'' for ''shall''.

Subsec. (m)(5)(D)(iii). Pub. L. 110–275, § 131(b)(3)(E)(ii)(III), inserted ''(or, in the case of a group practice under paragraph (3)(C), the group practice)'' after ''an eligible professional'', substituted ''incentive payment under this subsection'' for ''bonus incentive payment'', and inserted at end ''If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).''

Subsec. (m)(5)(E). Pub. L. 110–275, § 131(b)(5)(A)(iii), substituted ''1395ff of this title, section 1395*oo* of this title, or otherwise'' for ''1869 or 1878 of the Social Security Act or otherwise''.

Pub. L. 110–275, § 131(b)(3)(E)(iii)(I)–(III), struck out cl. (i) designation and heading before ''There shall be'', redesignated subcls. (I) to (IV) as cls. (i) to (iv), respectively, and struck out former cl. (ii). Prior to amendment, text of cl. (ii) read as follows: ''A determination under this subsection shall not be treated as a determination for purposes of section 1869 of the Social Security Act.''

Subsec. (m)(5)(E)(ii). Pub. L. 110–275, §131(b)(3)(E)(iii)(IV), substituted ''this subsection'' for ''paragraph (2)''.

Subsec. (m)(5)(E)(iii). Pub. L. 110–275, §132(a)(3), added cl. (iii) and struck out former cl. (iii) which read as follows: ''the determination of the payment limitation under paragraph (3); and''.

Subsec. (m)(5)(E)(iv). Pub. L. 110–275, §131(b)(3)(E)(iii)(V), substituted ''any'' for ''the bonus'' and inserted ''and the payment adjustment under subsection (a)(5)(A)'' before period at end.

Subsec. (m)(5)(F). Pub. L. 110–275, §131(b)(3)(E)(iv), (5)(A)(iv), substituted ''subsequent years,'' for ''2009, paragraph (3) shall not apply, and'', ''this subsection'' for ''paragraph (2)'', ''subsection (k)(2)(B)'' for ''paragraph (2)(B) of section 1848(k)'' of the Social Security Act (42 U.S.C. 1395w–4(k))'', and ''subsection (k)(4)'' for ''paragraph (4) of such section''.

Subsec. (m)(5)(G). Pub. L. 110–275, §131(b)(3)(E)(v), added subpar. (G).

Subsec. (m)(6)(A). Pub. L. 110–275, §131(b)(5)(B)(i), substituted ''subsection (k)(3)'' for ''section 1848(k)(3) of the Social Security Act, as added by subsection (b)''.

Subsec. (m)(6)(B). Pub. L. 110–275, §131(b)(5)(B)(ii), substituted ''subsection (k)'' for ''section 1848(k) of the Social Security Act, as added by subsection (b)''.

Subsec. (m)(6)(C). Pub. L. 110–275, §131(b)(3)(F), added subpar. (C) and struck out former subpar. (C). Prior to amendment, text read as follows: ''The term 'reporting period' means—

''(i) for 2007, the period beginning on July 1, 2007, and ending on December 31, 2007; and

''(ii) for 2008, all of 2008.''

Subsec. (m)(6)(D). Pub. L. 110–275, §131(b)(5)(C), struck out subpar. (D). Text read as follows: ''The term 'Secretary' means the Secretary of Health and Human Services.''

Subsec. (n). Pub. L. 110–275, §131(c)(1), added subsec. (n).

2007—Subsec. (d)(4)(B). Pub. L. 110–173, §101(a)(1)(A), substituted ''and the succeeding paragraphs of this subsection'' for ''and paragraphs (5) and (6)'' in introductory provisions.

Subsec. (d)(8). Pub. L. 110–173, §101(a)(1)(B), added par. (8).

Subsec. (e)(1)(E). Pub. L. 110–173, §103, substituted ''before July 1, 2008'' for ''before January 1, 2008''.

Subsec. (k)(2)(B). Pub. L. 110–173, §101(b)(1), in heading and cl. (i), inserted ''and 2009'' after ''2008'', and, in cls. (ii) and (iii), substituted ''of each of 2007 and 2008'' for '', 2007'' and inserted ''or 2009, as applicable'' after ''2008''.

Subsec. (*l*)(2)(A). Pub. L. 110–173, §101(a)(2)(A)(i), added subpar. (A) and struck out former subpar. (A), which read as follows: ''There shall be available to the Fund for expenditures an amount equal to $1,200,000,000, as reduced by section 524 and section 225(c)(1)(A) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008). In addition, there shall be available to the Fund for expenditures during 2009 an amount equal to $325,000,000, as reduced by section 225(c)(1)(B) of such Act, and for expenditures during or after 2013 an amount equal to $60,000,000.''

Pub. L. 110–161, §524, which directed amendment of subpar. (A) by reducing the dollar amount in the first sentence by $150,000,000, was executed by substituting ''$1,200,000,000'' for ''$1,350,000,000'' in first sentence.

Pub. L. 110–161, §225(c)(2), inserted, in first sentence, '', as reduced by section 524 and section 225(c)(1)(A) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008)'' after ''$1,350,000,000'' and, in second sentence, '', as reduced by section 225(c)(1)(B) of such Act,'' after ''$325,000,000''.

Pub. L. 110–90, §6(1), inserted at end: ''In addition, there shall be available to the Fund for expenditures during 2009 an amount equal to $325,000,000 and for expenditures during or after 2013 an amount equal to $60,000,000.''

Subsec. (*l*)(2)(B). Pub. L. 110–173, §101(a)(2)(A)(ii), substituted ''entire amount available for expenditures, after application of subparagraph (A)(ii), during—'' and cls. (i) to (iii) for ''entire amount specified in the first sentence of subparagraph (A) for payment with respect to physicians' services furnished during 2008 and for the obligation of the entire first amount specified in the second sentence of such subparagraph for payment with respect to physicians' services furnished during 2009 and of the entire second amount so specified for payment with respect to physicians' services furnished on or after January 1, 2013.''

Pub. L. 110–90, §6(2), in heading, struck out ''furnished during 2008'' after ''services'' and, in text, substituted ''specified in the first sentence of subparagraph (A)'' for ''specified in subparagraph (A)'' and inserted ''and for the obligation of the entire first amount specified in the second sentence of such subparagraph for payment with respect to physicians' services furnished during 2009 and of the entire second amount so specified for payment with respect to physicians' services furnished on or after January 1, 2013'' after ''furnished during 2008''.

2006—Subsec. (b)(4). Pub. L. 109–171, §5102(b)(1), added par. (4).

Subsec. (c)(2)(B)(ii)(II). Pub. L. 109–171, §5102(a)(1), substituted ''clauses (iv) and (v)'' for ''clause (iv)''.

Subsec. (c)(2)(B)(iv). Pub. L. 109–171, §5102(a)(2), inserted ''of certain additional expenditures'' after ''Exemption'' in heading.

Subsec. (c)(2)(B)(v). Pub. L. 109–171, §5102(a)(3), added cl. (v).

Subsec. (c)(2)(B)(v)(II). Pub. L. 109–171, §5102(b)(2), added subcl. (II).

Subsec. (d)(4)(B). Pub. L. 109–171, §5104(a)(1), substituted ''paragraphs (5) and (6)'' for ''paragraph (5)'' in introductory provisions.

Subsec. (d)(6). Pub. L. 109–171, §5104(a)(2), added par. (6).

Subsec. (d)(7). Pub. L. 109–432, §101(a), added par. (7).

Subsec. (e)(1)(E). Pub. L. 109–432, §102, substituted ''2008'' for ''2007''.

Subsec. (j)(3). Pub. L. 109–171, §5112(c), inserted ''(2)(AA),'' after ''(2)(W),''.

Subsec. (k). Pub. L. 109–432, §101(b), added subsec. (k).

Subsec. (*l*). Pub. L. 109–432, §101(d), added subsec. (*l*).

2003—Subsec. (c)(2)(B)(ii)(II). Pub. L. 108–173, §303(a)(1)(A)(i), substituted ''Subject to clause (iv), the adjustments'' for ''The adjustments''.

Subsec. (c)(2)(B)(iv). Pub. L. 108–173, §303(a)(1)(A)(ii), added cl. (iv).

Subsec. (c)(2)(H) to (J). Pub. L. 108–173, §303(a)(1)(B), added subpars. (H) to (J).

Subsec. (d)(4)(B). Pub. L. 108–173, §601(a)(2), inserted ''and paragraph (5)'' after ''subparagraph (D)'' in introductory provisions.

Subsec. (d)(5). Pub. L. 108–173, §601(a)(1), added par. (5).

Subsec. (e)(1)(A). Pub. L. 108–173, §602(1), as amended by Pub. L. 110–275, §134(c), substituted ''subparagraphs (B), (C), (E), and (G)'' for ''subparagraphs (B), (C), and (E)''.

Pub. L. 108–173, §412(1), substituted ''subparagraphs (B), (C), and (E)'' for ''subparagraphs (B) and (C)''.

Subsec. (e)(1)(E). Pub. L. 108–173, §412(2), added subpar. (E).

Subsec. (e)(1)(G). Pub. L. 108–173, §602(2), added subpar. (G).

Subsec. (f)(2)(C). Pub. L. 108–173, §601(b)(1), substituted ''annual average'' for ''projected'' and ''during the 10-year period ending with the applicable period involved'' for ''from the previous applicable period to the applicable period involved''.

Subsec. (i)(1)(B). Pub. L. 108–173, §303(g)(2), substituted ''subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section'' for ''subsection (c)(2)(F) of this section''.

Subsec. (i)(1)(C). Pub. L. 108–7 amended subpar. (C) generally. Prior to amendment, subpar. (C) read as fol-

lows: ''the determination of conversion factors under subsection (d) of this section,''.

Subsec. (i)(3)(A). Pub. L. 108–173, §736(b)(10), substituted ''comparable services'' for ''a comparable services''.

Subsec. (j)(3). Pub. L. 108–173, §611(c), inserted ''(2)(W),'' after ''(2)(S),''.

2000—Subsec. (j)(3). Pub. L. 106–554 inserted ''(13),'' after ''(4),''.

1999—Subsec. (d)(1)(A). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(3)(A)(i)], inserted ''(for years before 2001) and, for years beginning with 2001, multiplied by the update (established under paragraph (4)) for the year involved'' before period at end.

Subsec. (d)(1)(E). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(2)(A)], amended heading and text of subpar. (E) generally. Prior to amendment, text read as follows: ''The Secretary shall cause to have published in the Federal Register, during the last 15 days of October of—

''(i) 1991, the conversion factor which will apply to physicians' services for 1992, and the update determined under paragraph (3) for 1992; and

''(ii) each succeeding year, the conversion factor which will apply to physicians' services for the following year and the update determined under paragraph (3) for such year.''

Subsec. (d)(3). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(1)(A)(i)], inserted ''for 1999 and 2000'' after ''Update'' in heading.

Subsec. (d)(3)(A). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(1)(A)(ii)], substituted ''1999 and 2000'' for ''a year beginning with 1999'' in introductory provisions.

Subsec. (d)(3)(C). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(1)(A)(iii)], inserted ''and paragraph (4)'' after ''For purposes of this paragraph'' in introductory provisions.

Subsec. (d)(4). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(1)(B)], added par. (4).

Subsec. (f)(1). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(1)], amended heading and text of par. (1) generally. Prior to amendment, text read as follows: ''The Secretary shall cause to have published in the Federal Register the sustainable growth rate for each fiscal year beginning with fiscal year 1998. Such publication shall occur by not later than August 1 before each fiscal year, except that such rate for fiscal year 1998 shall be published not later than November 1, 1997.''

Subsec. (f)(2). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(2)(A)], substituted ''fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000'' for ''fiscal year 1998)'' in introductory provisions.

Subsec. (f)(2)(A). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(2)(B)], substituted ''applicable period'' for ''fiscal year''.

Subsec. (f)(2)(B), (C). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(2)(B)], substituted ''applicable period'' for ''fiscal year'' in two places.

Subsec. (f)(2)(D). Pub. L. 106–113, §1000(a)(6) [title II, §211(a)(3)(A)(ii), (b)(2)(B)], substituted ''applicable period'' for ''fiscal year'' in two places and ''subsection (d)(3)(B) or (d)(4)(B) of this section, as the case may be'' for ''subsection (d)(3)(B) of this section''.

Subsec. (f)(3). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(5)], added par. (3). Former par. (3) redesignated (4).

Subsec. (f)(3)(C). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(3)], added subpar. (C).

Subsec. (f)(4). Pub. L. 106–113, §1000(a)(6) [title II, §211(b)(4)], redesignated par. (3) as (4).

Subsec. (j)(3). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(5)], substituted ''section 1395x(*oo*)(2) of this title)'' for ''section 1395x(*oo*)(2) of this title,'', ''(B),'' for ''(B),'', and '', and (15)'' for ''and (15)''.

1997—Subsec. (b)(1). Pub. L. 105–33, §4644(d), substituted ''Before November 1 of the preceding year, for each year beginning with 1998'' for ''Before January 1 of each year beginning with 1992'' in introductory provisions.

Subsec. (c)(2)(B)(iii). Pub. L. 105–33, §4022(b)(2)(C), substituted ''Medicare Payment Advisory Commission'' for ''Physician Payment Review Commission''.

Subsec. (c)(2)(C)(ii). Pub. L. 105–33, §4505(b)(1)(A), which directed an amendment striking the comma at the end of cl. (ii) and inserting a period and the following: ''For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For 2001, such number of units shall be determined based 25 percent on such product and based 75 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.'', was executed by making the insertion at end of cl. (ii) to reflect the probable intent of Congress, because cl. (ii) ended with a period rather than a comma.

Pub. L. 105–33, §4505(a)(1), substituted ''1999'' for ''1998'' in two places.

Subsec. (c)(2)(C)(iii). Pub. L. 105–33, §4505(f)(1)(A), inserted ''for the service for years before 2000'' before ''equal'' in introductory provisions, substituted comma for period at end of subcl. (II), and inserted concluding provisions.

Subsec. (c)(2)(G). Pub. L. 105–33, §4505(e), added subpar. (G).

Subsec. (c)(3)(C)(ii). Pub. L. 105–33, §4505(b)(2), substituted ''2002'' for ''1999'' in introductory provisions.

Pub. L. 105–33, §4505(a)(2), substituted ''1999'' for ''1998'' in introductory provisions.

Subsec. (c)(3)(C)(iii). Pub. L. 105–33, §4505(f)(1)(B), substituted ''For years before 1999, the malpractice'' for ''The malpractice'' in introductory provisions.

Subsec. (d)(1)(A). Pub. L. 105–33, §4501(b)(1), (2), struck out ''(or factors)'' after ''conversion factor'' in two places and struck out ''or updates'' after ''update''.

Subsec. (d)(1)(C). Pub. L. 105–33, §4504(a)(1), substituted ''Except as provided in subparagraph (D), the single conversion factor'' for ''The single conversion factor''.

Pub. L. 105–33, §4501(a)(2), added subpar. (C). Former subpar. (C) redesignated (D).

Subsec. (d)(1)(D). Pub. L. 105–33, §4504(a)(3), added subpar. (D). Former subpar. (D) redesignated (E).

Pub. L. 105–33, §4501(b)(1), (3), struck out ''(or updates)'' after ''update'' in two places and struck out ''(or factors)'' after ''conversion factor'' in cl. (ii).

Pub. L. 105–33, §4501(a)(1), redesignated subpar. (C) as (D).

Subsec. (d)(1)(E). Pub. L. 105–33, §4504(a)(2), redesignated subpar. (D) as (E).

Subsec. (d)(2). Pub. L. 105–33, §4502(b), struck out heading and text of par. (2) which related to recommendation of update.

Subsec. (d)(2)(F). Pub. L. 105–33, §4022(b)(1)(B)(i), struck out heading and text of subpar. (F). Text read as follows: ''The Physician Payment Review Commission shall review the report submitted under subparagraph (A) in a year and shall submit to the Congress, by not later than May 15 of the year, a report including its recommendations respecting the update (or updates) in the conversion factor (or factors) for the following year.''

Subsec. (d)(3). Pub. L. 105–33, §4502(a)(1), amended heading and text generally. Prior to amendment, text related to updates of conversion factor based on index and made provision for adjustments in update.

Subsec. (f). Pub. L. 105–33, §4503(b), amended subsec. heading and heading and text of par. (1) generally. Prior to amendment, par. (1) related to process for establishing medicare volume performance standard rates of increase.

Subsec. (f)(1)(B). Pub. L. 105–33, §4022(b)(2)(B)(ii), struck out heading and text of subpar. (B). Text read as follows: ''The Physician Payment Review Commission shall review the recommendation transmitted during a year under subparagraph (A) and shall make its recommendation to Congress, by not later than May 15 of the year, respecting the performance standard rates of increase for the fiscal year beginning in that year.''

Subsec. (f)(2). Pub. L. 105–33, § 4503(a), added par. (2) and struck out heading and text of former par. (2) which related to specification of performance standard rates of increase for physician services for fiscal years beginning in 1991.

Subsec. (f)(3). Pub. L. 105–33, § 4503(a), added par. (3) and struck out heading and text of former par. (3). Text read as follows: ''The Secretary shall establish procedures for providing, on a quarterly basis to the the Congressional Budget Office, the Congressional Research Service, the Committees on Ways and Means and Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate, information on compliance with performance standard rates of increase established under this subsection.''

Pub. L. 105–33, § 4022(b)(2)(B)(iii), struck out ''Physician Payment Review Commission,'' before ''the Congressional Budget Office''.

Subsec. (f)(4), (5). Pub. L. 105–33, § 4503(a), struck out heading and text of par. (4) which related to separate group-specific performance standard rates of increase and par. (5) which defined ''physicians' services'' and ''HMO enrollee''.

Subsec. (g)(3)(A). Pub. L. 105–33, § 4714(b)(2), inserted before period at end ''and the provisions of section 1396a(n)(3)(A) of this title apply to further limit permissible charges under this section''.

Subsec. (g)(6)(C), (7)(C). Pub. L. 105–33, § 4022(b)(2)(C), substituted ''Medicare Payment Advisory Commission'' for ''Physician Payment Review Commission''.

Subsec. (j)(1). Pub. L. 105–33, § 4501(b)(4), substituted ''For services furnished before January 1, 1998, the term'' for ''The term''.

Subsec. (j)(3). Pub. L. 105–33, § 4106(b), substituted ''(4), (14)'' for ''(4) and (14)'' and inserted ''and (15)'' after ''1395x(nn)(2) of this title)''.

Pub. L. 105–33, § 4105(a)(2), inserted ''(2)(S),'' before ''(3)''.

Pub. L. 105–33, § 4103(d), inserted ''(2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1395x(*oo*)(2) of this title,'' after ''(2)(G)''.

Pub. L. 105–33, §§ 4102(d), 4104(d), inserted ''(2)(R) (with respect to services described in subparagraphs (B) , (C), and (D) of section 1395x(pp)(1) of this title),'' before ''(3)'' and substituted ''(4) and (14) (with respect to services described in section 1395x(nn)(2) of this title)'' for ''and (4)''.

1994—Subsec. (a)(2)(D)(iii). Pub. L. 103–432, § 126(b)(6), struck out ''that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989'' after ''nuclear medicine services'' and substituted ''provided under section 6105(b) of the Omnibus Budget Reconciliation Act of 1989'' for ''provided under such section''.

Subsec. (c)(2)(C)(ii). Pub. L. 103–432, § 121(b)(1), inserted ''for the service for years before 1998'' before ''equal to'' in introductory provisions, substituted comma for period at end of subcl. (II), and inserted ''and for years beginning with 1998 based on the relative practice expense resources involved in furnishing the service.'' as closing provisions.

Subsec. (c)(3)(C)(ii). Pub. L. 103–432, § 121(b)(2), substituted ''For years before 1998, the practice'' for ''The practice''.

Subsec. (c)(4). Pub. L. 103–432, § 126(g)(6), made technical amendment to directory language of Pub. L. 101–508, § 4118(f)(1)(D). See 1990 Amendment note below.

Subsec. (e)(1)(C). Pub. L. 103–432, § 126(g)(5), inserted ''date of the'' before ''last previous adjustment''.

Pub. L. 103–432, § 122(a), substituted ''shall, in consultation with appropriate representatives of physicians, review'' for ''shall review''.

Subsec. (e)(1)(D). Pub. L. 103–432, § 122(b), added subpar. (D).

Subsec. (f)(2)(A)(i). Pub. L. 103–432, § 126(g)(7), made technical amendment to directory language of Pub. L. 101–508, § 4118(f)(1)(N)(ii). See 1990 Amendment note below.

Subsec. (f)(2)(C). Pub. L. 103–432, § 126(g)(2)(B), inserted heading.

Subsec. (g)(1). Pub. L. 103–432, § 123(a)(1), amended heading and text of par. (1) generally. Prior to amendment, text read as follows: ''If a nonparticipating physician or nonparticipating supplier or other person (as defined in section 1395u(i)(2) of this title) knowingly and willfully bills on a repeated basis for physicians' services (including services which the Secretary excludes pursuant to subsection (j)(3) of this section, furnished with respect to an individual enrolled under this part on or after January 1, 1991) an actual charge in excess of the limiting charge described in paragraph (2) and for which payment is not made on an assignment-related basis under this part, the Secretary may apply sanctions against such physician, supplier, or other person in accordance with section 1395u(j)(2) of this title. In applying this subparagraph, any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.''

Subsec. (g)(3)(B). Pub. L. 103–432, § 123(a)(2), inserted after first sentence ''No person is liable for payment of any amounts billed for such a service in violation of the previous sentence.'' and in last sentence substituted ''first sentence'' for ''previous sentence''.

Subsec. (g)(6)(B). Pub. L. 103–432, § 123(d), inserted ''information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information'' after ''report to the Congress''.

Subsec. (i)(3). Pub. L. 103–432, § 126(g)(10)(A), struck out space before the period at end.

1993—Subsec. (a)(2)(B)(ii)(I). Pub. L. 103–66, § 13515(c)(1), inserted ''and under section 13515(b) of the Omnibus Budget Reconciliation Act of 1993'' after ''subsection (c)(2)(F)(ii) of this section''.

Pub. L. 103–66, § 13514(c)(1), inserted ''and as adjusted under subsection (c)(2)(F)(ii) of this section'' after ''for 1994''.

Subsec. (a)(3). Pub. L. 103–66, § 13517(a)(1), in heading inserted ''and suppliers'' after ''physicians'' and in text inserted ''or a nonparticipating supplier or other person'' after ''nonparticipating physician'' and inserted at end ''In the case of physicians' services (including services which the Secretary excludes pursuant to subsection (j)(3) of this section) of a nonparticipating physician, supplier, or other person for which payment is made under this part on a basis other than the fee schedule amount, the payment shall be based on 95 percent of the payment basis for such services furnished by a participating physician, supplier, or other person.''

Subsec. (a)(4). Pub. L. 103–66, § 13516(a)(1), added par. (4).

Pub. L. 103–66, § 13515(a)(1), struck out heading and text of par. (4). Text read as follows: ''In the case of physicians' services furnished by a physician before the end of the physician's first full calendar year of furnishing services for which payment may be made under this part, and during each of the 3 succeeding years, the fee schedule amount to be applied shall be 80 percent, 85 percent, 90 percent, and 95 percent, respectively, of the fee schedule amount applicable to physicians who are not subject to this paragraph. The preceding sentence shall not apply to primary care services or services furnished in a rural area (as defined in section 1395ww(d)(2) of this title) that is designated under section 249(a)(1)(A) of this title as a health manpower shortage area.''

Subsec. (b)(3). Pub. L. 103–66, § 13514(a), amended heading and text of par. (3) generally. Prior to amendment, text read as follows: ''If payment is made under this part for a visit to a physician or consultation with a physician and, as part of or in conjunction with the visit or consultation there is an electrocardiogram performed or ordered to be performed, no payment may be made under this part with respect to the interpretation of the electrocardiogram and no physician may bill an individual enrolled under this part separately for such an interpretation. If a physician knowingly and willfully bills one or more individuals in violation of the previous sentence, the Secretary may apply sanctions against the physician or entity in accordance with section 1395u(j)(2) of this title.''

Subsec. (c)(2)(A)(i). Pub. L. 103–66, §13515(c)(2), inserted before period at end ''and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993''.

Pub. L. 103–66, §13514(c)(2), inserted at end ''Such relative values are subject to adjustment under subparagraph (F)(i).''

Subsec. (c)(2)(E). Pub. L. 103–66, §13513, added subpar. (E).

Subsec. (c)(2)(F). Pub. L. 103–66, §13514(b), added subpar. (F).

Subsec. (d)(3)(A)(i). Pub. L. 103–66, §13511(a)(1)(A), substituted ''clauses (iii) through (v)'' for ''clause (iii)''.

Subsec. (d)(3)(A)(iv) to (vi). Pub. L. 103–66, §13511(a)(1)(B), added cls. (iv) to (vi).

Subsec. (d)(3)(B)(ii). Pub. L. 103–66, §13512(b), substituted ''1994'' for ''1994 or 1995'' in subcl. (II) and ''5'' for ''3'' in subcl. (III).

Subsec. (f)(2)(B). Pub. L. 103–66, §13512(a), added cls. (iii) to (v) and struck out former cl. (iii) which read as follows: ''for each succeeding year is 2 percentage points.''

Subsec. (g)(1). Pub. L. 103–66, §13517(a)(2)(C), (D), inserted '', supplier, or other person'' after ''such physician'' and inserted at end ''In applying this subparagraph, any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.''

Pub. L. 103–66, §13517(a)(2)(B), which directed insertion of ''including services which the Secretary excludes pursuant to subsection (j)(3) of this section,'' after ''physician's services ('', was executed by making the insertion after ''physicians' services ('' to reflect the probable intent of Congress.

Pub. L. 103–66, §13517(a)(2)(A), inserted ''or nonparticipating supplier or other person (as defined in section 1395u(i)(2) of this title)'' after ''nonparticipating physician''.

Subsec. (g)(2)(C). Pub. L. 103–66, §13517(a)(3), inserted ''or for nonparticipating suppliers or other persons'' after ''nonparticipating physicians''.

Subsec. (g)(2)(D). Pub. L. 103–66, §13517(a)(4), inserted ''(or, if payment under this part is made on a basis other than the fee schedule under this section, 95 percent of the other payment basis)'' after ''subsection (a) of this section''.

Subsec. (h). Pub. L. 103–66, §13517(a)(5), inserted ''or nonparticipating supplier or other person furnishing physicians' services (as defined in subsection (j)(3) of this section)'' after ''each physician'', inserted '', supplier, or other person'' after ''by the physician'', and inserted '', suppliers, and other persons'' after ''notices to physicians''.

Subsec. (i)(1)(B). Pub. L. 103–66, §13515(c)(3), inserted ''and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993'' after ''subsection (c)(2)(F) of this section''.

Pub. L. 103–66, §13514(c)(3), inserted at end ''including adjustments under subsection (c)(2)(F) of this section,''.

Subsec. (j)(1). Pub. L. 103–66, §13511(a)(2), substituted ''Secretary and including anesthesia services), primary care services (as defined in section 1395u(i)(4) of this title),'' for ''Secretary)''.

Subsec. (j)(3). Pub. L. 103–66, §13518(a), inserted ''(2)(G),'' after ''(2)(D),''.

Pub. L. 103–66, §13517(a)(6), inserted '', except for purposes of subsections (a)(3), (g), and (h) of this section'' after ''tests and''.

1990—Subsec. (a)(1). Pub. L. 101–508, §4104(b)(2), struck out ''or 1395m(f)'' after ''section 1395m(b)'' in introductory provisions.

Subsec. (a)(2)(C). Pub. L. 101–508, §4102(b), inserted ''and radiology'' after ''Special rule for anesthesia'' in heading and inserted at end ''With respect to radiology services, '109 percent' and '9 percent' shall be substituted for '115 percent' and '15 percent', respectively, in subparagraph (A)(ii).''

Subsec. (a)(2)(D)(ii). Pub. L. 101–508, §4102(g)(2)(A), inserted '', but excluding nuclear medicine services that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989'' after ''section 1395m(b)(6) of this title)''.

Subsec. (a)(2)(D)(iii). Pub. L. 101–508, §4102(g)(2)(B), added cl. (iii).

Subsec. (a)(4). Pub. L. 101–508, §4106(b)(1), added par. (4).

Subsec. (b)(3). Pub. L. 101–508, §4109(a), added par. (3).

Subsec. (c)(1)(B). Pub. L. 101–508, §4118(f)(1)(A), struck out at end ''In this subparagraph, the term 'practice expenses' includes all expenses for furnishing physicians' services, excluding malpractice expenses, physician compensation, and other physician fringe benefits.''

Subsec. (c)(3). Pub. L. 101–508, §4118(f)(1)(C), redesignated par. (3), relating to ancillary policies, as (4).

Subsec. (c)(3)(C)(ii)(II), (iii)(II). Pub. L. 101–508, §4118(f)(1)(B), struck out ''by'' before ''the proportion''.

Subsec. (c)(4). Pub. L. 101–508, §4118(f)(1)(D), as amended by Pub. L. 103–432, §126(g)(6), substituted ''section'' for ''subsection''.

Pub. L. 101–508, §4118(f)(1)(C), redesignated par. (3), relating to ancillary policies, as (4). Former par. (4) redesignated (5).

Pub. L. 101–508, §4118(d), struck out ''only for services furnished on or after January 1, 1993'' after ''visits and consultations''.

Subsec. (c)(5), (6). Pub. L. 101–508, §4118(f)(1)(C), redesignated pars. (4) and (5) as (5) and (6), respectively.

Subsec. (d)(1)(A). Pub. L. 101–508, §4118(f)(1)(E), (F)(i)(III), amended subpar. (A) identically, substituting ''paragraph (3)'' for ''subparagraph (C)''.

Pub. L. 101–508, §4118(f)(1)(F)(i)(I), (II), substituted ''conversion factor (or factors)'' for ''conversion factor'' in two places and ''update or updates'' for ''update''.

Subsec. (d)(1)(C)(i). Pub. L. 101–508, §4118(f)(1)(F)(ii)(I), substituted ''conversion factor'' for ''conversion factor (or factors)''.

Subsec. (d)(1)(C)(ii). Pub. L. 101–508, §4118(f)(1)(F)(ii)(II), inserted ''the conversion factor (or factors) which will apply to physicians' services for the following year and'' before ''the update (or updates)'' and substituted ''such year'' for ''the following year''.

Subsec. (d)(2)(A). Pub. L. 101–508, §4118(f)(1)(G), (I), substituted ''physicians' services (as defined in subsection (f)(5)(A) of this section)'' for ''physicians' services'' in first sentence and ''proportion of individuals who are enrolled under this part who are HMO enrollees'' for ''proportion of HMO enrollees'' in last sentence.

Subsec. (d)(2)(A)(ii). Pub. L. 101–508, §4118(f)(1)(H), substituted ''and for the services involved'' for ''(as defined in subsection (f)(5)(A) of this section)'' and ''such services'' for ''all such physicians' services''.

Subsec. (d)(2)(E)(i). Pub. L. 101–508, §4118(f)(1)(J), inserted ''the'' before ''most recent''.

Subsec. (d)(2)(E)(ii)(I). Pub. L. 101–508, §4118(f)(1)(K), substituted ''payments for physicians' services'' for ''physicians' services''.

Subsec. (d)(3)(A)(i). Pub. L. 101–508, §4105(a)(3)(A), inserted ''except as provided in clause (iii),'' after ''subparagraph (B),''.

Subsec. (d)(3)(A)(iii). Pub. L. 101–508, §4105(a)(3)(B), added cl. (iii).

Subsec. (d)(3)(B)(i). Pub. L. 101–508, §4118(f)(1)(L)(i)(II), which directed amendment of cl. (i) by substituting ''services in such category'' for ''physicians' services (as defined in subsection (f)(5)(A))'', was executed by making the substitution for ''physicians' services (as defined in section (f)(5)(A))'' to reflect the probable intent of Congress.

Pub. L. 101–508, §4118(f)(1)(L)(i)(I), substituted ''update for a category of physicians' services for a year'' for ''update for a year''.

Subsec. (d)(3)(B)(ii). Pub. L. 101–508, §4118(f)(1)(L)(ii), inserted ''more than'' after ''decrease of'' in introductory provisions and struck out ''more than'' before ''2 percentage points'' in subcl. (I).

Subsec. (e)(1)(A). Pub. L. 101–508, §4118(c)(1), substituted ''subparagraphs (B) and (C)'' for ''subparagraph (B)'' in introductory provisions.

Subsec. (e)(1)(C). Pub. L. 101–508, §4118(c)(2), added subpar. (C).

Subsec. (f)(1)(C). Pub. L. 101–508, §4105(c)(1), substituted ''1991'' for ''1990'' after ''beginning with''.

Subsec. (f)(1)(D)(i). Pub. L. 101–508, §4118(f)(1)(M), substituted ''portions of calendar years'' for ''calendar years''.

Subsec. (f)(2)(A). Pub. L. 101–508, §4118(b)(1), (f)(1)(N)(i), in introductory provisions, substituted ''the performance standard rate of increase, for all physicians' services and for each category of physicians' services,'' for ''each performance standard rate of increase'' and ''product'' for ''sum''.

Pub. L. 101–508, §4118(b)(6), substituted ''minus 1, multiplied by 100, and reduced'' for ''reduced'' in concluding provisions.

Subsec. (f)(2)(A)(i). Pub. L. 101–508, §4118(f)(1)(N)(ii), as amended by Pub. L. 103–432, §126(g)(7), substituted ''all physicians' services or for the category of physicians' services, respectively,'' for ''physicians' services (as defined in subsection (f)(5)(A) of this section)''.

Pub. L. 101–508, §4118(f)(1)(M), substituted ''portions of calendar years'' for ''calendar years''.

Pub. L. 101–508, §4118(b)(2), (3), substituted ''1 plus the Secretary's'' for ''the Secretary's'' and ''percentage increase (divided by 100)'' for ''percentage increase''.

Subsec. (f)(2)(A)(ii). Pub. L. 101–508, §4118(b)(2), (4), substituted ''1 plus the Secretary's'' for ''the Secretary's'' and inserted ''(divided by 100)'' after ''decrease''.

Subsec. (f)(2)(A)(iii). Pub. L. 101–508, §4118(f)(1)(N)(iii), substituted ''all physicians' services or of the category of physicians' services, respectively,'' for ''physicians' services''.

Pub. L. 101–508, §4118(b)(2), (5), substituted ''1 plus the Secretary's'' for ''the Secretary's'' and inserted ''(divided by 100)'' after ''percentage growth''.

Subsec. (f)(2)(A)(iv). Pub. L. 101–508, §4118(e), (f)(1)(N)(iv), substituted ''all physicians' services or of the category of physicians' services, respectively,'' for ''physicians' services (as defined in subsection (f)(5)(A) of this section)'' and inserted ''including changes in law and regulations affecting the percentage increase described in clause (i)'' after ''law or regulations''.

Pub. L. 101–508, §4118(b)(2), (4), substituted ''1 plus the Secretary's'' for ''the Secretary's'' and ''decrease (divided by 100)'' for ''decrease''.

Subsec. (f)(2)(C). Pub. L. 101–508, §4105(c)(2), added subpar. (C).

Subsec. (f)(4)(A). Pub. L. 101–508, §4118(f)(1)(O), substituted ''subparagraph (B)'' for ''paragraph (B)''.

Subsec. (f)(4)(B). Pub. L. 101–508, §4118(f)(1)(P), substituted ''specifically approved by law'' for ''Congress specifically approves the plan''.

Subsec. (g)(2)(A). Pub. L. 101–508, §4118(f)(1)(Q), inserted ''other than radiologist services subject to section 1395m(b) of this title,'' after ''during 1991,'' in introductory provisions.

Pub. L. 101–508, §4116, inserted at end ''In the case of evaluation and management services (as specified in section 1395u(b)(16)(B)(ii) of this title), the preceding sentence shall be applied by substituting '40 percent' for '25 percent'.''

Subsec. (g)(2)(B). Pub. L. 101–508, §4118(f)(1)(Q), inserted ''other than radiologist services subject to section 1395m(b) of this title,'' after ''during 1992,'' in introductory provisions.

Subsec. (i)(1)(A). Pub. L. 101–508, §4118(f)(1)(R), substituted ''adjusted historical payment basis (as defined in subsection (a)(2)(D)(i)'' for ''historical payment basis (as defined in subsection (a)(2)(C)(i)''.

Subsec. (i)(2). Pub. L. 101–508, §4107(a)(1), added par. (2).

Subsec. (i)(3). Pub. L. 101–508, §4118(k), added par. (3).

Subsec. (j)(1). Pub. L. 101–508, §4118(f)(1)(S), which directed the amendment of par. (1) by substituting ''(as defined by the Secretary) and all other physicians' services'' for '', and such other'' and all that follows through the period was executed by making the substitution for '', and such other category or categories of physicians' services as the Secretary, from time to time, defines in regulation.'' to reflect the probable intent of Congress.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2015 AMENDMENT

Pub. L. 114–10, title I, §106(b)(2)(C), Apr. 16, 2015, 129 Stat. 140, provided that: ''The amendments made by this subsection [amending this section and section 1395ww of this title] shall apply to meaningful EHR users [which term has the meaning given under 42 U.S.C. 1395f(*l*)(3), 42 U.S.C. 1395w–4(*o*), 42 U.S.C. 1395w–23(*l*), (m), and 42 U.S.C. 1395ww(n)] as of the date that is one year after the date of the enactment of this Act [Apr. 16, 2015].''

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–157, §5(b), Apr. 15, 2010, 124 Stat. 1117, provided that: ''The amendments made by subsection (a) [amending this section and section 1396b of this title] shall be effective as if included in the enactment of the HITECH Act [Pub. L. 111–5, div. A, title XIII, div. B, title IV] (included in the American Recovery and Reinvestment Act of 2009 (Public Law 111–5)).''

Pub. L. 111–152, title I, §1108, Mar. 30, 2010, 124 Stat. 1050, provided that the amendment made by section 1108 is effective as if included in the enactment of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Pub. L. 111–148, title III, §3002(c)(2), Mar. 23, 2010, 124 Stat. 365, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply for years after 2010.''

Amendment by section 4103(c)(2) of Pub. L. 111–148 applicable to services furnished on or after Jan. 1, 2011, see section 4103(e) of Pub. L. 111–148, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §144(a)(3), July 15, 2008, 122 Stat. 2547, provided that: ''The amendments made by this subsection [amending this section and section 1395x of this title] shall apply to items and services furnished on or after January 1, 2010.''

Pub. L. 110–275, title I, §152(b)(2), July 15, 2008, 122 Stat. 2553, provided that: ''The amendments made by this subsection [amending this section and sections 1395x and 1395y of this title] shall apply to services furnished on or after January 1, 2010.''

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110–173, title I, §101(a)(2)(B), Dec. 29, 2007, 121 Stat. 2494, provided that:

''(i) IN GENERAL.—Subject to clause (ii), the amendments made by subparagraph (A) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 29, 2007].

''(ii) SPECIAL RULE FOR COORDINATION WITH CONSOLIDATED APPROPRIATIONS ACT, 2008.—If the date of the enactment of the Consolidated Appropriations Act, 2008 [Dec. 26, 2007], occurs on or after the date described in clause (i), the amendments made by subparagraph (A) shall be deemed to be made on the day after the effective date of sections 225(c)(1) [121 Stat. 2190] and 524 [amending this section] of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008).''

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by section 5112(c) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2007, see section 5112(f) of Pub. L. 109–171, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title VI, §601(b)(2), Dec. 8, 2003, 117 Stat. 2301, provided that: ''The amendments made by

paragraph (1) [amending this section] shall apply to computations of the sustainable growth rate for years beginning with 2003.''

Pub. L. 108–173, title VI, § 611(e), Dec. 8, 2003, 117 Stat. 2304, provided that: ''The amendments made by this section [amending this section and sections 1395x and 1395y of this title] shall apply to services furnished on or after January 1, 2005, but only for individuals whose coverage period under part B [probably means part B of title XVIII of the Social Security Act, 42 U.S.C. 1395j et seq.] begins on or after such date.''

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106–554 applicable with respect to screening mammographies furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I, § 104(c)] of Pub. L. 106–554, set out as a note under section 1395m of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, § 1000(a)(6) [title II, § 211(d)], Nov. 29, 1999, 113 Stat. 1536, 1501A–350, provided that: ''The amendments made by this section [amending this section and sections 1395b–6 and 1395*l* of this title] shall be effective in determining the conversion factor under section 1848(d) of the Social Security Act (42 U.S.C. 1395w–4(d)) for years beginning with 2001 and shall not apply to or affect any update (or any update adjustment factor) for any year before 2001.''

Amendment by section 1000(a)(6) [title III, § 321(k)(5)] 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 4022(b)(2)(B), (C) of Pub. L. 105–33 effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105–33 set out as an Effective Date; Transition; Transfer of Functions note under section 1395b–6 of this title.

Amendment by section 4102(d) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4103(d) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 2000, see section 4103(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4104(d) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4105(a)(2) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4105(d)(1) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Amendment by section 4106(b) of Pub. L. 105–33 applicable to bone mass measurements performed on or after July 1, 1998, see section 4106(d) of Pub. L. 105–33, set out as a note under section 1395x of this title.

Pub. L. 105–33, title IV, § 4502(a)(2), Aug. 5, 1997, 111 Stat. 433, provided that: ''The amendment made by this subsection [amending this section] shall apply to the update for years beginning with 1999.''

Pub. L. 105–33, title IV, § 4504(b), Aug. 5, 1997, 111 Stat. 435, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1998.''

Amendment by section 4714(b)(2) of Pub. L. 105–33 applicable to payment for (and with respect to provider agreements with respect to) items and services furnished on or after Aug. 5, 1997, see section 4714(c) of Pub. L. 105–33, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 123(a) of Pub. L. 103–432 applicable to services furnished on or after Oct. 31, 1994, but inapplicable to services of nonparticipating supplier or other person furnished before Jan. 1, 1995, see section 123(f)(1) of Pub. L. 103–432, set out as a note under section 1395*l* of this title.

Pub. L. 103–432, title I, § 123(f)(5), Oct. 31, 1994, 108 Stat. 4413, provided that: ''The amendment made by subsection (d) [amending this section] shall apply to reports for years beginning with 1995.''

Amendment by section 126(b)(6), (g)(2)(B), (5)–(7), (10)(A) 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.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, § 13511(b), Aug. 10, 1993, 107 Stat. 581, provided that: ''The amendments made by this section [amending this section] shall apply to services furnished on or after January 1, 1994; except that amendment made by subsection (a)(2) shall not apply—

''(1) to volume performance standard rates of increase established under section 1848(f) of the Social Security Act [42 U.S.C. 1395w–4(f)] for fiscal years before fiscal year 1994, and

''(2) to adjustment in updates in the conversion factors for physicians' services under section 1848(d)(3)(B) of such Act for physicians' services to be furnished in calendar years before 1996.''

Pub. L. 103–66, title XIII, § 13514(d), Aug. 10, 1993, 107 Stat. 583, provided that: ''The amendments made by this section [amending this section] shall apply to services furnished on or after January 1, 1994.''

Amendment by section 13515(a)(1) of Pub. L. 103–66 applicable to services furnished on or after Jan. 1, 1994, see section 13515(d) of Pub. L. 103–66, set out as a note under section 1395u of this title.

Pub. L. 103–66, title XIII, § 13517(c), Aug. 10, 1993, 107 Stat. 586, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, § 13518(c), Aug. 10, 1993, 107 Stat. 586, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1995.''

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4102(b), (g)(2) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4102(i)(1) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4104(b)(2) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4104(d) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

Amendment by section 4106(b)(1) of Pub. L. 101–508 applicable to services furnished after 1991, see section 4106(d)(2) of Pub. L. 101–508, set out as a note under section 1395u of this title.

Pub. L. 101–508, title IV, § 4107(a)(2), Nov. 5, 1990, 104 Stat. 1388–62, as amended by Pub. L. 103–432, title I, § 126(d)(2), Oct. 31, 1994, 108 Stat. 4415, provided that: ''Section 1848(i)(2) of the Social Security Act [42 U.S.C. 1395w–4(i)(2)], as added by the amendment made by paragraph (1), shall apply to services furnished in 1991 in the same manner as it applies to services furnished after 1991. In applying the previous sentence, the prevailing charge shall be substituted for the fee schedule amount. In applying section 1848(g)(2)(D) of the Social Security Act for services of an assistant-at-surgery furnished during 1991, the recognized payment amount shall not exceed the maximum amount specified under section 1848(i)(2)(A) of such Act (as applied under this paragraph in such year).''

Pub. L. 101–508, title IV, § 4107(c), Nov. 5, 1990, 104 Stat. 1388–63, as amended by Pub. L. 103–432, title I, § 126(d)(1), Oct. 31, 1994, 108 Stat. 4415, provided that: ''The amendment made by subsection (a)(1) [amending this section] shall apply with respect to services furnished on or after January 1, 1992.''

Pub. L. 101–508, title IV, §4109(b), Nov. 5, 1990, 104 Stat. 1388–63, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1992. In applying section 1848(d)(1)(B) of the Social Security Act [42 U.S.C. 1395w–4(d)(1)(B)] (in computing the initial budget-neutral conversion factor for 1991), the Secretary shall compute such factor assuming that section 1848(b)(3) of such Act (as added by the amendment made by subsection (a)) had applied to physicians' services furnished during 1991.''

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.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103–7 (in which item 8 on page 94 identifies a reporting provision which, as subsequently amended, is contained in subsec. (g)(6)(B) of this section and in which item 9 on page 94 identifies a reporting provision which is contained in subsec. (g)(7)(B) of this section), see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

IMPLEMENTATION

Pub. L. 114–115, §4(c), Dec. 28, 2015, 129 Stat. 3133, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services shall implement the provisions of, and the amendments made by, subsections (a) and (b) [amending this section and section 1395ww of this title] by program instruction, such as through information on the Internet website of the Centers for Medicare & Medicaid Services.''

EDUCATION AND OUTREACH CAMPAIGN

Pub. L. 114–10, title I, §103(b)(1), Apr. 16, 2015, 129 Stat. 132, provided that:

''(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall conduct an education and outreach campaign to inform professionals who furnish items and services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] and individuals enrolled under such part of the benefits of chronic care management services described in section 1848(b)(8) of the Social Security Act [42 U.S.C. 1395w–4(b)(8)], as added by subsection (a), and encourage such individuals with chronic care needs to receive such services.

''(B) REQUIREMENTS.—Such campaign shall—

''(i) be directed by the Office of Rural Health Policy of the Department of Health and Human Services and the Office of Minority Health of the Centers for Medicare & Medicaid Services; and

''(ii) focus on encouraging participation by underserved rural populations and racial and ethnic minority populations.''

RECOMMENDATIONS FOR ACHIEVING WIDESPREAD ELECTRONIC HEALTH RECORD (EHR) INTEROPERABILITY

Pub. L. 114–10, title I, §106(b)(1), Apr. 16, 2015, 129 Stat. 138, provided that:

''(A) OBJECTIVE.—As a consequence of a significant Federal investment in the implementation of health information technology through the Medicare and Medicaid EHR incentive programs, Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018.

''(B) DEFINITIONS.—In this paragraph:

''(i) WIDESPREAD INTEROPERABILITY.—The term 'widespread interoperability' means interoperability between certified EHR technology systems employed by meaningful EHR users under the Medicare and Medicaid EHR incentive programs and other clinicians and health care providers on a nationwide basis.

''(ii) INTEROPERABILITY.—The term 'interoperability' means the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes.

''(C) ESTABLISHMENT OF METRICS.—Not later than July 1, 2016, and in consultation with stakeholders, the Secretary [of Health and Human Services] shall establish metrics to be used to determine if and to the extent that the objective described in subparagraph (A) has been achieved.

''(D) RECOMMENDATIONS IF OBJECTIVE NOT ACHIEVED.—If the Secretary of Health and Human Services determines that the objective described in subparagraph (A) has not been achieved by December 31, 2018, then the Secretary shall submit to Congress a report, by not later than December 31, 2019, that identifies barriers to such objective and recommends actions that the Federal Government can take to achieve such objective. Such recommended actions may include recommendations—

''(i) to adjust payments for not being meaningful EHR users under the Medicare EHR incentive programs; and

''(ii) for criteria for decertifying certified EHR technology products.''

[As used in section 106(b)(1) of Pub. L. 114–10, set out above, ''certified EHR technology'' has the meaning given in 42 U.S.C. 1395w–4(*o*)(4); ''meaningful EHR user'' has the meaning given under the ''Medicare EHR incentive programs'', which term means the incentive programs under 42 U.S.C. 1395f(*l*)(3), 42 U.S.C. 1395w–4(*o*), 42 U.S.C. 1395w–23(*l*), (m), and 42 U.S.C. 1395ww(n); and ''Medicaid EHR incentive program'' means the incentive program under 42 U.S.C. 1396b(a)(3)(F), (t). See Pub. L. 114–10, title I, §106(b)(4), Apr. 16, 2015, 129 Stat. 140.]

DISCLOSURE OF DATA USED TO ESTABLISH MULTIPLE PROCEDURE PAYMENT REDUCTION POLICY

Pub. L. 113–93, title II, §220(i), Apr. 1, 2014, 128 Stat. 1076, which required the Secretary of Health and Human Services to make publicly available information used to establish the multiple procedure payment reduction policy to the professional component of imaging services in the final rule published in the Federal Register on Nov. 16, 2012, was repealed by Pub. L. 114–113, div. O, title V, §502(a)(2)(C), Dec. 18, 2015, 129 Stat. 3019.

CENTERS FOR MEDICARE & MEDICAID SERVICES TO STUDY REFORM OF PHYSICIAN REIMBURSEMENTS

Pub. L. 113–67, div. B, §1002, Dec. 26, 2013, 127 Stat. 1195, provided that: ''In order to support the provision of quality care for our nation's seniors, Congress finds it appropriate to reform physician reimbursements under the Medicare program. SGR reform legislation provides such an opportunity, but not until next year. In order to facilitate such reform, Congress finds that the Centers for Medicare & Medicaid Services should continue to focus its efforts on the following areas:

''(1) SIMPLIFY AND REDUCE ADMINISTRATIVE BURDEN ON PHYSICIANS.—The application and assessment of measures and other activities under SGR reform should be facilitated by the Centers for Medicare and Medicaid Services (CMS) in a way that accounts for the administrative burden such measurement places on physicians. Therefore, the Congress encourages

CMS to identify and implement, to the extent practicable, mechanisms to ensure that the application and assessment of measures be coordinated across programs.

''(2) TIMELY FEEDBACK FOR PHYSICIANS.—In order for measure and assessment programs to encourage the highest quality care for Medicare seniors, the Congress finds it critical that CMS provide physicians with feedback on performance in as close to real time as possible. Such timely feedback will ensure that physicians can excel under a system of meaningful measurement.

''(3) ENCOURAGE DEVELOPMENT OF NEW MODELS.—There is great need to test alternatives to Fee-For-Service reimbursement in the Medicare program. One option is the promotion and adoption of new models of care for physicians. To date, there has been significant development and testing of models for primary care. Congress supports these efforts and encourages them to continue in the future. Congress also encourages the development and testing of models of specialty care.''

IMPLEMENTATION OF 2010 AMENDMENT

Pub. L. 111–157, § 5(c), Apr. 15, 2010, 124 Stat. 1118, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section [amending this section and section 1396b of this title and enacting provisions set out as a note under this section] by program instruction or otherwise.''

Pub. L. 111–148, title III, § 3111(a)(2), Mar. 23, 2010, 124 Stat. 421, provided that: ''Notwithstanding any other provision of law, the Secretary may implement the amendments made by paragraph (1) [amending this section] by program instruction or otherwise.''

Pub. L. 111–148, title III, § 3134(b)(1), Mar. 23, 2010, 124 Stat. 435, provided that:

''(A) Chapter 35 of title 44, United States Code and the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to this section [amending this section and section 1395ee of this title and repealing provisions set out as a note under this section] or the amendment made by this section.

''(B) Notwithstanding any other provision of law, the Secretary may implement subparagraphs (K) and (L) of [section] 1848(c)(2) of the Social Security Act [42 U.S.C. 1395w–4(c)(2)(K), (L)], as added by subsection (a), by program instruction or otherwise.

''(C) [Repealed section 4505(d) of Pub. L. 105–33, formerly set out below.]

''(D) Except for provisions related to confidentiality of information, the provisions of the Federal Acquisition Regulation shall not apply to this section or the amendment made by this section.''

AUTHORITY TO INCORPORATE MAINTENANCE OF CERTIFICATION PROGRAMS INTO MEASURES OF QUALITY OF CARE

Pub. L. 111–148, title III, § 3002(c)(3), as added by Pub. L. 111–148, title X, § 10327(b), Mar. 23, 2010, 124 Stat. 963, provided that: ''For years after 2014, if the Secretary of Health and Human Services determines it to be appropriate, the Secretary may incorporate participation in a Maintenance of Certification Program and successful completion of a qualified Maintenance of Certification Program practice assessment into the composite of measures of quality of care furnished pursuant to the physician fee schedule payment modifier, as described in section 1848(p)(2) of the Social Security Act (42 U.S.C. 1395w–4(p)(2)).''

NO CHANGE IN BILLING

Pub. L. 110–275, title I, § 131(b)(4)(B), July 15, 2008, 122 Stat. 2525, provided that: ''Nothing in the amendment made by subparagraph (A) [amending this section] shall be construed to change the way in which billing for audiology services (as defined in section 1861(*ll*)(2) of the Social Security Act (42 U.S.C. 1395x(*ll*)(2))) occurs under title XVIII of such Act [42 U.S.C. 1395 et seq.] as of July 1, 2008.''

NO EFFECT ON INCENTIVE PAYMENTS FOR 2007 OR 2008

Pub. L. 110–275, title I, § 131(b)(6), July 15, 2008, 122 Stat. 2526, provided that: ''Nothing in the amendments made by this subsection or section 132 [amending this section] shall affect the operation of the provisions of section 1848(m) of the Social Security Act [42 U.S.C. 1395w–4(m)], as redesignated and amended by such subsection and section, with respect to 2007 or 2008.''

ADJUSTMENT FOR MEDICARE MENTAL HEALTH SERVICES

Pub. L. 110–275, title I, § 138, July 15, 2008, 122 Stat. 2541, as amended by Pub. L. 111–148, title III, § 3107, Mar. 23, 2010, 124 Stat. 418; Pub. L. 111–309, title I, § 107, Dec. 15, 2010, 124 Stat. 3288; Pub. L. 112–78, title III, § 307, Dec. 23, 2011, 125 Stat. 1285, provided that:

''(a) PAYMENT ADJUSTMENT.—

''(1) IN GENERAL.—For purposes of payment for services furnished under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) during the period beginning on July 1, 2008, and ending on February 29, 2012, the Secretary of Health and Human Services shall increase the fee schedule otherwise applicable for specified services by 5 percent.

''(2) NONAPPLICATION OF BUDGET-NEUTRALITY.—The budget-neutrality provision of section 1848(c)(2)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)(ii)) shall not apply to the adjustments described in paragraph (1).

''(b) DEFINITION OF SPECIFIED SERVICES.—In this section, the term 'specified services' means procedure codes for services in the categories of the Health Care Common Procedure Coding System, established by the Secretary of Health and Human Services under section 1848(c)(5) of the Social Security Act (42 U.S.C. 1395w–4(c)(5)), as of July 1, 2007, and as subsequently modified by the Secretary, consisting of psychiatric therapeutic procedures furnished in office or other outpatient facility settings or in inpatient hospital, partial hospital, or residential care facility settings, but only with respect to such services in such categories that are in the subcategories of services which are—

''(1) insight oriented, behavior modifying, or supportive psychotherapy; or

''(2) interactive psychotherapy.

''(c) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this section by program instruction or otherwise.''

TRANSFER OF FUNDS TO PART B TRUST FUND

Pub. L. 110–173, title I, § 101(a)(2)(C), Dec. 29, 2007, 121 Stat. 2494, provided that: ''Amounts that would have been available to the Physician Assistance and Quality Initiative Fund under section 1848(*l*)(2) of the Social Security Act (42 U.S.C. 1395w–4(*l*)(2)) for payment with respect to physicians' services furnished prior to January 1, 2013, but for the amendments made by subparagraph (A) [amending this section], shall be deposited into, and made available for expenditures from, the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).''

TRANSITIONAL BONUS INCENTIVE PAYMENTS FOR QUALITY REPORTING IN 2007 AND 2008

Pub. L. 109–432, div. B, title I, § 101(c), Dec. 20, 2006, 120 Stat. 2977, as amended, formerly set out as a note under this section, was transferred to subsec. (m) of this section.

TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL

Pub. L. 108–173, title III, § 303(a)(2), Dec. 8, 2003, 117 Stat. 2236, provided that: ''The Secretary [of Health and Human Services] shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the

Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments made by paragraph (1) [amending this section].''

PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE

Pub. L. 108–173, title III, §303(a)(3), Dec. 8, 2003, 117 Stat. 2236, provided that:

''(A) REVIEW OF POLICY.—The Secretary [of Health and Human Services] shall review the policy, as in effect on October 1, 2003, with respect to payment under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for the administration of more than 1 drug or biological to an individual on a single day through the push technique.

''(B) MODIFICATION OF POLICY.—After conducting the review under subparagraph (A), the Secretary shall modify such payment policy as the Secretary determines to be appropriate.

''(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE.—If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).''

TRANSITIONAL ADJUSTMENT

Pub. L. 108–173, title III, §303(a)(4), Dec. 8, 2003, 117 Stat. 2237, provided that:

''(A) IN GENERAL.—In order to provide for a transition during 2004 and 2005 to the payment system established under the amendments made by this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395*l*, 1395u, 1395x, 1395y, and 1396r–8 of this title, and repealing provisions set out as a note under section 1395u of this title], in the case of physicians' services consisting of drug administration services described in subparagraph (H)(iv) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), furnished on or after January 1, 2004, and before January 1, 2006, in addition to the amount determined under the fee schedule under section 1848(b) of such Act (42 U.S.C. 1395w–4(b)) there also shall be paid to the physician from the Federal Supplementary Medical Insurance Trust Fund an amount equal to the applicable percentage specified in subparagraph (B) of such fee schedule amount for the services so determined.

''(B) APPLICABLE PERCENTAGE.—The applicable percentage specified in this subparagraph for services furnished—

''(i) during 2004, is 32 percent; and

''(ii) during 2005, is 3 percent.''

MEDPAC REVIEW AND REPORTS; SECRETARIAL RESPONSE

Pub. L. 108–173, title III, §303(a)(5), Dec. 8, 2003, 117 Stat. 2237, provided that:

''(A) REVIEW.—The Medicare Payment Advisory Commission shall review the payment changes made under this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395*l*, 1395u, 1395x, 1395y, and 1396r–8 of this title, enacting provisions set out as notes under this section and sections 1395u, 1395w–3a, and 1395w–3b of this title, and repealing provisions set out as a note under section 1395u of this title] insofar as they affect payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.]—

''(i) for items and services furnished by oncologists; and

''(ii) for drug administration services furnished by other specialists.

''(B) OTHER MATTERS STUDIED.—In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect—

''(i) the quality of care furnished to individuals enrolled under part B and the satisfaction of such individuals with that care;

''(ii) the adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and

''(iii) the impact on physician practices.

''(C) REPORTS.—The Commission shall submit to the Secretary [of Health and Human Services] and Congress—

''(i) not later than January 1, 2006, a report on the review conducted under subparagraph (A)(i); and

''(ii) not later than January 1, 2007, a report on the review conducted under subparagraph (A)(ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

''(D) SECRETARIAL RESPONSE.—As part of the rulemaking with respect to payment for physicians services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for 2007, the Secretary may make appropriate adjustments to payment for items and services described in subparagraph (A)(i), taking into account the report submitted under such subparagraph (C)(i).''

MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL, AND TRANSITIONAL ADJUSTMENT

Pub. L. 108–173, title III, §303(g)(3), Dec. 8, 2003, 117 Stat. 2253, provided that: ''There shall be no administrative or judicial review under section 1869 [probably means section 1869 of the Social Security Act, 42 U.S.C. 1395ff], section 1878 [probably means section 1878 of the Social Security Act, 42 U.S.C. 1395*oo*], or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (2) through (4) of subsection (a) [enacting provisions set out as notes under this section].''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable 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, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES

Pub. L. 108–173, title IV, §413(c), Dec. 8, 2003, 117 Stat. 2277, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

''(A) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

''(B) an evaluation of the measures used for such adjustment, including the frequency of revisions;

''(C) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component; and

''(D) an evaluation of the effect of the adjustment to the physician work geographic index under section 1848(e)(1)(E) of the Social Security Act [42 U.S.C. 1395w–4(e)(1)(E)], as added by section 412, on physician location and retention in areas affected by such adjustment, taking into account—

''(i) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

''(ii) the mobility of physicians, including specialists, over the last decade.

''(2) REPORT.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).''

AMENDMENTS NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION

Pub. L. 109–171, title V, § 5104(b), Feb. 8, 2006, 120 Stat. 41, provided that: ''The amendments made by subsection (a) [amending this section] shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).''

Pub. L. 108–173, title VI, § 601(a)(3), Dec. 8, 2003, 117 Stat. 2301, provided that: ''The amendments made by this subsection [amending this section] shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).''

COLLABORATIVE DEMONSTRATION-BASED REVIEW OF PHYSICIAN PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT DATA

Pub. L. 108–173, title VI, § 605, Dec. 8, 2003, 117 Stat. 2302, provided that:

''(a) IN GENERAL.—Not later than January 1, 2005, the Secretary [of Health and Human Services] shall, in collaboration with State and other appropriate organizations representing physicians, and other appropriate persons, review and consider alternative data sources than those currently used in establishing the geographic index for the practice expense component under the medicare physician fee schedule under section 1848(e)(1)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(A)(i)).

''(b) SITES.—The Secretary shall select two physician payment localities in which to carry out subsection (a). One locality shall include rural areas and at least one locality shall be a statewide locality that includes both urban and rural areas.

''(c) REPORT AND RECOMMENDATIONS.—

''(1) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the review and consideration conducted under subsection (a). Such report shall include information on the alternative developed data sources considered by the Secretary under subsection (a), including the accuracy and validity of the data as measures of the elements of the geographic index for practice expenses under the medicare physician fee schedule as well as the feasibility of using such alternative data nationwide in lieu of current proxy data used in such index, and the estimated impacts of using such alternative data.

''(2) RECOMMENDATIONS.—The report submitted under paragraph (1) shall contain recommendations on which data sources reviewed and considered under subsection (a) are appropriate for use in calculating the geographic index for practice expenses under the medicare physician fee schedule.''

MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES

Pub. L. 108–173, title VI, § 606, Dec. 8, 2003, 117 Stat. 2302, provided that:

''(a) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

''(1) The effect of such refinements on payment for physicians' services.

''(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

''(3) The appropriateness of the amount of compensation by reason of such refinements.

''(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

''(5) The effect of such refinements on physician participation under the medicare program.

''(b) VOLUME OF PHYSICIANS' SERVICES.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians' services under part B [42 U.S.C. 1395j et seq.] of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

''(1) An analysis of recent and historic growth in the components that the Secretary [of Health and Human Services] includes under the sustainable growth rate (under section 1848(f) of the Social Security Act (42 U.S.C. 1395w–4(f))).

''(2) An examination of the relative growth of volume in physicians' services between medicare beneficiaries and other populations.

''(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

''(4) An examination of the impact on volume of demographic changes.

''(5) An examination of shifts in the site of service or services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have effected these changes.

''(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.''

MEDPAC STUDY OF PAYMENT FOR CARDIO-THORACIC SURGEONS

Pub. L. 108–173, title VI, § 644, Dec. 8, 2003, 117 Stat. 2323, provided that:

''(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the 'Commission') shall conduct a study on the practice expense relative values established by the Secretary of Health and Human Services under the medicare physician fee

schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

''(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.''

REPORT ON PHYSICIAN COMPENSATION

Pub. L. 108–173, title IX, §953(a)(2), Dec. 8, 2003, 117 Stat. 2428, provided that: ''Not later than 12 months after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).''

TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE

Pub. L. 106–554, §1(a)(6) [title V, §542], Dec. 21, 2000, 114 Stat. 2763, 2763A–550, as amended by Pub. L. 108–173, title VII, §732, Dec. 8, 2003, 117 Stat. 2352; Pub. L. 109–432, div. B, title I, §104, Dec. 20, 2006, 120 Stat. 2981; Pub. L. 110–173, title I, §104, Dec. 29, 2007, 121 Stat. 2495; Pub. L. 110–275, title I, §136, July 15, 2008, 122 Stat. 2540; Pub. L. 111–148, title III, §3104, Mar. 23, 2010, 124 Stat. 417; Pub. L. 111–309, title I, §105, Dec. 15, 2010, 124 Stat. 3287; Pub. L. 112–78, title III, §305, Dec. 23, 2011, 125 Stat. 1284; Pub. L. 112–96, title III, §3006, Feb. 22, 2012, 126 Stat. 189, provided that:

''(a) IN GENERAL.—When an independent laboratory furnishes the technical component of a physician pathology service to a fee-for-service medicare beneficiary who is an inpatient or outpatient of a covered hospital, the Secretary of Health and Human Services shall treat such component as a service for which payment shall be made to the laboratory under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and not as an inpatient hospital service for which payment is made to the hospital under section 1886(d) of such Act (42 U.S.C. 1395ww(d)) or as an outpatient hospital service for which payment is made to the hospital under section 1833(t) of such Act (42 U.S.C. 1395*l*(t)).

''(b) DEFINITIONS.—For purposes of this section:

''(1) COVERED HOSPITAL.—The term 'covered hospital' means, with respect to an inpatient or an outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service medicare beneficiaries who were hospital inpatients or outpatients, respectively, and submitted claims for payment for such component to a medicare carrier (that has a contract with the Secretary under section 1842 of the Social Security Act, 42 U.S.C. 1395u) and not to such hospital.

''(2) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term 'fee-for-service medicare beneficiary' means an individual who—

''(A) is entitled to benefits under part A, or enrolled under part B, or both, of such title [42 U.S.C. 1395c et seq., 1395j et seq.]; and

''(B) is not enrolled in any of the following:

''(i) A Medicare+Choice plan under part C of such title [42 U.S.C. 1395w–21 et seq.].

''(ii) A plan offered by an eligible organization under section 1876 of such Act (42 U.S.C. 1395mm).

''(iii) A program of all-inclusive care for the elderly (PACE) under section 1894 of such Act (42 U.S.C. 1395eee).

''(iv) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203) [101 Stat. 1330–65].

''(c) EFFECTIVE DATE.—This section shall apply to services furnished during the 2-year period beginning on January 1, 2001, and for services furnished during 2005, 2006, 2007, 2008, 2009, 2010, 2011, and the first six months of 2012.

''(d) GAO REPORT.—

''(1) STUDY.—The Comptroller General of the United States shall conduct a study of the effects of the previous provisions of this section on hospitals and laboratories and access of fee-for-service medicare beneficiaries to the technical component of physician pathology services.

''(2) REPORT.—Not later than April 1, 2002, the Comptroller General shall submit to Congress a report on such study. The report shall include recommendations about whether such provisions should be extended after the end of the period specified in subsection (c) for either or both inpatient and outpatient hospital services, and whether the provisions should be extended to other hospitals.''

ONE-TIME PUBLICATION OF INFORMATION ON TRANSITION

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §211(a)(2)(C)], Nov. 29, 1999, 113 Stat. 1536, 1501A–347, provided that: ''The Secretary of Health and Human Services shall cause to have published in the Federal Register, not later than 90 days after the date of the enactment of this section [Nov. 29, 1999], the Secretary's determination, based upon the best available data, of—

''(i) the allowed expenditures under subclauses (I) and (II) of subsection (d)(4)(C)(ii) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), as added by subsection (a)(1)(B), for the 9-month period beginning on April 1, 1999, and for 1999;

''(ii) the estimated actual expenditures described in subsection (d) of such section for 1999; and

''(iii) the sustainable growth rate under subsection (f) of such section for 2000.''

USE OF DATA COLLECTED BY ORGANIZATIONS AND ENTITIES IN DETERMINING PRACTICE EXPENSE RELATIVE VALUES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §212], Nov. 29, 1999, 113 Stat. 1536, 1501A–350, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall establish by regulation (after notice and opportunity for public comment) a process (including data collection standards) under which the Secretary will accept for use and will use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations (other than the Department of Health and Human Services) to supplement the data normally collected by that Department in determining the practice expense component under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)) for purposes of determining relative values for payment for physicians' services under the fee schedule under section 1848 of such Act (42 U.S.C. 1395w–4). The Secretary shall first promulgate such regulation on an interim final basis in a manner that permits the submission and use of data in the computation of practice expense relative value units for payment rates for 2001.

''(b) PUBLICATION OF INFORMATION.—The Secretary shall include, in the publication of the estimated and final updates under section 1848(c) of such Act (42 U.S.C. 1395w–4(c)) for payments for 2001 and for 2002, a description of the process established under subsection (a) for the use of external data in making adjustments in relative value units and the extent to which the Secretary has used such external data in making such adjustments for each such year, particularly in cases in which the data otherwise used are inadequate because

such data are not based upon a large enough sample size to be statistically reliable.''

CONSULTATION WITH ORGANIZATIONS IN ESTABLISHING PAYMENT AMOUNTS FOR SERVICES PROVIDED BY PHYSICIANS

Pub. L. 105–33, title IV, § 4105(a)(3), Aug. 5, 1997, 111 Stat. 367, provided that: ''In establishing payment amounts under section 1848 of the Social Security Act [42 U.S.C. 1395w–4] for physicians' services consisting of diabetes outpatient self-management training services, the Secretary of Health and Human Services shall consult with appropriate organizations, including such organizations representing individuals or medicare beneficiaries with diabetes.''

DEVELOPMENT OF RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS

Pub. L. 105–33, title IV, § 4505(d), Aug. 5, 1997, 111 Stat. 435, which required the Secretary of Health and Human Services to develop new resource-based relative value units in accordance with certain procedures, transmit a report by Mar. 1, 1998, to certain Congressional Committees, publish a notice of proposed rulemaking with the new relative value units on or before May 1, 1998, and allow public comment, was repealed by Pub. L. 111–148, title III, § 3134(b)(1)(C), Mar. 23, 2010, 124 Stat. 435.

APPLICATION OF CERTAIN BUDGET NEUTRALITY PROVISIONS

Pub. L. 105–33, title IV, § 4505(f)(2), Aug. 5, 1997, 111 Stat. 437, provided that: ''In implementing the amendment made by paragraph (1)(A)(ii) [amending this section], the provisions of clauses (ii)(II) and (iii) of section 1848(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)) shall apply in the same manner as they apply to adjustments under clause (ii)(I) of such section.''

DEVELOPMENT OF RESOURCE-BASED METHODOLOGY FOR PRACTICE EXPENSES

Pub. L. 103–432, title I, § 121(a), Oct. 31, 1994, 108 Stat. 4408, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services shall develop a methodology for implementing in 1998 a resource-based system for determining practice expense relative value units for each physicians' service. The methodology utilized shall recognize the staff, equipment, and supplies used in the provision of various medical and surgical services in various settings.

''(2) REPORT.—The Secretary shall transmit a report by June 30, 1996, on the methodology developed under paragraph (1) to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate. The report shall include a presentation of data utilized in developing the methodology and an explanation of the methodology.''

APPLICATION OF SUBSECTION (c)(2)(B)(ii)(II), (iii)

Pub. L. 103–432, title I, § 121(b)(3), Oct. 31, 1994, 108 Stat. 4409, provided that: ''In implementing the amendment made by paragraph (1)(C) [amending this section], the provisions of clauses (ii)(II) and (iii) of section 1848(c)(2)(B) of the Social Security Act [42 U.S.C. 1395w–4(c)(2)(B)(ii)(II), (iii)] shall apply in the same manner as they apply to adjustments under clause (ii)(I) of such section.''

REPORT ON REVIEW PROCESS

Pub. L. 103–432, title I, § 122(c), Oct. 31, 1994, 108 Stat. 4409, provided that not later than 1 year after Oct. 31, 1994, Secretary of Health and Human Services was to study and report to Congress on data necessary to review and revise indices established under subsec. (e)(1)(A) of this section, any limitations on availability of data necessary to review and revise such indices at least every three years, ways of addressing such limitations, with particular attention to the development of alternative data sources for input components for which current index values are based on data collected less frequently than every three years, and costs of developing more accurate and timely data.

RELATIVE VALUE FOR PEDIATRIC SERVICES

Pub. L. 103–432, title I, § 124(a), Oct. 31, 1994, 108 Stat. 4413, provided that: ''The Secretary of Health and Human Services shall fully develop, by not later than July 1, 1995, relative values for the full range of pediatric physicians' services which are consistent with the relative values developed for other physicians' services under section 1848(c) of the Social Security Act [42 U.S.C. 1395w–4(c)]. In developing such values, the Secretary shall conduct such refinements as may be necessary to produce appropriate estimates for such relative values.''

BUDGET NEUTRALITY ADJUSTMENT

For provisions requiring reduction of relative values established under subsec. (c) of this section and amounts determined under subsec. (a)(2)(B)(ii)(I) of this section for 1994 (to be applied for that year and subsequent years) in order to assure that the amendments to this section and section 1395u of this title by section 13515(a) of Pub. L. 103–66 will not result in expenditures under this part that exceed the amount of such expenditures that would have been made if such amendments had not been made, see section 13515(b) of Pub. L. 103–66, set out as a note under section 1395u of this title.

Pub. L. 103–66, title XIII, § 13518(b), Aug. 10, 1993, 107 Stat. 586, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services shall implement the amendment made by subsection (a) [amending this section] in a manner to assure that such amendment will result in expenditures under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in 1995 for services described in such amendment that shall be equal to the amount of expenditures for such services that would have been made if such amendment had not been made.''

ANCILLARY POLICIES; ADJUSTMENT FOR INDEPENDENT LABORATORIES FURNISHING PHYSICIAN PATHOLOGY SERVICES

Pub. L. 101–508, title IV, § 4104(c), Nov. 5, 1990, 104 Stat. 1388–59, provided that: ''The Secretary of Health and Human Services, in establishing ancillary policies under section 1848(c)(3) of the Social Security Act [42 U.S.C. 1395w–4(c)(3)], shall consider an appropriate adjustment to reflect the technical component of furnishing physician pathology services through a laboratory that is independent of a hospital and separate from an attending or consulting physician's office.''

COMPUTATION OF CONVERSION FACTOR FOR 1992

Pub. L. 101–508, title IV, § 4105(b)(2), Nov. 5, 1990, 104 Stat. 1388–60, as amended by Pub. L. 103–432, title I, § 126(g)(2)(A)(i), Oct. 31, 1994, 108 Stat. 4415, provided that: ''In computing the conversion factor under section 1848(d)(1)(B) of the Social Security Act for 1992 [42 U.S.C. 1395w–4(d)(1)(B)], the Secretary of Health and Human Services shall determine the estimated aggregate amount of payments under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] for physicians' services in 1991 assuming that the amendment made by this subsection [amending section 1395u of this title] did not apply.''

Pub. L. 101–508, title IV, § 4106(c), Nov. 5, 1990, 104 Stat. 1388–62, as amended by Pub. L. 103–432, title I, § 126(g)(3), Oct. 31, 1994, 108 Stat. 4416, provided that: ''In computing the conversion factor under section 1848(d)(1)(B) of the Social Security Act [42 U.S.C. 1395w–4(d)(1)(B)] for 1992, the Secretary of Health and Human Services shall determine the estimated aggre-

gate amount of payments under part B [42 U.S.C. 1395j et seq.] for physicians' services in 1991 assuming that the amendments made by this section [amending this section, section 1395u of this title, and provisions set out as a note under section 1395u of this title] (notwithstanding subsection (d) [set out as an Effective Date of 1990 Amendment note under section 1395u of this title]) applied to all services furnished during such year.''

PUBLICATION OF PERFORMANCE STANDARD RATES

Pub. L. 101–508, title IV, §4105(d), Nov. 5, 1990, 104 Stat. 1388–60, as amended by Pub. L. 103–432, title I, §126(g)(2)(C), Oct. 31, 1994, 108 Stat. 4416, provided that: ''Not later than 45 days after the date of the enactment of this Act [Nov. 5, 1990], the Secretary of Health and Human Services, based on the most recent data available, shall estimate and publish in the Federal Register the performance standard rates of increase specified in section 1848(f)(2)(C) of the Social Security Act [42 U.S.C. 1395w–4(f)(2)(C)] for fiscal year 1991.''

STUDY OF REGIONAL VARIATIONS IN IMPACT OF MEDICARE PHYSICIAN PAYMENT REFORM

Pub. L. 101–508, title IV, §4115, Nov. 5, 1990, 104 Stat. 1388–65, provided that:

''(a) STUDY.—The Secretary of Health and Human Services shall conduct a study of—

''(1) factors that may explain geographic variations in Medicare reasonable charges for physicians' services that are not attributable to variations in physician practice costs (including the supply of physicians in an area and area variations in the mix of services furnished);

''(2) the extent to which the geographic practice cost indices applied under the fee schedule established under section 1848 of the Social Security Act [42 U.S.C. 1395w–4] accurately reflect variations in practice costs and malpractice costs (and alternative sources of information upon which to base such indices);

''(3) the impact of the transition to a national, resource-based fee schedule for physicians' services under Medicare on access to physicians' services in areas that experience a disproportionately large reduction in payments for physicians' services under the fee schedule by reason of such variations; and

''(4) appropriate adjustments or modifications in the transition to, or manner of determining payments under, the fee schedule established under section 1848 of the Social Security Act, to compensate for such variations and ensure continued access to physicians' services for Medicare beneficiaries in such areas.

''(b) REPORT.—By not later than July 1, 1992, the Secretary shall submit to Congress a report on the study conducted under subsection (a).''

STATEWIDE FEE SCHEDULE AREAS FOR PHYSICIANS' SERVICES

Pub. L. 101–508, title IV, §4117, Nov. 5, 1990, 104 Stat. 1388–65, as amended by Pub. L. 103–432, title I, §126(f), Oct. 31, 1994, 108 Stat. 4415, provided that: ''Notwithstanding section 1848(j)(2) of the Social Security Act (42 U.S.C. 1395w–4(j)(2)), in the case of the States of Nebraska and Oklahoma the Secretary of Health and Human Services (Secretary) shall treat the State as a single fee schedule area for purposes of determining—

''(1) the adjusted historical payment basis (as defined in section 1848(a)(2)(D) of such Act (42 U.S.C. 1395w–4(a)(2)(D))), and

''(2) the fee schedule amount (as referred to in section 1848(a) (42 U.S.C. 1395w–4(a)) of such Act),

for physicians' services (as defined in section 1848(j)(3) of such Act (42 U.S.C. 1395w–4(j)(3))) furnished on or after January 1, 1992.''

STUDIES

Pub. L. 101–239, title VI, §6102(d), Dec. 19, 1989, 103 Stat. 2185, as amended by Pub. L. 103–432, title I, §126(h)(1), Oct. 31, 1994, 108 Stat. 4416; Pub. L. 105–362, title VI, §601(b)(5), Nov. 10, 1998, 112 Stat. 3286, provided for various studies and reports as follows: (1) directed Comptroller General to conduct study of alternative payment methodology for malpractice component for physicians' services, and to submit report to Congress by not later than Apr. 1, 1991; (2) directed Secretary of Health and Human Services to conduct study of how payments under this section may affect payments to eligible organizations with risk-sharing contracts under section 1395mm of this title, and to submit report to Congress by not later than Apr. 1, 1990; (3) directed Secretary to conduct study of volume performance standard rates of increase for services furnished by geography, specialty, and type of service, and to submit report with appropriate recommendations to Congress by not later than July 1, 1990; (4) directed Physician Payment Review Commission to conduct study of payment for practice and malpractice expenses, including appropriate methods for allocating malpractice expenses to particular procedures which could be incorporated into the determination of relative values for such procedures using a consensus panel and other appropriate methodologies, and to submit report and recommendations to Congress by not later than July 1, 1991; (5) directed Physician Payment Review Commission to conduct study of feasibility and desirability of using Metropolitan Statistical Areas or other payment areas for purposes of payment for physicians' services under this part, and to submit report to Congress by not later than July 1, 1991; (6) directed Physician Payment Review Commission to conduct study of payment for nonphysician providers of medicare services, including physician assistants, clinical psychologists, nurse midwives, and other health practitioners whose services can be billed under medicare program on a fee-for-service basis, and to submit report to Congress by not later than July 1, 1991; (7) directed Physician Payment Review Commission to conduct study of physician fees under State medicaid programs established under subchapter XIX of this chapter, and to submit report with recommendations to Congress by no later than July 1, 1991; and (8) directed Comptroller General to conduct study of effect of anti-trust laws on ability of physicians to act in groups to educate and discipline peers of such physicians in order to reduce and eliminate ineffective practice patterns and inappropriate utilization, and to submit report to Congress by no later than July 1, 1991.

DISTRIBUTION OF MODEL FEE SCHEDULE

Pub. L. 101–239, title VI, §6102(e)(11), Dec. 19, 1989, 103 Stat. 2188, as amended by Pub. L. 101–508, title IV, §4118(f)(2)(E), Nov. 5, 1990, 104 Stat. 1388–70, provided that: ''By September 1, 1990, the Secretary of Health and Human Services shall develop a Model Fee Schedule, using the methodology set forth in section 1848 of the Social Security Act [42 U.S.C. 1395w–4]. The Model Fee Schedule shall include as many services as the Secretary of Health and Human Services concludes can be assigned valid relative values. The Secretary of Health and Human Services shall submit the Model Fee Schedule to the appropriate committees of Congress and make it generally available to the public.''

§ 1395w–5. Public reporting of performance information

(a) In general

(1) Development

Not later than January 1, 2011, the Secretary shall develop a Physician Compare Internet website with information on physicians enrolled in the Medicare program under section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) and other eligible professionals who participate in the Physician Quality Reporting Initiative under section 1848 of such Act (42 U.S.C. 1395w–4).

(2) Plan

Not later than January 1, 2013, and with respect to reporting periods that begin no earlier than January 1, 2012, the Secretary shall also implement a plan for making publicly available through Physician Compare, consistent with subsection (c), information on physician performance that provides comparable information for the public on quality and patient experience measures with respect to physicians enrolled in the Medicare program under such section 1866(j). To the extent scientifically sound measures that are developed consistent with the requirements of this section are available, such information, to the extent practicable, shall include—

(A) measures collected under the Physician Quality Reporting Initiative;

(B) an assessment of patient health outcomes and the functional status of patients;

(C) an assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use;

(D) an assessment of efficiency;

(E) an assessment of patient experience and patient, caregiver, and family engagement;

(F) an assessment of the safety, effectiveness, and timeliness of care; and

(G) other information as determined appropriate by the Secretary.

(b) Other required considerations

In developing and implementing the plan described in subsection (a)(2), the Secretary shall, to the extent practicable, include—

(1) processes to assure that data made public, either by the Centers for Medicare & Medicaid Services or by other entities, is statistically valid and reliable, including risk adjustment mechanisms used by the Secretary;

(2) processes by which a physician or other eligible professional whose performance on measures is being publicly reported has a reasonable opportunity, as determined by the Secretary, to review his or her individual results before they are made public;

(3) processes by the Secretary to assure that the implementation of the plan and the data made available on Physician Compare provide a robust and accurate portrayal of a physician's performance;

(4) data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent practicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance;

(5) processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of a patient;

(6) processes to ensure timely statistical performance feedback is provided to physicians concerning the data reported under any program subject to public reporting under this section; and

(7) implementation of computer and data systems of the Centers for Medicare & Medicaid Services that support valid, reliable, and accurate public reporting activities authorized under this section.

(c) Ensuring patient privacy

The Secretary shall ensure that information on physician performance and patient experience is not disclosed under this section in a manner that violates sections[1] 552 or 552a of title 5 with regard to the privacy of individually identifiable health information.

(d) Feedback from multi-stakeholder groups

The Secretary shall take into consideration input provided by multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Social Security Act [42 U.S.C. 1395aaa(b)(7), 1395aaa–1], as added by section 3014 of this Act, in selecting quality measures for use under this section.

(e) Consideration of transition to value-based purchasing

In developing the plan under this[2] subsection (a)(2), the Secretary shall, as the Secretary determines appropriate, consider the plan to transition to a value-based purchasing program for physicians and other practitioners developed under section 131 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275).

(f) Report to Congress

Not later than January 1, 2015, the Secretary shall submit to Congress a report on the Physician Compare Internet website developed under subsection (a)(1). Such report shall include information on the efforts of and plans made by the Secretary to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(g) Expansion

At any time before the date on which the report is submitted under subsection (f), the Secretary may expand (including expansion to other providers of services and suppliers under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]) the information made available on such website.

(h) Financial incentives to encourage consumers to choose high quality providers

The Secretary may establish a demonstration program, not later than January 1, 2019, to provide financial incentives to Medicare beneficiaries who are furnished services by high quality physicians, as determined by the Secretary based on factors in subparagraphs (A) through (G) of subsection (a)(2). In no case may Medicare beneficiaries be required to pay increased premiums or cost sharing or be subject to a reduction in benefits under title XVIII of the Social Security Act as a result of such demonstration program. The Secretary shall ensure that any such demonstration program does not disadvantage those beneficiaries without reason-

[1] So in original. Probably should be ''section''.

[2] So in original. The word ''this'' probably should not appear.

able access to high performing physicians or create financial inequities under such title.

(i) Definitions

In this section:

(1) Eligible professional

The term ''eligible professional'' has the meaning given that term for purposes of the Physician Quality Reporting Initiative under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(2) Physician

The term ''physician'' has the meaning given that term in section 1861(r) of such Act (42 U.S.C. 1395x(r)).

(3) Physician Compare

The term ''Physician Compare'' means the Internet website developed under subsection (a)(1).

(4) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(Pub. L. 111–148, title X, § 10331, Mar. 23, 2010, 124 Stat. 966.)

REFERENCES IN TEXT

Section 3014 of this Act, referred to in subsec. (d), is section 3014 of Pub. L. 111–148 which enacted section 1395aaa–1 of this title and amended section 1395aaa of this title.

Section 131 of the Medicare Improvements for Patients and Providers Act of 2008, referred to in subsec. (e), is section 131 of Pub. L. 110–275, 122 Stat. 2520, which amended section 1395w–4 of this title, enacted provisions set out as notes under section 1395w–4 of this title, and redesignated provisions formerly set out as a note under section 1395w–4 of this title as section 1395w–4(m).

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Social Security Act which comprises this chapter.

§ 1395w–6. Empowering beneficiary choices through continued access to information on physicians' services

(a) In general

On an annual basis (beginning with 2015), the Secretary shall make publicly available, in an easily understandable format, information with respect to physicians and, as appropriate, other eligible professionals on items and services furnished to Medicare beneficiaries under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(b) Type and manner of information

The information made available under this section shall be similar to the type of information in the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File released by the Secretary with respect to 2012 and shall be made available in a manner similar to the manner in which the information in such file is made available.

(c) Requirements

The information made available under this section shall include, at a minimum, the following:

(1) Information on the number of services furnished by the physician or other eligible professional under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.), which may include information on the most frequent services furnished or groupings of services.

(2) Information on submitted charges and payments for services under such part.

(3) A unique identifier for the physician or other eligible professional that is available to the public, such as a national provider identifier.

(d) Searchability

The information made available under this section shall be searchable by at least the following:

(1) The specialty or type of the physician or other eligible professional.

(2) Characteristics of the services furnished, such as volume or groupings of services.

(3) The location of the physician or other eligible professional.

(e) Integration on physician compare

Beginning with 2016, the Secretary shall integrate the information made available under this section on Physician Compare.

(f) Definitions

In this section:

(1) Eligible professional; physician; Secretary

The terms ''eligible professional'', ''physician'', and ''Secretary'' have the meaning given such terms in section 1395w–5(i) of this title.

(2) Physician compare

The term ''Physician Compare'' means the Physician Compare Internet website of the Centers for Medicare & Medicaid Services (or a successor website).

(Pub. L. 114–10, title I, § 104, Apr. 16, 2015, 129 Stat. 132.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a) and (c)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to this subchapter. Part B of title XVIII of the Act is classified generally to this part. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Medicare Access and CHIP Reauthorization Act of 2015, and not as part of the Social Security Act which comprises this chapter.

PART C—MEDICARE+CHOICE PROGRAM

PRIOR PROVISIONS

A prior part C of this subchapter, consisting of section 1395x et seq., was redesignated part E of this subchapter.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate