

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method for providing coverage of immunosuppressive drugs under the medicare program on a permanent basis, was repealed by Pub.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 1395l, 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 1395l, 1395n, 1395x, and 1395y of this title], out-of-home services as alternative services to in-home care, was repealed by Pub.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 1395l, 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, subsection (a)(2)(B)(i) of this section will be administered as if subclause II of subsection (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 hospital 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”.

#### § 1395l. 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), (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)

(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), 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), the amount paid shall be equal to 100 percent of such negotiated rate,<sup>1</sup> (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) 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), the amounts paid, subject to subsection (i)(9), 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 (I), (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<sup>2</sup> (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 serv-

ices 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 prosthetics (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)(i) except as provided in clause (ii), subject to subparagraph (EE), 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

<sup>1</sup> So in original.

<sup>2</sup> So in original. The word "and" probably should not appear.

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), and (ii) with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1395x(n) of this title, the amounts paid shall be, subject to the fourth sentence of this subsection, 80 percent of the payment amount established under section 1395w-3a of this title (or section 1395w-3b of this title, if applicable) for such insulin, (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) subject to subsection (dd), 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), (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, (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, (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1395m(u) of this title, (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1395m(w) of this title less any copayment required as specified by the Secretary, (DD) with respect to a specified COVID-19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, the amounts paid shall be 100 percent of the payment amount otherwise recognized under such respective specified outpatient payment provision for such service, (EE) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1395w-3a(i) of this title) furnished on or after April 1, 2023, for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1320f-1(c) of this title for which, the payment amount described in section 1395w-3a(b)(1)(B) of this title) for such drug for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be equal to the percent of the payment amount under paragraph (3)(A)(ii)(I) of such section or section 1395w-3a(b)(1)(B) of this title, as applicable, that equals the difference between (i) 100 percent, and (ii) the percent applied under section 1395w-3a(i)(5)(B) of this title<sup>3</sup> (FF) with respect to marriage and family therapist services and mental health counselor services under section 1395x(s)(2)(II) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L), (GG) with respect to lymphedema compression treatment items (as defined in section 1395x(mmm) of this title), the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under the payment basis determined under section 1395m(z) of this title, and (HH) with respect to items and services related to the administra-

<sup>3</sup> So in original. Probably should be followed by a comma.

tion of intravenous immune globulin furnished on or after January 1, 2024, as described in section 1395x(zz) of this title, the amounts paid shall be the lesser of the 80 percent of the actual charge or the payment amount established under section 1395u(o)(8) of this title;

(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), 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) (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), 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), 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) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(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,<sup>4</sup> 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—

<sup>4</sup> See 2010 Amendment note for subsec. (a)(2)(F) to (H) below.

(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 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 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; 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), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(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 but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, 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;

(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; and

(10) with respect to rural emergency hospital services furnished on or after January 1, 2023, the amounts determined under section 1395m(x) 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(o) of this title. For services furnished on or after January 1, 2022, paragraph (1)(Y) 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. The Secretary shall make such adjustments as may be necessary to the amounts paid as specified under paragraph (1)(S)(ii) for insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1395x(n) of this title, such that the amount of coinsurance payable by an individual enrolled under this part for a month's supply of such insulin does not exceed \$35.

#### (b) Deductible provision

Before applying subsection (a) 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) 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 1395l(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,<sup>1</sup> (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) 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), (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), (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), (11) such deductible shall not apply with respect to any specified COVID-19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, (12) such deductible shall not apply with respect<sup>5</sup> a COVID-19 vaccine and its administration described in section 1395x(s)(10)(A) of this title, and (13) such deductible shall not apply with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1395x(n) of this title.<sup>1</sup> 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 accordance 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 or intensive outpatient 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.

**(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**

(1) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such

<sup>5</sup> So in original. Probably should be followed by “to”.

clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided prior to April 1, 2021—

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

(B) in a subsequent year (before April 1, 2021), at the limit established under this paragraph 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.

(2) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic (other than a rural health clinic described in paragraph (3)(B)), the Secretary shall establish such limit, for services provided—

(A) in 2021, after March 31, at \$100 per visit;

(B) in 2022, at \$113 per visit;

(C) in 2023, at \$126 per visit;

(D) in 2024, at \$139 per visit;

(E) in 2025, at \$152 per visit;

(F) in 2026, at \$165 per visit;

(G) in 2027, at \$178 per visit;

(H) in 2028, at \$190 per visit; and

(I) in a subsequent year, at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year.

(3)(A) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic described in subparagraph (B), the Secretary shall establish such limit, with respect to each such rural health clinic, for services provided—

(i) in 2021, after March 31, at an amount equal to the greater of—

(I) with respect to a rural health clinic that had a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or

(bb) the limit described in paragraph (2)(A); and

(II) with respect to a rural health clinic that did not have a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2021; or

(bb) the limit described in paragraph (2)(A); and

(ii) in a subsequent year, at an amount equal to the greater of—

(I) the amount established under subclause (I) or (II) of clause (i), as applicable, or this subclause for the previous year with respect to such rural health clinic, increased by the percentage increase in the MEI applicable to

primary care services furnished as of the first day of such subsequent year; or

(II) the limit established under paragraph (2) for such subsequent year.

(B) A rural health clinic described in this subparagraph is a rural health clinic that—

(i) as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver under subsection (b)(1)(A) of section 1320b-5 of this title during the emergency period described in subsection (g)(1)(B) of such section); and

(ii)(I) as of December 31, 2020, was enrolled under section 1395cc(j) of this title (including temporary enrollment during such emergency period for such emergency period); or

(II) submitted an application for enrollment under section 1395cc(j) of this title (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.

**(g) Physical therapy services**

(1)(A) 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(l)(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). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1395x(p) of this title, speech-language pathology services of the type described in such section through the application of section 1395x(l)(2) of this title, 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, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(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)(A) 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). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1395x(p) of this title 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, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(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.

(E)(i)<sup>6</sup> 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<sup>7</sup> 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, except as such process is applied under paragraph (7)(B).

(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

<sup>6</sup> So in original. There is no subpar. (D).

<sup>7</sup> So in original. Probably should be preceded by "a".

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.

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

**(A) Inclusion of appropriate modifier**

The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

**(B) Targeted medical review for certain services above threshold**

**(i) In general**

In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such services shall be subject to the process for medical review implemented under paragraph (5)(E).

**(ii) Threshold**

The threshold under this clause for—

(I) a year before 2028, is \$3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for 2028; and

(III) a subsequent year, is the amount specified in 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;

except that if an increase under subclause (II) or (III) for a year is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

**(iii) Application**

The threshold under clause (ii) shall be applied separately—

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

(II) for occupational therapy services.

**(iv) Funding**

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 to the Centers for Medicare & Medicaid Services Program Management Account, of \$5,000,000 for each fiscal year beginning with fiscal year 2018, 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.

(8) 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 de-

nial that is made by reason of section 1395y(a)(1) 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.

(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 fur-

nished 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 representing 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), 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)),<sup>8</sup> receives requests for testing during the year in which the test is performed<sup>8</sup> 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<sup>9</sup> 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 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

<sup>8</sup>So in original. The comma after "subclause (II)" probably should follow "is performed".

<sup>9</sup>So in original. Probably should be "such paragraph applies".

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 “HCPSC” 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 glycosylated 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.

(i) 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, 1395oo 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); 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<sup>10</sup> 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.

(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section 1395l(t) of this title,<sup>11</sup> including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).

(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1395w-3a(i) of this title) for which payment under this subsection is not packaged into a payment for a service furnished on or after April 1, 2023, under the revised payment system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1395w-3a(i)(5) of this title and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1395w-3a(i)(5) of this title and subsection (a) apply under such section and subsection.

(10) TEMPORARY ADDITIONAL PAYMENTS FOR NON-OPIOID TREATMENTS FOR PAIN RELIEF.—

(A) IN GENERAL.—In the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, the payment system described in paragraph (2)(D)(i) shall provide, in a budget-neutral manner, for an additional payment for a non-opioid treatment for pain relief (as defined in clause (iv) of subsection (t)(16)(G)) furnished as part of such services in the amount specified in clause (ii) of such subsection, subject to the limitation under clause (iii) of such subsection.

(B) TRANSITION.—A drug or biological that meets the requirements of section 416.174 of title 42, Code of Federal Regulations (or any successor regulation) and is a non-opioid treatment for pain relief (as defined in clause (iv) of subsection (t)(16)(G)) shall receive additional payment in the amount specified in clause (ii) of such subsection, subject to the limitation under clause (iii) of such subsection.

**(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 ei-

<sup>10</sup> So in original. The word “this” probably should not appear.

<sup>11</sup> So in original. The closing parenthesis preceding the comma probably should not appear.

ther 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 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 (or, in the case of such a determination made with respect to a payment made on or after March 27, 2020, and during the emergency period described in section 1320b-5(g)(1)(B) of this title under the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation), at a rate of 4 percent).

**(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 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—<sup>12</sup>

(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

<sup>12</sup>So in original. Probably should be "are—".

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 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<sup>13</sup> (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).

(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 1395oo 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)<sup>14</sup> 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) 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) 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), 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—

<sup>13</sup> So in original. Probably should be "subparagraph".

<sup>14</sup> So in original. No par. (2) has been enacted.

(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)), or (for procedures described in subsection (a)(2)(E)(ii)), 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) furnished on or after April 1, 1989 and for services described in subsection (a)(2)(E)(ii) 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) 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).

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)(i) 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, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1396f(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) 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 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) 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 temporary additional payments for non-opioid treatments for pain relief under paragraph (16)(G), 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 palla-

dium-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) 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) 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 co-payment 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), 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 co-payment 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 ambulatory 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 (i) 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**

Subject to subparagraph (K), 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**

Subject to subparagraph (G), 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) subject to subparagraph (H), 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. This clause shall not apply for 2018 or 2020.

**(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 bio-equivalent, as determined by the Commissioner of Food and Drugs.

**(G) Pass-through extension for certain drugs and biologicals**

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

**(H) Temporary payment rule for certain drugs and biologicals**

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the

period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

**(I) Special payment adjustment rules for last quarter of 2018**

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD<sup>15</sup> service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

**(J) Additional pass-through extension and special payment adjustment rule for certain diagnostic radiopharmaceuticals**

In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

**(K) Pass-through extension for certain devices**

**(i) In general**

In the case of a device whose period of pass-through status under this paragraph

<sup>15</sup> So in original. Probably should be "a covered OPD".

will end on December 31, 2022, such pass-through status shall be extended for a 1-year period beginning on January 1, 2023.

**(ii) No adjustment for packaged costs**

For purposes of the 1-year period described in clause (i), the Secretary shall not remove the packaged costs of such device (as determined by the Secretary) from the payment amount under this subsection for a covered OPD service (or group of services) with which it is packaged.

**(iii) No application of aggregate limit or budget neutrality**

Notwithstanding any other provision of this subsection, this subparagraph shall not be taken into account—

(I) in applying the limit on annual aggregate adjustments under subparagraph (E) for 2023; or

(II) in making any budget neutrality adjustments under this subsection for 2023.

**(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 term “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).

**(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).

**(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.

**(F) Part B rebatable drugs**

In the case of a part B rebatable drug (as defined in paragraph (2) of section

1395w-3a(i) of this title, except if such drug does not have a copayment amount as a result of application of subparagraph (E)) for which payment under this part is not packaged into a payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under this subsection is the same as the amount for a calendar quarter under paragraph (3)(A)(ii)(I) of section 1395w-3a(i) of this title, under the system under this subsection, in lieu of calculation of the copayment amount and the amount of payment otherwise applicable under this subsection (other than the application of the limitation described in subparagraph (C)), the provisions of section 1395w-3a(i)(5) of this title and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1395w-3a(i)(5) of this title and subsection (a) apply under such section and subsection.

**(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, 1395oo 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)(i)(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 ac-

count 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 multi-source 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 lin-

ear 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.

**(G) Temporary additional payments for non-opioid treatments for pain relief**

**(i) In general**

Notwithstanding any other provision of this subsection, with respect to a non-opioid treatment for pain relief (as defined in clause (iv)) furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for such non-opioid treatment for pain relief into a payment for a covered OPD service (or group of services), and shall make an additional payment as specified in clause (ii) for such non-opioid treatment for pain relief.

**(ii) Amount of payment**

Subject to the limitation under clause (iii), the amount of the payment specified in this clause is, with respect to a non-opioid treatment for pain relief that is—

(I) a drug or biological product, the amount of payment for such drug or biological determined under section 1395w-3a of this title that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(II) a medical device, the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device.

**(iii) Limitation**

The additional payment amount specified in clause (ii) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or

group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

**(iv) Definition of non-opioid treatment for pain relief**

In this subparagraph, the term “non-opioid treatment for pain relief” means a drug, biological product, or medical device that—

(I) in the case of a drug or biological product, has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors;

(II) in case of a medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has—

(aa) an application under section 360e of title 21 that has been approved with respect to the device, been cleared for market under section 360(k) of such title, or is exempt from the requirements of section 360(k) of such title pursuant to subsection (l) or (m) or section 360 of such title or section 360j(g) of such title; and

(bb) demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal;

(III) does not receive transitional pass-through payment under paragraph (6); and

(IV) has payment that is packaged into a payment for a covered OPD service (or group of services).

**(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 man-

ner, 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 opportunity 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, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

**(C) Target PCR adjustment**

In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1395ww(d)(1)(B)(v) of this title. In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

**(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<sup>16</sup> subsection.

**(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 the subsequent provisions of this subparagraph, 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.

**(iii) Deemed treatment for 2017**

For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

**(iv) Alternative exception beginning with 2018**

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term “off-campus outpatient department of a provider” also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after December 13, 2016), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1395cc(j) of this title; and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after December 13, 2016, from the chief

<sup>16</sup>So in original. Probably should be preceded by “under”.

executive officer or chief operating officer of the provider a written certification that the department met such requirement.

**(v) Mid-build requirement described**

The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

**(vi) Exclusion for certain cancer hospitals**

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term “off-campus outpatient department of a provider” also shall not include a department of a provider (as so defined) that is not described in clause (i) if the provider is a hospital described in section 1395ww(d)(1)(B)(v) of this title and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before December 13, 2016, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date; or

(II) in the case of a department that meets such requirements after such date, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

**(vii) Audit**

Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term “off-campus outpatient department of a provider” under such clause.

**(viii) Implementation**

For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44 shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses

(iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), \$10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), \$2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

**(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 1395oo 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).

(iv) The determination of an audit under subparagraph (B)(vii).

**(22) Review and revisions of payments for non-opioid alternative treatments**

**(A) In general**

With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a

goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

**(B) Priority**

In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

**(C) Revisions**

If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

**(D) Rules of construction**

Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

**(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 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, 1395oo 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) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

**(4) Limitation on review**

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

**(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) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

**(4) Application**

The provisions of paragraph<sup>17</sup> (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) 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 2026 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 (or, with respect to 2025, 3.5 percent, or, with respect to 2026, 1.88 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

<sup>17</sup>So in original. Probably should be “paragraphs”.

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 through 2026**

With respect to each of 2021 through 2026, 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 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 serv-

ices 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<sup>18</sup> 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 2027**

With respect to 2027 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—

<sup>18</sup>So in original. Probably should be “exceed”.

(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<sup>18</sup> 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. With respect to 2023, 2024, 2025, and 2026, the Secretary shall use the same percentage criteria for counts of patients that are used in 2022.

**(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, 1395oo<sup>19</sup> 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).

<sup>19</sup>So in original. Probably should be preceded by “section”.

(B) The determination of the amount of the 5 percent (or, with respect to 2025, 3.5 percent, or, with respect to 2026, 1.88 percent) payment incentive under paragraph (1)(A), including any estimation as part of such determination.

**(aa) 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<sup>1</sup> 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 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 sub-

section 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.

**(bb) Additional payments for certain rural health clinics with physicians or practitioners receiving data 2000 waivers**

**(1) In general**

In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1395x(aa)(1) of this title) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

**(2) Application**

In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

**(3) Requirements**

For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

(B) The physician or practitioner first begins prescribing narcotic drugs in schedule

III, IV, or V of section 812 of title 21 for the purpose of maintenance or detoxification treatment on or after January 1, 2021.

**(4) Funding**

For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, \$2,000,000, which shall remain available until expended.

**(cc) Specified COVID-19 testing-related services**

For purposes of subsection (a)(1)(DD):

**(1) Description**

**(A) In general**

A specified COVID-19 testing-related service described in this paragraph is a medical visit that—

(i) is in any of the categories of HCPCS evaluation and management service codes described in subparagraph (B);

(ii) is furnished during any portion of the emergency period (as defined in section 1320b-5(g)(1)(B) of this title) (beginning on or after March 18, 2020);

(iii) results in an order for or administration of a clinical diagnostic laboratory test described in section 1395w-22(a)(1)(B)(iv)(IV) of this title; and

(iv) relates to the furnishing or administration of such test or to the evaluation of such individual for purposes of determining the need of such individual for such test.

**(B) Categories of HCPCS codes**

For purposes of subparagraph (A), the categories of HCPCS evaluation and management services codes are the following:

(i) Office and other outpatient services.

(ii) Hospital observation services.

(iii) Emergency department services.

(iv) Nursing facility services.

(v) Domiciliary, rest home, or custodial care services.

(vi) Home services.

(vii) Online digital evaluation and management services.

**(2) Specified outpatient payment provision**

A specified outpatient payment provision described in this paragraph is any of the following:

(A) The hospital outpatient prospective payment system under subsection (t).

(B) The physician fee schedule under section 1395w-4 of this title.

(C) The prospective payment system developed under section 1395m(o) of this title.

(D) Section 1395m(g) of this title, with respect to an outpatient critical access hospital service.

(E) The payment basis determined in regulations pursuant to subsection (a)(3) for rural health clinic services.

**(dd) Special coinsurance rule for certain colorectal cancer screening tests**

**(1) In general**

In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection

(a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

**(2) Specified percent defined**

For purposes of paragraph (1), the term “specified percent” means—

- (A) for 2022, 80 percent;
- (B) for 2023 through 2026, 85 percent; and
- (C) for 2027 through 2029, 90 percent.

(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; Pub. L. 114–255, div. A, title V, §5012(c)(1), div. C, title XVI, §§16001(a), 16002(a), (b), Dec. 13, 2016, 130 Stat. 1202, 1324–1326; Pub. L. 115–123, div. E, title II, §50202, Feb. 9, 2018, 132 Stat. 176; Pub. L. 115–141, div. S, title XIII, §1301(a)(1), (2), Mar. 23, 2018, 132 Stat. 1149, 1150; Pub. L. 115–271, title II, §2005(c)(1), title VI, §§6082, 6083(b), Oct. 24, 2018, 132 Stat. 3929, 3992, 3994; Pub. L. 116–94, div. N, title I, §107(a), Dec. 20, 2019, 133 Stat. 3102; Pub. L. 116–127, div. F, §6002(a), Mar. 18, 2020, 134 Stat. 202; Pub. L. 116–136, div. A, title III, §3713(b), Mar. 27, 2020, 134 Stat. 423; Pub. L. 116–159, div. C, title V, §2501(b)(2), Oct. 1, 2020, 134 Stat. 736; Pub. L. 116–260, div. CC, title I, §§114(a), 122(a), (b), 125(a)(2)(A), 130, Dec. 27, 2020, 134 Stat. 2948, 2955, 2956, 2963, 2973; Pub. L. 117–7, §2(a)(1), Apr. 14, 2021, 135 Stat. 251; Pub. L. 117–169, title I, §§11101(b), 11407(a), (b), Aug. 16, 2022, 136 Stat. 1869, 1904; Pub. L. 117–215, title I, §103(b)(4)(A), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(5), title IV, §§4111(a), 4121(a)(3), 4124(b)(3), 4133(a)(2)(A), 4134(d), 4135(a), (b), 4141(a), Dec. 29, 2022, 136 Stat. 5682, 5897, 5903, 5909, 5919, 5921, 5922, 5928; Pub. L. 118–42, div. G, title I, §304(a), Mar. 9, 2024, 138 Stat. 415.)

### Editorial Notes

#### 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, 1395l, 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.

#### 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

2024—Subsec. (z)(1)(A). Pub. L. 118–42, §304(a)(1), substituted “with 2026” for “with 2025” and inserted “, or, with respect to 2026, 1.88 percent” after “3.5 percent” in introductory provisions.

Subsec. (z)(2)(B). Pub. L. 118–42, §304(a)(2)(A), substituted “2026” for “2025” in heading and introductory provisions.

Subsec. (z)(2)(C). Pub. L. 118–42, §304(a)(2)(B), substituted “2027” for “2026” in heading and introductory provisions.

Subsec. (z)(2)(D). Pub. L. 118–42, §304(a)(2)(C), substituted “2025, and 2026” for “and 2025”.

Subsec. (z)(4)(B). Pub. L. 118–42, §304(a)(3), inserted “, or, with respect to 2026, 1.88 percent” after “3.5 percent”.

2022—Subsec. (a). Pub. L. 117–169, §11407(b)(2), inserted at end of concluding provisions “The Secretary shall make such adjustments as may be necessary to the amounts paid as specified under paragraph (1)(S)(ii) for insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1395x(n) of this title, such that the amount of coinsurance payable by an individual enrolled under this part for a month’s supply of such insulin does not exceed \$35.”

Subsec. (a)(1)(G). Pub. L. 117–169, §11101(b)(1)(A), inserted “, subject to subsection (i)(9),” after “the amounts paid”.

Subsec. (a)(1)(S). Pub. L. 117–169, §11407(b)(1), designated existing provisions as cl. (i), inserted “except as provided in clause (ii),” before “with respect to drugs and biologicals”, and added cl. (ii).

Pub. L. 117–169, §11101(b)(1)(B), substituted “subject to subparagraph (EE), with respect to” for “with respect to”.

Subsec. (a)(1)(EE). Pub. L. 117–169, §11101(b)(1)(C), (D), added subpar. (EE).

Subsec. (a)(1)(FF). Pub. L. 117–328, §4121(a)(3), added subpar. (FF).

Subsec. (a)(1)(GG). Pub. L. 117–328, §4133(a)(2)(A), added subpar. (GG).

Subsec. (a)(1)(HH). Pub. L. 117–328, §4134(d), added subpar. (HH).

Subsec. (b)(13). Pub. L. 117–169, §11407(a), added par. (13).

Subsec. (c)(2). Pub. L. 117–328, §4124(b)(3), inserted “or intensive outpatient services” after “partial hospitalization services”.

Subsec. (i)(9). Pub. L. 117–169, §11101(b)(2), added par. (9).

Subsec. (i)(10). Pub. L. 117–328, §4135(b), added par. (10).

Subsec. (t)(2)(E). Pub. L. 117–328, §4135(a)(1), inserted “and temporary additional payments for non-opioid treatments for pain relief under paragraph (16)(G),” after “payments under paragraph (6)”.

Subsec. (t)(6)(B)(iii). Pub. L. 117–328, §4141(a)(1), substituted “Subject to subparagraph (K), a category” for “A category” in introductory provisions.

Subsec. (t)(6)(K). Pub. L. 117–328, §4141(a)(2), added subpar. (K).

Subsec. (t)(8)(F). Pub. L. 117–169, §11101(b)(3), added subpar. (F).

Subsec. (t)(16)(G). Pub. L. 117–328, §4135(a)(2), added subpar. (G).

Subsec. (z)(1)(A). Pub. L. 117–328, §4111(a)(1), substituted “2025” for “2024” and inserted “(or, with respect to 2025, 3.5 percent)” after “5 percent” in introductory provisions.

Subsec. (z)(2)(B). Pub. L. 117–328, §4111(a)(2)(A), substituted “2025” for “2024” in heading and introductory provisions.

Subsec. (z)(2)(C). Pub. L. 117–328, §4111(a)(2)(B), substituted “2026” for “2025” in heading and introductory provisions.

Subsec. (z)(2)(D). Pub. L. 117–328, §4111(a)(2)(C), substituted “2023, 2024, and 2025” for “2023 and 2024”.

Subsec. (z)(4)(B). Pub. L. 117–328, §4111(a)(3), inserted “(or, with respect to 2025, 3.5 percent)” after “5 percent”.

Subsec. (bb)(3)(B). Pub. L. 117-328, §1262(b)(5), which directed substitution of “first begins prescribing narcotic drugs in schedule III, IV, or V of section 812 of title 21 for the purpose of maintenance or detoxification treatment on or after January 1, 2021” for “first receives a waiver under section 823(g) of title 21 on or after January 1, 2019”, was executed by making the substitution for “first receives a waiver under section 823(h) of title 21 on or after January 1, 2019”, to reflect the probable intent of Congress and the intervening amendment by Pub. L. 117-215. See note below.

Pub. L. 117-215 substituted “823(h)” for “823(g)”.  
2021—Subsec. (f)(3)(A)(i). Pub. L. 117-7, §2(a)(1)(A)(i), added subcls. (I) and (II) and struck out former subcls. (I) and (II) which read as follows:

“(I) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or

“(II) the limit described in paragraph (2)(A); and”.

Subsec. (f)(3)(A)(ii)(I). Pub. L. 117-7, §2(a)(1)(A)(ii), substituted “under subclause (I) or (II) of clause (i), as applicable,” for “under clause (i)(I)”.

Subsec. (f)(3)(B). Pub. L. 117-7, §2(a)(1)(B), added subpar. (B) and struck out former subpar. (B) which read as follows:

“(B) A rural health clinic described in this subparagraph is a rural health clinic that, as of December 31, 2019, was—

“(i) in a hospital with less than 50 beds; and

“(ii) enrolled under section 1395cc(j) of this title.”

2020—Subsec. (a). Pub. L. 116-260, §122(a), in concluding provisions, substituted “section 1395m(o) of this title” for “section 1395m(0) of this title”, realigned margins, and inserted at end “For services furnished on or after January 1, 2022, paragraph (1)(Y) 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. (a)(1)(Y). Pub. L. 116-260, §122(b)(1), inserted “subject to subsection (dd),” before “with respect to”.

Subsec. (a)(1)(DD). Pub. L. 116-127, §6002(a)(1), which directed adding subpar. (DD) before the period at the end of par. (1), was executed by adding it before the semicolon at the end, to reflect the probable intent of Congress.

Subsec. (a)(10). Pub. L. 116-260, §125(a)(2)(A), added par. (10).

Subsec. (b)(11). Pub. L. 116-127, §6002(a)(2), added par. (11).

Subsec. (b)(12). Pub. L. 116-136 added par. (12).

Subsec. (f). Pub. L. 116-260, §130(2), (3)(A), (4), designated existing provisions as par. (1), redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), and added pars. (2) and (3).

Subsec. (f)(1). Pub. L. 116-260, §130(3)(B), which directed insertion of “prior to April 1, 2021” after “services provided”, was executed by making the insertion after “services provided” the second place appearing, to reflect the probable intent of Congress.

Subsec. (f)(2). Pub. L. 116-260, §130(1), inserted “(before April 1, 2021)” after “in a subsequent year” and substituted “this paragraph” for “this subsection”.

Subsec. (j). Pub. L. 116-159 inserted before period at end “(or, in the case of such a determination made with respect to a payment made on or after March 27, 2020, and during the emergency period described in section 1320b-5(g)(1)(B) of this title under the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation), at a rate of 4 percent)”.

Subsec. (z)(2)(B). Pub. L. 116-260, §114(a)(1), substituted “through 2024” for “and 2022” in heading and “each of 2021 through 2024” for “2021 and 2022” in introductory provisions.

Subsec. (z)(2)(C). Pub. L. 116-260, §114(a)(2), substituted “2025” for “2023” in heading and introductory provisions.

Subsec. (z)(2)(D). Pub. L. 116-260, §114(a)(3), inserted at end “With respect to 2023 and 2024, the Secretary shall use the same percentage criteria for counts of patients that are used in 2022.”

Subsec. (cc). Pub. L. 116-127, §6002(a)(3), added subsec. (cc).

Subsec. (dd). Pub. L. 116-260, §122(b)(2), added subsec. (dd).

2019—Subsec. (t)(6)(E)(i). Pub. L. 116-94, §107(a)(1), substituted “2018 or 2020” for “2018”.

Subsec. (t)(6)(J). Pub. L. 116-94, §107(a)(2), added subpar. (J).

2018—Subsec. (a)(1)(CC). Pub. L. 115-271, §2005(c)(1), added subpar. (CC).

Subsec. (g)(1). Pub. L. 115-123, §50202(1), designated existing provisions as subpar. (A), inserted “The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.” after “for purposes of subsections (a) and (b).”, and added subpar. (B).

Subsec. (g)(3). Pub. L. 115-123, §50202(2), designated existing provisions as subpar. (A), inserted “The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.” after “for purposes of subsections (a) and (b).”, and added subpar. (B).

Subsec. (g)(5)(D). Pub. L. 115-123, §50202(3)(A), redesignated subpar. (D) as par. (8) of subsec. (g).

Subsec. (g)(5)(E)(iv). Pub. L. 115-123, §50202(3)(B), inserted “, except as such process is applied under paragraph (7)(B)” before period at end.

Subsec. (g)(7). Pub. L. 115-123, §50202(4), added par. (7).

Subsec. (g)(8). Pub. L. 115-123, §50202(3)(A), redesignated par. (5)(D) as par. (8).

Subsec. (i)(8). Pub. L. 115-271, §6082(b), added par. (8).

Subsec. (t)(6)(C)(i). Pub. L. 115-141, §1301(a)(1)(A), substituted “Subject to subparagraph (G), the payment” for “The payment” in introductory provisions.

Subsec. (t)(6)(D)(i). Pub. L. 115-141, §1301(a)(1)(B), inserted “subject to subparagraph (H),” before “in the case”.

Subsec. (t)(6)(E)(i). Pub. L. 115-141, §1301(a)(2), inserted at end “This clause shall not apply for 2018.”

Subsec. (t)(6)(G) to (I). Pub. L. 115-141, §1301(a)(1)(C), inserted subpars. (G) to (I).

Subsec. (t)(22). Pub. L. 115-271, §6082(a), added par. (22).

Subsecs. (z), (aa). Pub. L. 115-271, §6083(b)(1), redesignated subsec. (z), relating to medical review of spinal subluxation services, as (aa).

Subsec. (bb). Pub. L. 115-271, §6083(b)(2), added subsec. (bb).

2016—Subsec. (a)(1)(BB). Pub. L. 114-255, §5012(c)(1), added subpar. (BB).

Subsec. (t)(18)(B). Pub. L. 114-255, §16002(b)(1), inserted “, subject to subparagraph (C),” after “shall”.

Subsec. (t)(18)(C). Pub. L. 114-255, §16002(b)(2), added subpar. (C).

Subsec. (t)(21)(B)(i). Pub. L. 114-255, §16001(a)(1)(A), substituted “the subsequent provisions of this subparagraph” for “clause (ii)”.

Subsec. (t)(21)(B)(iii) to (v). Pub. L. 114-255, §16001(a)(1)(B), added cls. (iii) to (v).

Subsec. (t)(21)(B)(vi). Pub. L. 114-255, §16002(a)(1), added cl. (vi).

Subsec. (t)(21)(B)(vii). Pub. L. 114-255, §16002(a)(2), inserted after first sentence “Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department.”

Pub. L. 114-255, §16001(a)(1)(B), added cl. (vii).

Subsec. (t)(21)(B)(viii). Pub. L. 114-255, §16001(a)(1)(B), added cl. (viii).

Subsec. (t)(21)(B)(viii)(III). Pub. L. 114-255, §16002(a)(3), inserted at end “For purposes of carrying out this subparagraph with respect to clause (vi) and clause (vii) insofar as it relates to such clause, \$2,000,000 shall be available from the Federal Supple-

mentary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.”

Subsec. (t)(21)(E)(iv). Pub. L. 114–255, §16001(a)(2), added cl. (iv).

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) (for tests furnished before January 1, 2017)” for “subsection (h)(1)”, 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) (for tests furnished before January 1, 2017)” for “subsection (h)(1)”, 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 services (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), imme-

diately 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 services,” 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(l)(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 subparagraph (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)”.

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)”.

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)” 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 (b)” 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. (j)(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 re-

spect 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) 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 revised 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 de-

ductible 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 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 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) furnished under this part on or after October 1, 1988, and for services described in subsection (a)(2)(E)(ii) 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)” 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) 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),” 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),” 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).”

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 per-

formed 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 reduced 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).

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117-328, div. FF, title IV, §4121(c), Dec. 29, 2022, 136 Stat. 5903, provided that: “The amendments made by this section [amending this section and sections 1395u, 1395x, and 1395yy of this title] shall apply with respect to services furnished on or after January 1, 2024.”

Amendment by section 4124(b)(3) of Pub. L. 117-328 applicable with respect to items and services furnished on or after Jan. 1, 2024, see section 4124(d) of Pub. L. 117-328, set out as a note under section 1395k of this section.

##### EFFECTIVE DATE OF 2021 AMENDMENT

Pub. L. 117-7, §2(a)(2), Apr. 14, 2021, 135 Stat. 252, provided that: “The amendments made by this subsection [amending this section] shall take effect as if included in the enactment of the Consolidated Appropriations Act, 2021 (Public Law 116-260).”

##### EFFECTIVE DATE OF 2020 AMENDMENT

Pub. L. 116-260, div. CC, title I, §114(c), Dec. 27, 2020, 134 Stat. 2948, provided that: “The amendments made by this section [amending this section and section 1395w-4 of this title] shall take effect on the date of the enactment of this Act [Dec. 27, 2020].”

Pub. L. 116-260, div. CC, title I, §125(g), Dec. 27, 2020, 134 Stat. 2966, provided that: “The amendments made by this section [amending this section and sections 1395m, 1395x, 1395aa, 1395cc, and 1395dd of this title] shall apply to items and services furnished on or after January 1, 2023.”

Pub. L. 116-136, div. A, title III, §3713(d), Mar. 27, 2020, 134 Stat. 424, provided that: “The amendments made by this section [amending this section and sections 1395w-22 and 1395x of this title] shall take effect on the date of enactment of this Act [Mar. 27, 2020] and shall apply with respect to a COVID-19 vaccine beginning on the date that such vaccine is licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).”

## EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114-255, div. A, title V, § 5012(d), Dec. 13, 2016, 130 Stat. 1202, as amended by Pub. L. 115-123, div. E, title IV, § 50401(b)(2), Feb. 9, 2018, 132 Stat. 217, provided that: “The amendments made by this section [amending this section and sections 1395m, 1395u, and 1395x of this title] shall apply to items and services furnished on or after January 1, 2021, except that the amendments made by paragraphs (1) and (2) of subsection (c) shall apply to items and services furnished on or after January 1, 2019.”

Pub. L. 114-255, div. C, title XVI, § 16001(b), Dec. 13, 2016, 130 Stat. 1325, provided that: “The amendments made by this section [amending this section] shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).”

Pub. L. 114-255, div. C, title XVI, § 16002(c), Dec. 13, 2016, 130 Stat. 1326, provided that: “The amendments made by this section [amending this section] shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).”

## 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. 1395f(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. 1395f(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. 1395f(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 sec-

tion [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. 1395f(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(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. 1395l(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. 1395f(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. 1395f(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 sec-

tion [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 du-

rable 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. 1395l(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 pre-

venting a hospital from waiving the amount of any co-insurance 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(t)).”

#### IMPLEMENTATION OF 2022 AMENDMENT

Pub. L. 117-328, div. FF, title IV, §4141(b), Dec. 29, 2022, 136 Stat. 5929, provided that: “Notwithstanding any other provision of law, the Secretary of Health and Human Service may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.”

Pub. L. 117-169, title I, §11407(c), Aug. 16, 2022, 136 Stat. 1905, provided that: “The Secretary of Health and Human Services shall implement this section [amending this section] for 2023 by program instruction or other forms of program guidance.”

#### PROVIDER OUTREACH AND REPORTING ON CERTAIN BEHAVIORAL HEALTH INTEGRATION SERVICES

Pub. L. 117-328, div. FF, title IV, §4128, Dec. 29, 2022, 136 Stat. 5916, provided that:

“(a) OUTREACH.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to behavioral health integration services described by any of HCPCS codes 99492 through 99494 or 99484 (or any successor code). Such outreach shall include a comprehensive, one-time education initiative to inform such physicians and practitioners of the inclusion of such services as a covered benefit under the Medicare program, including describing the requirements to bill for such codes and the requirements for beneficiary eligibility for such services.

“(b) REPORTS TO CONGRESS.—

“(1) PROVIDER OUTREACH.—Not later than 1 year after the date of the completion of the education initiative described in subsection (a), the Secretary shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the outreach conducted under such subsection. Such report shall include a description of the methods used for such outreach.

“(2) UTILIZATION RATES.—Not later than 18 months after the date of the completion of the education initiative described in subsection (a), and two years thereafter, the Secretary shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the number of Medicare beneficiaries (including those beneficiaries accessing services in rural and underserved areas) who, during the preceding year, were furnished services described in subsection (a) for which payment was made under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).”

#### OUTREACH AND REPORTING ON OPIOID USE DISORDER TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS

Pub. L. 117-328, div. FF, title IV, §4129, Dec. 29, 2022, 136 Stat. 5916, provided that:

“(a) OUTREACH.—

“(1) PROVIDER OUTREACH.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to opioid use disorder treatment services furnished by an opioid treatment program (as defined in

section 1861(jjj) of the Social Security Act (42 U.S.C. 1395x(jjj))). Such outreach shall include a comprehensive, one-time education initiative to inform such physicians and practitioners of the inclusion of such services as a covered benefit under the Medicare program, including describing the requirements for billing and the requirements for beneficiary eligibility for such services.

“(2) BENEFICIARY OUTREACH.—The Secretary shall conduct outreach to Medicare beneficiaries with respect to opioid use disorder treatment services furnished by an opioid treatment program (as defined in section 1861(jjj) of the Social Security Act (42 U.S.C. 1395x(jjj))), including a comprehensive, one-time education initiative informing such beneficiaries about the eligibility requirements to receive such services.

“(b) REPORTS TO CONGRESS.—

“(1) OUTREACH.—Not later than 1 year after the date of the completion of the education initiatives described in subsection (a), the Secretary shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the outreach conducted under such subsection. Such report shall include a description of the methods used for such outreach.

“(2) UTILIZATION RATES.—Not later than 18 months after the date of the completion of the education initiatives described in subsection (a), and two years thereafter, the Secretary shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the number of Medicare beneficiaries who, during the preceding year, were furnished opioid use disorder treatment services by an opioid treatment program (as defined in section 1861(jjj) of the Social Security Act (42 U.S.C. 1395x(jjj))) for which payment was made under title XVIII of such Act (42 U.S.C. 1395 et seq.).”

#### CENTERS FOR MEDICARE & MEDICAID SERVICES PROVIDER OUTREACH AND REPORTING ON COGNITIVE ASSESSMENT AND CARE PLAN SERVICES

Pub. L. 116-260, div. CC, title I, §116, Dec. 27, 2020, 134 Stat. 2949, provided that:

“(a) OUTREACH.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to Medicare payment for cognitive assessment and care plan services furnished to individuals with cognitive impairment such as Alzheimer’s disease and related dementias, identified as of January 1, 2018, by HCPCS code 99483, or any successor to such code (in this section referred to as ‘cognitive assessment and care plan services’). Such outreach shall include a comprehensive, one-time education initiative to inform such physicians and practitioners of the addition of such services as a covered benefit under the Medicare program, including the requirements for eligibility for such services.

“(b) REPORTS.—

“(1) HHS REPORT ON PROVIDER OUTREACH.—Not later than one year after the date of enactment of this Act [Dec. 27, 2020], the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the outreach conducted under subsection (a). Such report shall include a description of the methods used for such outreach.

“(2) GAO REPORT ON UTILIZATION RATES.—Not later than 3 years after such date of enactment, the Comptroller General of the United States shall submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the

Senate a report on the number of Medicare beneficiaries who were furnished cognitive assessment and care plan services for which payment was made under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.). Such report shall include information on barriers Medicare beneficiaries face to access such services, and recommendations for such legislative and administrative action as the Comptroller General deems appropriate.”

#### IMPLEMENTATION OF 2020 AMENDMENT

Pub. L. 116-136, div. A, title III, §3713(e), Mar. 27, 2020, 134 Stat. 424, provided that: “Notwithstanding any other provision of law, the Secretary [probably means Secretary of Health and Human Services] may implement the provisions of, and the amendments made by, this section [amending this section and sections 1395w-22 and 1395x of this title] by program instruction or otherwise.”

#### CLAIMS MODIFIER

Pub. L. 116-127, div. F, §6002(b), Mar. 18, 2020, 134 Stat. 203, provided that: “The Secretary of Health and Human Services shall provide for an appropriate modifier (or other identifier) to include on claims to identify, for purposes of subparagraph (DD) of section 1833(a)(1) [probably means section 1833(a)(1)(DD) of the Social Security Act, 42 U.S.C. 1395l(a)(1)(DD)], as added by subsection (a), specified COVID-19 testing-related services described in paragraph (1) of section 1833(cc) of the Social Security Act [42 U.S.C. 1395l(cc)], as added by subsection (a), for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection.”

#### IMPLEMENTATION OF PROVISIONS OF PUB. L. 116-127

Pub. L. 116-127, div. F, §6002(c), Mar. 18, 2020, 134 Stat. 203, provided that: “Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including amendments made by, this section [amending this section and enacting provisions set out as a note above] through program instruction or otherwise.”

#### IMPLEMENTATION OF 2019 AMENDMENT

Pub. L. 116-94, div. N, title I, §107(b), Dec. 20, 2019, 133 Stat. 3102, 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 2018 AMENDMENT

Pub. L. 115-141, div. S, title XIII, §1301(a)(3), Mar. 23, 2018, 132 Stat. 1150, provided that: “Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by paragraphs (1) and (2) [amending this section] by program instruction or otherwise.”

#### 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, as amended by Pub. L. 115-63, title III, §302, Sept. 29, 2017, 131 Stat. 1172; Pub. L. 116-260, div. CC, title I, §104, Dec. 27, 2020, 134 Stat. 2943, 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 and, subject to the availability of funds under subsection (g), the period beginning on October 1, 2017, and ending on December 31, 2023.

“(A) if the date of enactment of the Disaster Tax Relief and Airport and Airway Extension Act of 2017 is on or before September 30, 2017 [Pub. L. 115-63 was approved Sept. 29, 2017], for the period beginning on October 1, 2017, and ending on December 31, 2020; and

“(B) if the date of enactment of such Act is after September 30, 2017, for the period beginning on the date of enactment of such Act and ending on December 31, 2020.

“(2) SCOPE.—The Secretary shall enroll for participation in the demonstration project for the period beginning on October 1, 2014, and ending on September 30, 2020, not more than 4,000 Medicare beneficiaries who have been diagnosed with primary immunodeficiency disease and for the period beginning on October 1, 2014, and ending on December 31, 2023, not more than 6,500 Medicare beneficiaries who have been so diagnosed. A Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time. Subject to the preceding sentence, a Medicare beneficiary enrolled in the demonstration project on September 30, 2017, shall be automatically enrolled during the period beginning on the date of the enactment of the Disaster Tax Relief and Airport and Airway Extension Act of 2017 and ending on December 31, 2023, without submission of another application.

“(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) UPDATED EVALUATION AND REPORT.—Not later than 2 years after the date of the enactment of [the] Consolidated Appropriations Act, 2021 [Dec. 27, 2020], the Secretary shall submit to Congress an updated report that contains the following:

“(A) The total number of beneficiaries enrolled in the demonstration project during the updated report period.

“(B) The total number of claims submitted for services during the updated report period, disaggregated by month.

“(C) An analysis of the impact of the demonstration on beneficiary access to the in-home administration of intravenous immune globin, including the impact on beneficiary health.

“(D) An analysis of the impact of in-home administration of intravenous immune globin on overall costs to Medicare, including the cost differential between in-home administration of intravenous immune globin and administration of intravenous immune globin in a healthcare facility.

“(E) To the extent practicable, a survey of providers and enrolled beneficiaries that participated in the demonstration project that identifies barriers to accessing services, including reimbursement for items and services.

“(F) Recommendations to Congress on the appropriateness of establishing a permanent bundled services payment for the in-home administration of intravenous immune globin for Medicare beneficiaries.

“(3) 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.

“(4) UPDATED REPORT PERIOD.—The term ‘updated report period’ means the period beginning on October 1, 2014, and ending on September 30, 2020.”

[Pub. L. 116-260, §104(b), (c), which directed amendment of section 101 without specifying the Act to be amended, was executed to section 101 of Pub. L. 112-242, set out above, to reflect the probable intent of Congress.]

#### IMPLEMENTATION OF 2013 AMENDMENT

Pub. L. 112-240, title VI, §603(d), Jan. 2, 2013, 126 Stat. 2347, provided that: “Notwithstanding any other provi-

sion 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. 1395l(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. 1395l(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 1395oo), or otherwise of the process (including the establishment of the process) under section 1833(g)(5) of such Act [42 U.S.C. 1395f(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, required the Comptroller General of the United States to conduct a study to examine the adequacy of reimbursements for inhalation therapy under the Medicare program, and to submit to Congress a report on this study not later than 1 year after Dec. 8, 2003.

#### 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. 1395l) 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(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. 1395f(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. 1395f(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 Gen-

eral 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. 1395f 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, related to GAO study of reduction in medigap premium levels resulting from reductions in coinsurance and subsequent report to Congress, prior to repeal by Pub. L. 114-301, §2(b), Dec. 16, 2016, 130 Stat. 1514.

**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 de-

creased 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. 1395f(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. 1395www).

“(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. 1395f(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. 1395f(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. 1395f(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, required the Secretary of Health and Human Services to conduct a study of the implications of eliminating the “in the room” supervision requirement for medicare payment for services of physical therapy assistants who are supervised by physical therapists and of such requirement on the cap imposed under subsec. (g) of this section on physical therapy services, and to submit to Congress a report on the study no later than 18 months after Dec. 21, 2000.

#### 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. 1395f(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(7)], 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. 1395f(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 appropriateness (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.

1395I(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. 1395I(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. 1395I(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 Commission 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. 1395l).

“(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, §451(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. 1395l(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 451(d)(2) of Pub. L. 105-33, set out above] shall take effect as if included in the enactment of section 451 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, required the Secretary to 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, including a review of the adequacy of the current methodology and recommendations regarding alternative payment systems analysis and of the relationship between such payment systems and access to high quality laboratory tests for medicare beneficiaries, including availability and access to new testing methodologies, and to report to Congress the results of the study and any recommendations for legislation not later than 2 years after Aug. 5, 1997..”

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. 1395i(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. 1395i(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. 1395i(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. 1395i(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 1395l of this title] or section 222 of the Social Security Amendments of 1972 [Pub. L. 92-603, amending sections 1395b-1 and 1395l 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 chapter 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(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(m) of this title with respect to physician services performed in health man-

power 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(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. 1395f(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. 1395f(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 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 es-