42 USCS § 1395y

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United States Code Service - Titles 1 through 54 > TITLE 42. THE PUBLIC HEALTH AND WELFARE > CHAPTER 7. SOCIAL SECURITY ACT > TITLE XVIII. HEALTH INSURANCE FOR THE AGED AND DISABLED > PART E. MISCELLANEOUS PROVISIONS

§ 1395y. Exclusions from coverage and medicare as secondary payer [Caution: See prospective amendment note below.]

(a) Items or services specifically excluded. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], no payment may be made under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] for any expenses incurred for items or services--

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1) [*42 USCS § 1395x(ddd)(1)*]), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B)in the case of items and services described in section 1861(s)(10) [*42 USCS § 1395x(s)(10)*], which are not reasonable and necessary for the prevention of illness,

(C)in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D)in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E)in the case of research conducted pursuant to section 1142 [*42 USCS § 1320b-12*], which is not reasonable and necessary to carry out the purposes of that section,

(F)in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) [*42 USCS § 1395m(c)(2)*] or which is not conducted by a facility described in section 1834(c)(1)(B) [*42 USCS § 1395m(c)(1)(B)*], in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn) [*42 USCS § 1395x(nn)*], and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu) [*42 USCS § 1395x(uu)*],

(G)in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H)in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d) [*42 USCS § 1395m(d)*],

(I)the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J)in the case of a drug or biological specified in section 1847A(c)(6)(C) [*42 USCS § 1395w-3a(c)(6)(C)*] for which payment is made under part B [*42 USCS §§ 1395j* et seq.] that is furnished in a competitive area under section 1847B [*42 USCS § 1395w-3b*], that is not furnished by an entity under a contract under such section,

(K)in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B [*42 USCS §§ 1395j* et seq.],

(L)in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1) [*42 USCS § 1395x(xx)(1)*]), which are performed more frequently than is covered under section 1861(xx)(2) [*42 USCS § 1395x(xx)(2)*],

(M)in the case of a diabetes screening test (as defined in section 1861(yy)(1) [*42 USCS § 1395x(yy)(1)*]), which is performed more frequently than is covered under section 1861(yy)(3) [*42 USCS § 1395x(yy)(3)*],

(N)in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA) [*42 USCS § 1395x(s)(2)(AA)*],

(O)in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg) [*42 USCS § 1395x(ggg)*]), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P)in the case of personalized prevention plan services (as defined in section 1861(hhh)(1) [*42 USCS § 1395x(hhh)(1)*]), which are performed more frequently than is covered under such section;

(2)for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3)which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1) [*42 USCS § 1395x(aa)(1)*], in the case of Federally qualified health center services, as defined in section 1861(aa)(3) [*42 USCS § 1395x(aa)(3)*], in the case of services for which payment may be made under section 1880(e) [*42 USCS § 1395qq(e)*], and in such other cases as the Secretary may specify;

(4)which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) [*42 USCS § 1395(f)*] and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this *title [42 USCS §§ 1395* et seq.], physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5)which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part [*42 USCS §§ 1395c* et seq. or *1395j* et seq.];

(6)which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7)where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8) [*42 USCS § 1395x(s)(8)*]) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) [*42 USCS § 1395x(s)(10)*] and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8)where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12) [*42 USCS § 1395x(s)(12)*];

(9)where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10)where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11)where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12)where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A [*42 USCS §§ 1395c* et seq.] in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13)where such expenses are for--

(A)the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B)the treatment of subluxations of the foot, or

(C)routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14)which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K) [*42 USCS § 1395x(s)(2)(K)*], certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI [*42 USCS §§ 1320c* et seq.]) or a carrier under section 1842 [*42 USCS § 1395u*] has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B)which are for services of an assistant at surgery to which section 1848(i)(2)(B) [*42 USCS § 1395w-4(i)(2)(B)*] applies;

(16)in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17)where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a) [*42 USCS § 1395w-3(a)*]) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) [*42 USCS § 1395w-3(b)*] for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18)which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) [*42 USCS § 1395yy(e)(2)(A)(i)*] and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D) [*42 USCS § 1395x(s)(2)(D)*], which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [*42 USCS § 1395x(w)(1)*]) with the entity made by the skilled nursing facility;

(19)which are for items or services which are furnished pursuant to a private contract described in section 1802(b) [*42 USCS § 1395a(b)*];

(20)in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A) [*42 USCS § 1395x(s)(2)(A)*]), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) [*42 USCS § 1395x(p)*] (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861 [*42 USCS § 1395x*]) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21)where such expenses are for home health services (including medical supplies described in section 1861(m)(5) [*42 USCS § 1395x(m)(5)*], but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22)subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23)which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) [*42 USCS § 1395m(e)(1)(B)*] for which payment is made under the fee schedule established under section 1848(b) [*42 USCS § 1395w-4(b)*] and that are furnished by a supplier (as defined in section 1861(d) [*42 USCS § 1395x(d)*]), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B) [*42 USCS § 1395m(e)(2)(B)*];

(24)where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) [*42 USCS § 1395rr(b)(14)*]) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25)not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B) [*42 USCS § 1395x(aa)(3)(B)*]. In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f) [*42 USCS § 1395ff(f)*]) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) Medicare as secondary payer.

(1) Requirements of group health plans.

(A) Working aged under group health plans.

(i) In general. A group health plan--

(I)may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a) [*42 USCS § 426(a)*], and

(II)shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer. Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans. Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease. Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [*42 USCS § 426*]) would upon application be, entitled to benefits under section 226A [*42 USCS § 426-1*].

(v)"Group health plan" defined. In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in *section 5000(b)(1) of the Internal Revenue Code of 1986* [*26 USCS § 5000(b)(1)*], without regard to section 5000(d) of such Code [*26 USCS § 5000(d)*].

(B) Disabled individuals in large group health plans.

(i) In general. A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] under section 226(b) [*42 USCS § 426(b)*].

(ii) Exception for individuals with end stage renal disease. Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [*42 USCS § 426*]) would upon application be, entitled to benefits under section 226A [*42 USCS § 426-1*].

(iii) Large group health plan defined. In this subparagraph, the term "large group health plan" has the meaning given such term in *section 5000(b)(2) of the Internal Revenue Code of 1986* [*26 USCS § 5000(b)(2)*], without regard to section 5000(d) of such Code [*26 USCS § 5000(d)*].

(C) Individuals with end stage renal disease. A group health plan (as defined in subparagraph (A)(v))--

(i)may not take into account that an individual is entitled to or eligible for benefits under this *title [42 USCS §§ 1395* et seq.] under section 226A [*42 USCS § 426-1*] during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] under the provisions of section 226A [*42 USCS § 426-1*], or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A [*42 USCS § 426-1*] if the individual had filed an application for such benefits; and

(ii)may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this *title [42 USCS §§ 1395* et seq.] when an individual is entitled to or eligible for benefits under this *title [42 USCS §§ 1395* et seq.] under section 226A [*42 USCS § 426-1*] after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997

[enacted Aug. 5, 1997], (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18-month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997][,] (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) Treatment of certain members of religious orders. In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under *section 3121(r) of the Internal Revenue Code of 1986* [*26 USCS § 3121(r)*].

(E) General provisions. For purposes of this subsection:

(i) Aggregation rules.

(I) All employers treated as a single employer under subsection (a) or (b) of *section 52 of the Internal Revenue Code of 1986* [*26 USCS § 52(a)* or (b)] shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code [*26 USCS § 414(m)*]) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code [*26 USCS § 414(n)(2)*]) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code [*26 USCS § 414(n)*].

In applying sections of the Internal Revenue Code of 1986 [*26 USCS §§ 1* et seq.] under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) Current employment status defined. An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers. The term "employer" includes a self-employed person.

(F) Limitation on beneficiary liability. An individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.] and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer.

(A) In general. Payment under this *title [42 USCS §§ 1395* et seq.] may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that--

(i)payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii)payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or

profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Conditional payment.

(i) Authority to make conditional payment. The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Repayment required. Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this *title [42 USCS §§ 1395* et seq.] with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) Action by United States. In order to recover payment made under this *title [42 USCS §§ 1395* et seq.] for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) Subrogation rights. The United States shall be subrogated (to the extent of payment made under this *title [42 USCS §§ 1395* et seq.] for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights. The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this *title [42 USCS §§ 1395* et seq.].

(vi) Claims-filing period. Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) Use of website to determine final conditional reimbursement amount.

(I) Notice to Secretary of expected date of a settlement, judgment, etc. In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) Secretarial providing access to claims information through a website. The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) Use of timely web download as basis for final conditional amount. If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) Resolution of discrepancies. If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) Protected period. In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment relating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) Effective date. The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause [enacted Jan. 10, 2013].

(VII) Website including successor technology. In this clause, the term "website" includes any successor technology.

(viii) Right of appeal for secondary payer determinations relating to liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans. The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination[.]

(C) Treatment of questionnaires. The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) Enforcement.

(A) Private cause of action. There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans. For provision imposing an excise tax with respect to nonconforming group health plans, see *section 5000 of the Internal Revenue Code of 1986* [*26 USCS § 5000*].

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan. It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this *title [42 USCS §§ 1395* et seq.] not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $ 5,000 for each such violation. The provisions of section 1128A [*42 USCS § 1320a-7a*] (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 1128A(a) [*42 USCS § 1320a-7a(a)*].

(4) Coordination of benefits. Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this *title [42 USCS §§ 1395* et seq.] (without regard to deductibles and coinsurance under this *title [42 USCS §§ 1395* et seq.]) for the remainder of such charge, but--

(A)payment under this *title [42 USCS §§ 1395* et seq.] may not exceed an amount which would be payable under this *title [42 USCS §§ 1395* et seq.] for such item or service if paragraph (2)(A) did not apply; and

(B)payment under this *title [42 USCS §§ 1395* et seq.], when combined with the amount payable under the primary plan, may not exceed--

(i)in the case of an item or service payment for which is determined under this *title [42 USCS §§ 1395* et seq.] on the basis of reasonable cost (or other cost-related basis) or under section 1886 [*42 USCS § 1395ww*], the amount which would be payable under this *title [42 USCS §§ 1395* et seq.] on such basis, and

(ii)in the case of an item or service for which payment is authorized under this *title [42 USCS §§ 1395* et seq.] on another basis--

(I)the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II)the reasonable charge or other amount which would be payable under this *title [42 USCS §§ 1395* et seq.] (without regard to deductibles and coinsurance under this *title [42 USCS §§ 1395* et seq.]),

whichever is greater.

(5) Identification of secondary payer situations.

(A) Requesting matching information.

(i) Commissioner of Social Security. The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in *section 6103(l)(12) of the Internal Revenue Code of 1986* [*26 USCS § 6103(l)(12)*]) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator. The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to

disclose to the Administrator the information described in subparagraph (B) of *section 6103(l)(12) of the Internal Revenue Code of 1986* [*26 USCS § 6103(l)(12)(B)*].

(B) Disclosure to fiscal intermediaries and carriers. In addition to any other information provided under this *title [42 USCS §§ 1395* et seq.] to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers.

(i) In general. With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under *section 6051 of the Internal Revenue Code of 1986* [*26 USCS § 6051*] by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code [*26 USCS § 6103(l)(12)(E)(iii)*]), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response. Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $ 1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1128A [*42 USCS § 1320a-7a*] (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 1128A(a) [*42 USCS § 1320a-7a(a)*].

(D) Obtaining information from beneficiaries. Before an individual applies for benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolls under part B [*42 USCS §§ 1395j* et seq.], the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) End date. The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) Screening requirements for providers and suppliers.

(A) In general. Notwithstanding any other provision of this *title [42 USCS §§ 1395* et seq.], no payment may be made for any item or service furnished under part B [*42 USCS §§ 1395j* et seq.] unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties. An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $ 2,000 for each such incident. The provisions of section 1128A [*42 USCS § 1320a-7a*] (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 1128A(a) [*42 USCS § 1320a-7a(a)*].

(7) Required submission of information by group health plans.

(A) Requirement. On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall--

(i)secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been--

(I)a primary plan to the program under this title; or

(II)for calendar quarters beginning on or after January 1, 2020, a primary payer with respect to benefits relating to prescription drug coverage under part D; and

(ii)submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Enforcement.

(i) In general. An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $ 1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A [*42 USCS § 1320a-7a*] 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 1128A(a) [*42 USCS § 1320a-7a(a)*]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) Deposit of amounts collected. Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817 [*42 USCS § 1395i*].

(C) Sharing of information. Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary--

(i)shall share information on entitlement under Part A [*42 USCS §§ 1395c* et seq.] and enrollment under Part B under this *title [42 USCS §§ 1395j* et seq.] with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii)may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii)may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) Implementation. Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) Required submission of information by or on behalf of liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans.

(A) Requirement. On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an applicable plan shall--

(i)determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this *title [42 USCS §§ 1395* et seq.] on any basis; and

(ii)if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Required information. The information described in this subparagraph is--

(i)the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii)such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence [enacted Jan. 10, 2013], the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) Timing. Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) Claimant. For purposes of subparagraph (A), the term "claimant" includes--

(i)an individual filing a claim directly against the applicable plan; and

(ii)an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) Enforcement.

(i) In general. An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $ 1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A [*42 USCS § 1320a-7a*] 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 1128A(a) [*42 USCS § 1320a-7a(a)*]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this *title [42 USCS §§ 1395* et seq.] with respect to an individual.

(ii) Deposit of amounts collected. Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) Applicable plan. In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) Sharing of information. The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) Implementation. Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(I) Regulations. Not later than 60 days after the date of the enactment of this subparagraph [enacted Jan. 10, 2013], the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) Exception.

(A) In general. Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) Annual computation of threshold.

(i) In general. Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for 2014 shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for a year, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

(ii) Publication. The Secretary shall include, as part of such publication for a year--

(I)the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II)a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) Exclusion of ongoing expenses. For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this *title [42 USCS §§ 1395* et seq.].

(D) Report to Congress. Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment

obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall--

(i)calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii)include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) Drug products. No payment may be made under part B [*42 USCS §§ 1395j* et seq.] for any expenses incurred for--

(1)a drug product--

(A)which is described in section 107(c)(3) of the Drug Amendments of 1962 [*21 USCS § 321* note],

(B)which may be dispensed only upon prescription,

(C)for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 355(e)*] on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D)for which the Secretary has not determined there is a compelling justification for its medical need; and

(2)any other drug product--

(A)which is identical, related, or similar (as determined in accordance with *section 310.6 of title 21 of the Code of Federal R*egulations) to a drug product described in paragraph (1), and

(B)for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) Payment for EMTALA-mandated screening and stabilization services. For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 [*42 USCS § 1395dd*] to an individual who is entitled to benefits under this *title [42 USCS §§ 1395* et seq.], determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e) Item or service by excluded individual or entity or at direction of excluded physician; limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities.

(1) No payment may be made under this *title [42 USCS §§ 1395* et seq.] with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished--

(A)by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [*42 USCS § 1320a-7*, *1320a-7a*, *1320c-5*, or *1395u(j)(2)*] from participation in the program under this *title [42 USCS §§ 1395* et seq.]; or

(B)at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [*42 USCS § 1320a-7*, *1320a-7a*, *1320c-5*, or *1395u(j)(2)*] from participation in the program under this *title [42 USCS §§ 1395* et seq.]

and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this *title [42 USCS §§ 1395* et seq.] submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this *title [42 USCS §§ 1395* et seq.], pursuant to section 1128, 1128A, 1156, 1160 [*42 USCS § 1320a-7*, *1320a-7a*, *1320c-5*, *1320c-9*] (as in effect on September 2, 1982), 1842(j)(2), 1862(d) [*42 USCS § 1395u(j)(2)*, *1395y(d)*] (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987 [enacted Aug. 18, 1987]), or 1866 [*42 USCS § 1395cc*], and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this *title [42 USCS §§ 1395* et seq.], and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) Utilization guidelines for provision of home health services. The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B [*42 USCS §§ 1395c* et seq. or *1395j* et seq.] for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) Contracts with quality improvement organizations. The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this *title [42 USCS §§ 1395* et seq.], enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act [*42 USCS §§ 1320c* et seq.].

(h) Waiver of electronic submission of claims.

(1) The Secretary--

(A)shall waive the application of subsection (a)(22) in cases in which--

(i)there is no method available for the submission of claims in an electronic form; or

(ii)the entity submitting the claim is a small provider of services or supplier; and

(B)may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means--

(A)a provider of services with fewer than 25 full-time equivalent employees; or

(B)a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) Awards and contracts for original research and experimentation of new and existing medical procedures; conditions. In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) [*42 USCS § 1395ww(e)*] in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) [*42 USCS § 1395ww(e)(6)(E)(ii)*] with respect to such a procedure if the Secretary finds that--

(1)such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2)research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3)such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j) Advisory committees with respect to exclusions from medicare coverage.

(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that--

(A)is exempt from disclosure pursuant to subsection (a) of *section 552 of title 5, United States Code*, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B)the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k) Treatment of certain dental claims.

(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2)A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) National and local coverage determination process.

(1) Factors and evidence used in making national coverage determinations. The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. 371(h)*).

(2) Timeframe for decisions on requests for national coverage determinations. In the case of a request for a national coverage determination that--

(A)does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B)requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) Process for public comment in national coverage determinations.

(A) Period for proposed decision. Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B)30-day period for public comment. Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C)60-day period for final decision. Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall--

(i)make a final decision on the request;

(ii)include in such final decision summaries of the public comments received and responses to such comments;

(iii)make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv)in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) Consultation with outside experts in certain national coverage determinations. With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) Local coverage determination process.

(A) Plan to promote consistency of coverage determinations. The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) Consultation. The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) Dissemination of information. The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(D) Local coverage determinations **[Caution: This subparagraph is applicable to local coverage determinations that are proposed or revised on or after 6/11/2017, as provided by § 4009(b) of Act Dec. 13, 2016, P.L. 114-255, which appears as a note to this section.]**. The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv)A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

(6) National and local coverage determination defined. For purposes of this subsection--

(A) National coverage determination. The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) Local coverage determination. The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B) [*42 USCS § 1395ff(f)(2)(B)*].

(m) Coverage of routine costs associated with certain clinical trials of category A devices.

(1) In general. In the case of an individual entitled to benefits under part A [*42 USCS §§ 1395c* et seq.], or enrolled under part B [*42 USCS §§ 1395j* et seq.], or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) Category A clinical trial. For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if--

(A)the trial is of an experimental/investigational (category A) medical device (as defined in regulations under *section 405.201(b) of title 42, Code of Federal R*egulations (as in effect as of September 1, 2003));

(B)the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C)in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) Requirement of a surety bond for certain providers of services and suppliers.

(1) In general. The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $ 50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) Provider of services or supplier described. A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C) [*42 USCS §§ 1395m(a)(16)(B)* and *1395x(o)(7)(C)*].

(o) Suspension of payments pending investigation of credible allegations of fraud.

(1) In general. The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) Consultation. The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) Promulgation of regulations. The Secretary shall promulgate regulations to carry out this subsection and section 1903(i)(2)(C) [*42 USCS § 1396b(i)(2)(C)*].

(4) [Caution: This paragraph is applicable with respect to plan years beginning on or after 1/1/2020, as provided by § 2008(e) of Act Oct. 24, 2018, P.L. 115-271, which appears as *42 USCS § 1395w-27* note.] Credible allegation of fraud. In carrying out this subsection, section 1860D-12(b)(7) [*42 USCS § 1395w-112(b)(7)*] (including as applied pursuant to section 1857(f)(3)(D) [*42 USCS § 1395w-27(f)(3)(D)*]), and section 1903(i)(2)(C) [*42 USCS § 1396b(i)(2)(C)*], a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

History

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1862, as added July 30, 1965,P.L. 89-97 Title I, Part 1, § 102(a), 79 Stat. 325; Jan. 2, 1968, P.L. 90-248, Title I, Part 3, §§ 127(b), 128, 81 Stat. 846, 847; Oct. 30, 1972, P.L. 92-603, Title II, §§ 210, 211(c)(1), 229(a), 256(c), 86 Stat. 1382, 1384, 1408, 1447; Dec. 31, 1973, P.L. 93-233, § 18(k)(3), 87 Stat. 970; Oct. 26, 1974, P.L. 93-480, § 4(a), 88 Stat. 1454; Dec. 31, 1975, P.L. 94-182, Title I, § 103, 89 Stat. 1051; Oct. 25, 1977, P.L. 95-142, §§ 7(a), 13(a), (b)(1), (2), 91 Stat. 1192, 1197, 1198; Dec. 13, 1977, P.L. 95-210, § 1(f), 91 Stat. 1487; June 17, 1980, P.L. 96-272, Title III, § 308(a), 94 Stat. 531; Dec. 5, 1980, P.L. 96-499, Title IX, Part A, Subpart II, § 913(b), Part B, Subpart I, §§ 936(c), 939(a), Subpart II, § 953, 94 Stat. 2620, 2640, 2647; Dec. 28, 1980, P.L. 96-611, § 1(a)(3), 94 Stat. 3566; Aug. 13, 1981, *P.L. 97-35*, Title XXI, Subtitle A, Ch 1, § 2103(a)(1) Subtitle B, Ch 3, § 2146(a), Ch 4, 2152(a), 95 Stat. 787, 800, 802; Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart C, § 116(b), Part II, § 122(f), (g)(1), Part III, § 128(a)(2)-(4), Subtitle C, §§ 142, 148(a), *96 Stat. 353*, 362, 366, 381, 394; Jan. 12, 1983, P.L. 97-448, Title III, § 309(b)(10), *96 Stat. 2409*; April 20, 1983, P.L. 98-21, Title VI, §§ 601(f), 602(e), 97 Stat. 162; July 18, 1984, P.L. 98-369, Division B, Title III, Subtitle A, Part I, §§ 2301(a), 2304(c), 2313(c), Part II, §§ 2344(a)-(c), 2354(b)(30), (31), *98 Stat. 1063*, 1068, 1078, 1095, 1101; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart A, § 9201(a), Part 3, Subpart A, § 9307(a), Part 4, § 9401(c), *100 Stat. 170*, 193, 199; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, §§ 9316(b), 9319(a), (b), 9320(h)(1), Part 3, 9343(c)(1), 100 Stat. 2007, 2010, 2015, 2039; Aug. 18, 1987, P.L. 100-93, § 8(c)(1), (3), 101 Stat. 692, 693; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 1, § 4009(j)(6)(C), Part 2, Subpart C, §§ 4034(a), 4036(a)(1), 4039(c)(1), Part 3, Subpart D, §§ 4072(c), 4085(i)(15), (16), 101 Stat. 1330-77, 1330-79, 1330-82, 1330-117, 1330-133; July 1, 1988, *P.L. 100-360*, Title II, Subtitle A, §§ 202(d), 204(d)(2), 205(e)(1), Title IV, Subtitle B, § 411(f)(4)(D)(i), (ii)(iv)(i)(4)(D), *102 Stat. 715*, 729, 731, 778, 790; Oct. 13, 1988, *P.L. 100-485*, Title VI, § 608(d)(24)(C)(i), (ii)(III), *102 Stat. 2421*; Dec. 13, 1989, *P.L. 101-234*, Title II, § 201(a)(1), *103 Stat. 1981*; Dec. 19, 1989, *P.L. 101-239*, Title VI, Subtitle A, Part 1, Subpart A, § 6003(g)(3)(D)(xi), Part 2, Subpart A, §§ 6103(b)(3)(B), 6115(b), Part 3, Subpart A, § 6202(a)(2)(A), (b)(1), (e)(1), Subtitle B, Part 2, § 6411(d)(2), *103 Stat 2154*, 2199, 2219, 2228, 2229, 2234, 2271; Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 2, Subpart A, § 4107(b), Subpart B, §§ 4153(b)(2)(B), 4157(c)(1), 4161(a)(3)(C), 4163(d)(2), 4203(a)(1), (b), (c), 4204(g)(1), *104 Stat. 1388*-62, 1388-84, 1388-89, 1388-94, 1388-100, 1388-107, 1388-112; Aug. 10, 1993, *P.L. 103-66*, Title XIII, Ch 2, Subch A, Part III, §§ 13561(a)(1), (b), (c), (d)(1), (e)(1), Part V, 13581(b), *107 Stat. 593*-595, 611; Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle B, Part III, §§ 145(c)(1), 147(e)(6), Subtitle C, §§ 151(a)(1)(A), (C), (2)(A), (b)(3)(A), (B), (c)(1), (4)-(6), (9), 156(a)(2)(D), 157(b)(7), *108 Stat. 4427*, 4430, 4432-4436, 4441, 4442; Oct. 2, 1996, *P.L. 104-224*, § 1, *110 Stat. 3031*; Oct. 2, 1996, *P.L. 104-226*, § 1(b)(1), *110 Stat. 3033*; April 30, 1997, *P.L. 105-12*, § 9(a)(1), *111 Stat. 26*; Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle A, Ch 1, Subch A, § 4001, Ch 3, § 4022(b)(1)(B), Subtitle B, §§ 4102(c), 4103(c), 4104(c)(3), Subtitle C, § 4201(c)(1), Subtitle D, Ch 2, § 4319(b), Subtitle E, Ch 3, § 4432(b)(1), Subtitle F, Ch 1, Subch A, § 4507(a)(2)(B), Subch B, § 4511(a)(2)(C), Ch 4, § 4541(b), Subtitle G, Ch 1, Subch A, § 4603(c)(2)(C), Subch B, § 4614(a), Ch 3, §§ 4631(a)(1), (b), (c)(1), 4632(a), 4633(a), (b), *111 Stat. 275*, 354, 361, 362, 365, 373, 394, 420, 440, 442, 456, 471, 474, 486, 487; Nov. 29, 1999, *P.L. 106-113*, Div B, § 1000(a)(6), *113 Stat. 1536*; Dec. 21, 2000, *P.L. 106-554*, § 1(a)(6), *114 Stat. 2763*; Dec. 27, 2001, *P.L. 107-105*, § 3(a), *115 Stat. 1006*; Dec. 8, 2003, *P.L. 108-173*, Title I, § 101(a)(1), Title III, §§ 301(a)-(c), 303(i)(3)(B), Title VI, Subtitle B, §§ 611(d)(1), 612(c), 613(c), Title VII, Subtitle D, § 731(a)(1), (b)(1), Title IX, § 900(e)(1)(J), Subtitle E, §§ 944(a)(1), 948(a), 950(a), *117 Stat. 2071*, 2221, 2254, 2304, 2305, 2306, 2349, 2351, 2372, 2422, 2425, 2426.)

(As amended Feb. 8, 2006,*P.L. 109-171*, Title V, Subtitle B, Ch. 2, § 5112(d), *120 Stat. 44*; Dec. 29, 2007, *P.L. 110-173*, Title I, § 111(a), *121 Stat. 2497*; July 15, 2008, *P.L. 110-275*, Title I, Subtitle A, Part I, § 101(a)(3), (b)(3), (4), Subtitle C, Part I, § 135(a)(2)(A), Part II, §§ 143(b)(7), 152(b)(1)(D), 153(b)(2), *122 Stat. 2497*, 2498, 2535, 2543, 2552, 2555; March 23, 2010, *P.L. 111-148*, Title I, Subtitle B, § 1104(d), Title IV, Subtitle B, § 4103(d), Title VI, Subtitle E, § 6402(g)(3), (h)(1), *124 Stat. 153*, 556, 759; Oct. 21, 2011, *P.L. 112-40*, Title II, Subtitle C, Part II, § 261(a)(3)(A), *125 Stat. 423*; Jan. 10, 2013, *P.L. 112-242*, Title II, §§ 201, 202(a), 203-205(a), *126 Stat. 2375*, 2380; Nov. 26, 2014, P.L. 113-188, Title IX, § 902(d), *128 Stat. 2022*; April 16, 2015, *P.L. 114-10*, Title V, Subtitle A, § 516(a), *129 Stat. 175*; Dec. 13, 2016, P.L. 114-255, Div A, Title IV, § 4009(a), 130 Stat. 1185; Oct. 24, 2018, P.L. 115-271, Title II, § 2008(c), (d), Title IV, § 4002, 132 Stat. 3931, 3959.)

Annotations

Notes

References in text:

"Section 1886(e)(6)", referred to in this section, is § 1886(e)(6) of Act Aug. 14, 1935, ch 531, Title XVIII, Part D[C], as added Sept. 3, 1982, *P.L. 97-248*, Title I, Subtitle A, Part I, Subpart A, § 101(a)(1), *96 Stat. 331*, which appeared as *42 USCS § 1395ww(e)(6)*, and was repealed by Act Aug. 5, 1997, *P.L. 105-33*, Title IV, § 4022(b)(1)(A)(i), *111 Stat. 354*.

The "Assisted Suicide Funding Restriction Act of 1997", referred to in this section, is Act April 30, 1997, *P.L. 105-12*, *111 Stat. 23*, which appears generally as *42 USCS §§ 14401* et seq. For full classification of this Act, consult USCS Tables volumes.

"This Act", referred to in this section, is Act Aug. 14, 1935, ch 531, *49 Stat. 620*, the Social Security Act, which appears generally as *42 USCS §§ 301* et seq. For full classification of such Act, consult USCS Tables volumes.

Explanatory notes:

The comma in subsec. (b)(1)(C) has been enclosed in brackets to indicate the probable intent of Congress to delete such punctuation.

The bracketed period has been inserted in subsec. (b)(2)(B)(viii) to indicate the probable intent of Congress to include such punctuation.

The provisions of *42 USCS § 1395aaa* (Act Aug. 14, 1935, ch 531, Title XVIII, Part C, § 1890, as added Aug. 18, 1987, *P.L. 100-93*, § 10, *101 Stat. 696*) were redesignated as subsec. (e)(2) of this section by Act July 1, 1988, *P.L. 100-360*, Title IV, Subtitle B, § 411(i)(4)(D)(ii), *102 Stat. 790*.

The amendments made by § 1000(a)(6) of Act Nov. 29, 1999, *P.L. 106-113*, are based on §§ 305(b) of Subtitle A 321(k)(10) of Subtitle C of Title III of H.R. 3426 (*113 Stat. 1501*A-362, 367), as introduced on Nov. 17, 1999, which was enacted into law by such § 1000(a)(6).

The amendments made by § 1(a)(6) of Act Dec. 21, 2000, *P.L. 106-554*, are based on § 102(c) of Subtitle A of Title I, § 313(a) of Subtitle B of Title III, § 432(b)(1) of Subtitle C of Title IV, and § 522(b) of Subtitle C of Title V of H.R. 5661 (*114 Stat. 2763*A-468, 499, 526, 546), as introduced on Dec. 14, 2000, which was enacted into law by such § 1(a)(6).

Prospective amendment:

Amendment of subsec. (o)(3), applicable with respect to plan years beginning on or after January 1, 2020. Act Oct. 24, 2018, *P.L. 115-271*, Title II, § 2008(c), *132 Stat. 3931* (applicable with respect to plan years beginning on or after 1/1/2020, as provided by § 2008(e), which appears as *42 USCS § 1395w-27* note), provides that subsec. (o)(3) is amended by inserting ", section 1860D-12(b)(7) [*42 USCS § 1395w-112(b)(7)*] (including as applied pursuant to section 1857(f)(3)(D) [*42 USCS § 1395w-27(f)(3)(D)*])," after "this subsection".

Amendments:

1968 . Act Jan. 2, 1968, in subsec. (a), in para. (7), inserted "procedures performed (during the course of any eye examination) to determine the refractive state of the eyes,".

Such Act further (applicable as provided by § 127(c) of such Act, which appears as *42 USCS § 1395x* note), in para. (11), deleted "or" following the semicolon, in para. (12), substituted "; or" for a period and added para. (13).

1972 . Act Oct. 30, 1972, added subsec. (c).

Such Act further (applicable as provided by § 211(d) of such Act, which appears as *42 USCS § 1395f* note), in subsec. (a), in para. (4), deleted "emergency" following "except for" and inserted "and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished".

Such Act further, added subsec. (d).

Such Act further (applicable as provided by § 256(d) of such Act, which appears as *42 USCS § 1395f* note), in subsec. (a), in para. (12), inserted ", except that payment may be made under part A in the case of inpatient hospital services in connection with a dental procedure where the individual suffers from impairments of such severity as to require hospitalization".

1973 . Act Dec. 31, 1973 (effective as provided by § 18(z-3)(2) of such Act, which appears as *42 USCS § 1395f* note., in subsec. (a)(12), substituted "the provision of such dental services if the individual, because of his underlying medical condition and clinical status, requires hospitalization in connection with the provision of such services; or" for "a dental procedure where the individual suffers from impairments of such severity as to require hospitalization; or".

1974 . Act Oct. 26, 1974, in subsec. (c), substituted "January 1, 1976" for "January 1, 1975".

1975 . Act Dec. 31, 1975, deleted subsec. (c), which read:

"(c) No payment may be made under this title with respect to any item or service furnished to or on behalf of any individual on or after January 1, 1976, if such item or service is covered under a health benefits plan in which such individual is enrolled under chapter 89 of title 5, United States Code, unless prior to the date on which such item or service is so furnished the Secretary shall have determined and certified that such plan or the Federal employees health benefits program under chapter 89 of such title 5 has been modified so as to assure that--

"(1) there is available to each Federal employee or annuitant enrolled in such plan, upon becoming entitled to benefits under part A or B, or both parts A and B of this title, in addition to the health benefits plans available before he becomes so entitled, one or more health benefits plans which offer protection supplementing the protection he has under this title, and

"(2) the Government or such plan will make available to such Federal employee or annuitant a contribution in an amount at least equal to the contribution which the Government makes toward the health insurance of any employee or annuitant enrolled for high option coverage under the Government-wide plans established under chapter 89 of such title 5, with such contribution being in the form of (A) a contribution toward the supplementary protection referred to in paragraph (1), (B) a payment to or on behalf of such employee or annuitant to offset the cost to him of his coverage under this title, or (C) a combination of such contribution and such payment.".

1977 . Act Oct. 25, 1977, § 13(a), (b)(1), (2) (effective 10/25/77 as provided by § 13(c) of that Act, which appears as a note to this section), in subsec. (d) in para. (1), in subpara. (B), deleted ", with the concurrence of the appropriate program review team appointed pursuant to paragraph (4)," following "which the Secretary finds", substituted subpara. (C) for one which read: "has furnished services or supplies which are determined by the Secretary, with the concurrence of the members of the appropriate program review team appointed pursuant to paragraph (4) who are physicians or other professional personnel in the health care field, to be substantially in excess of the needs of individuals or to be harmful to individuals or to be of a grossly inferior quality.", and deleted para. (4), which read:

"For the purposes of paragraph (1)(B) and (C) of this subsection, and clause (F) of section 1866(b)(2), the Secretary shall, after consultation with appropriate State and local professional societies, the appropriate carriers and intermediaries utilized in the administration of this title, and consumer representatives familiar with the health needs of residents of the State, appoint one or more program review teams (composed of physicians, other professional personnel in the health care field, and consumer representatives) in each State which shall, among other things--

"(A) undertake to review such statistical data on program utilization as may be submitted by the Secretary,

"(B) submit to the Secretary periodically, as may be prescribed in regulations, a report on the results of such review, together with recommendations with respect thereto,

"(C) undertake to review particular cases where there is a likelihood that the person or persons furnishing services and supplies to individuals may come within the provisions of paragraph (1)(B) and (C) of this subsection or clause (F) of section 1866(b)(2), and

"(D) submit to the Secretary periodically, as may be prescribed in regulations, a report of cases reviewed pursuant to subparagraph (C) along with an analysis of, and recommendations with respect to, such cases.".

Section 7(a) such Act added subsec. (e).

Act Dec. 13, 1977 (applicable as provided by § 1(j) of such Act, which appears as *42 USCS § 1395k* note), in subsec. (a)(3), substituted "in the case of rural health clinic services, as defined in section 1861(aa)(1), and in such other cases" for "in such cases".

1980 . Act June 17, 1980, added subsec. (d)(4).

Act Dec. 5, 1980 (applicable with respect to services provided on or after 7/1/81, as provided by § 936(d) of such Act, which appears as *42 USCS § 1395f* note), in subsec. (a), in para. (12), inserted "or because of the severity of the dental procedure".

Such Act further (applicable with respect to services furnished on or after 7/1/81, as provided by § 939(b) of such Act, which appears as a note to this section), in subsec. (a), in para. (13)(C), deleted ", warts," following "corns,".

Such Act further, in subsec. (b), inserted "or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance", ", policy, plan, or insurance" and "The Secretary may waive the provisions of this subsection in the case of an individual claim if he determines that the probability of recovery or amount involved in such claim does not warrant the pursuing of the claim."; and substituted subsec. (e) for one which read:

"(e)

(1) Whenever the Secretary determines that a physician or other individual practitioner has been convicted (on or after the date of the enactment of this subsection, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to such physician's or practitioner's involvement in the programs under this title or the program under title XIX, the Secretary shall suspend such physician or practitioner from participation in the program under this title for such period as he may deem appropriate; and no payment may be made under this title with respect to any item or service furnished by such physician or practitioner during the period of such suspension. The provisions of paragraphs (2) and (3) of subsection (d) shall apply with respect to determinations made by the Secretary under this subsection.

"(2) In any case where the Secretary under paragraph (1) suspends any physician or other individual practitioner from participation in the program under this title, he shall--

"(A) promptly notify each single State agency which administers or supervises the administration of a State plan approved under title XIX of the fact, circumstances, and period of such suspension; and

"(B) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of such physician or practitioner of the fact and circumstances of such suspension, request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and request that such State or local agency or authority keep the Secretary and the Inspector General of the Department of Health, Education, and Welfare fully and currently informed with respect to any actions taken in response to such request.".

Act Dec. 28, 1980 (effective 7/1/81, as provided by § 2 in part of such Act, which appears as *42 USCS § 1395l* note), in subsec. (a), in para. (1) inserted ", or, in the case of items and services described in section 1861(s)(10),

which are not reasonable and necessary for the prevention of illness", and, in para. (7), inserted "(except as otherwise allowed under section 1861(s)(10) and paragraph (1))".

1981 . Act Aug. 13, 1981 (effective 10/1/81, as provided by § 2146(c)(1) of such Act, which appears as a note to this section), in subsec. (b), designated the existing provisions as para. (1), and added para. (2).

Such Act further (applicable with respect to expenses incurred on or after 10/1/81, as provided by § 2103(a)(2) of such Act, which appears as a note to this section), added subsec. (c).

Such Act further added subsec. (f).

1982 . Act Sept. 3, 1982 (applicable with respect to items and services furnished on or after 1/1/1983, as provided by § 116(c) of such Act, which appears as *29 USCS § 623* note), added subsec. (b)(3).

Such Act further (applicable to hospice care provided on or after 11/1/83, as provided by § 122(h)1)(A) of such Act, which appears as *42 USCS § 1395c* note), in subsec. (a), substituted para. (1) for one which read: "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, or, in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness;", in para. (6), inserted "(except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C))", in para. (7), substituted "paragraph (1)(B)" for "paragraph (1)", and in para. (9), inserted "(except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C)"; and in subsec. (f), substituted "paragraph (1)(A)" for "paragraph (1)".

Such Act further (effective as provided by § 128(e)(2) of such Act, which appears as *42 USCS § 1395x* note), in subsec. (b), in para. (1), deleted "or plan" following "such a law", in para. (2), in subpara. (A), substituted "section 162(i)(2)" for "section 162(h)(2)", and in subpara. (B), inserted "furnished".

Such Act further (effective as provided by § 149 of such Act, which appears as *42 USCS § 1320c* note), in subsec. (d)(1)(C), substituted "on the basis of information acquired by the Secretary in the administration of this title" for ", on the basis of reports transmitted to him in accordance with section 1157 of this Act (or, in the absence of any such report, on the basis of such data as he acquires in the administration of the program under this title),"; and added subsec. (g).

1983 . Jan. 12, 1983, in subsec. (b)(3)(A)(i), inserted "in any month" following "service furnished" and inserted "during any part of such month", wherever appearing.

Act April 20, 1983, §§ 601(f), 602(e)(1), (2) (applicable as provided by § 604 of such Act, which appears as *42 USCS § 1395ww* note), in subsec. (a), in para. (1), in subpara. (A), substituted "(B), (C), or (D)" for "(B) or (C)", in subpara. (B), deleted "and" following the concluding comma, in subpara. (C), substituted ", and" for a concluding semicolon, and added subpara. (D), in para. (12), deleted "or" following the concluding semicolon, and in para. (13), substituted "; or" for a concluding period.

Section 602(e)(3) of such Act (effective 10/1/83, as provided by § 604(a)(2) of such Act, which appears as *42 USCS § 1395ww* note) further, in subsec. (a), added para. (14).

1984 . Act July 18, 1984, § 2301 (applicable as provided by § 2301(c)(1) of such Act, which appears as a note to this section), in subsec. (b)(3)(A)(i), deleted "over 64 but" preceding "70 years" wherever it appears.

Section 2304 of such Act further (applicable as provided by § 2304(d) of such Act, which appears as a note to this section), added subsec. (h).

Section 2313 of such Act further (effective 7/18/84, as provided by § 2313(e) of such Act, which appears as a note to this section), added subsec. (i).

Section 2344 of such Act further (applicable as provided by § 2344(d) of such Act, which appears as a note to this section), in subsec. (b), in para. (1), inserted "promptly" and "or could be" and added the sentences beginning "In order to recover payment . . .", and "The United States shall . . .", in para. (2)(B), inserted "or could be" and added the sentences beginning "In order to recover payment . . .", and "The United States shall . . .", and in para. (3)(A)(ii), inserted "or could be" and added the sentences beginning "In order to recover payment . . ." and "The United States shall . . .".

Section 2354 of such Act further (effective 7/18/84, as provided by § 2354(e) of such Act, which appears as 42 USCS § 1320a-1 note), in subsec. (a)(12), deleted the second comma following "dental procedure"; and in subsec. (b)(3)(A)(iii), inserted "before the month" following "ending with the month".

1986 . Act April 7, 1986, § 9201(a) (applicable as provided by § 9201(d)(1), which appears as a note to this section), in subsec. (b)(3)(A), in cl. (i), deleted "who is under 70 years of age during any part of such month" following "to an individual" and deleted ", if the spouse is under 70 years of age during any part of such month" following "such individual", and, in cl. (iii), deleted "and ending with the month before the month in which such individual attains the age of 70" following "226(a)".

Section 9307(a) of such Act (applicable as provided by § 9307(e) of such Act, which appears as 42 USCS § 1320c-3 note), in subsec. (a), in para. (13)(C) deleted "or" following "care);", in para. (14), substituted "; or" for the concluding period, and added para. (15).

Section 9320(h)(1) of such Act (effective as to services furnished on or after Jan. 1, 1989, as provided by § 9320(i) of such Act, which appears as 42 USCS § 1395k note), in subsec. (a)(14), inserted "or are services or a certified registered nurse anesthetist".

Section 9401(c) of such Act, in subsec. (a), in para. (14), deleted "; or" following "hospital", in para. (15), substituted "; or" for the concluding period and added para. (16).

Act Oct. 21, 1986, § 9316(b), in subsec. (a)(1), in subpara. (C), deleted "and" following "illness,", in subpara. (D), substituted ", and" for a semicolon, and added subpara. (E).

Section 9319(a), (b) of Act (applicable as provided by § 9319(f) of such Act, which appears as a note to this section), in subsec. (b), added paras. (3) and (4).

Section 9343(c)(1) of such Act (applicable as provided by § 9343(h)(2) of such Act, which appears as 42 USCS § 1395l note), in subsec. (a)(14), substituted "patient" for "inpatient".

1987 . Act Aug. 18, 1987 (effective as provided by § 15 of such Act, which appears as 42 USCS § 1320a-7 note) deleted subsec. (d), which read:

"(d)

(1) No payment may be made under this title with respect to any item or services furnished to an individual by a person where the Secretary determines under this subsection that such person--

"(A) has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application for payment under this title or for use in determining the right to a payment under this title;

"(B) has submitted or caused to be submitted (except in the case of a provider of services), bills or requests for payment under this title containing charges (or in applicable cases requests for payment of costs to such person) for services rendered which the Secretary finds, to be substantially in excess of such person's customary charges (or in applicable cases substantially in excess of such person's costs) for such services, unless the Secretary finds there is good cause for such bills or requests containing such charges (or in applicable cases, such costs); or

"(C) has furnished services or supplies which are determined by the Secretary on the basis of information acquired by the Secretary in the administration of this title to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care.

"(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of inpatient hospital services, posthospital extended care services, and home health services such determination shall be effective in the manner provided in section 1866(b)(3) and (4) with respect to terminations of agreements), and shall remain in effect until the Secretary finds

and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

"(3) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

"(4) The Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under title XIX of any determination made under the provisions of this subsection.".

Such Act further substituted subsec. (e) for one which read: "(e) No payment may be made under this title with respect to any item or service furnished by a physician or other individual during the period when he is barred pursuant to section 1128 from participation in the program under this title."; and, in subsec. (h)(4), in the introductory matter, substituted "subsections (c), (f), and (g) of section 1128" for "paragraphs (2) and (3) of subsection (d)".

Act Dec. 22, 1987, § 4009(j)(6)(C) (effective as if included in Act Oct. 21, 1986 as provided by § 4009(j)(6) of the 1987 Act, which appears as *42 USCS § 1395ww* note), in subsec. (a)(14), made a technical change which did not affect the wording of the section.

Section 4034(a) of such Act (applicable as provided by § 4034(b) of such Act, which appears as a note to this section), in subsec. (b)(4)(B)(i), substituted "subsection (b) of *section 5000 of the Internal Revenue Code of 1986* without regard to subsection (d) of such section" for "*section 5000(b) of the Internal Revenue Code of 1986*".

Section 4036(a)(1) (applicable as provided by § 4036(a)(2) of such act, which appears as a note to this section), in subsec. (b)(2)(A), substituted cl. (ii) for one which read:

"the Secretary determines will be made under such a plan as promptly as would otherwise be the case if payment were made by the Secretary under this title.".

Section 4039(c)(1) of such Act (effective on 1/1/88 as provided by § 4039(c)(2) of such Act, which appears as a note to this section), in subsec. (h), in para. (1), in subpara. (B), substituted "law (and any amount paid to a provider under any such warranty)," for "law,", in subpara. (D), inserted "in determining the amount subject to repayment under paragraph (2)(C),", in para. (2), in subpara. (A), deleted "and" following "title,", in subpara. (B), substituted", and" for the concluding period, and added subpara. (C), and, in para. (4)(B), substituted ", has" for "or has", and inserted "or has failed to make repayment to the Secretary as required under paragraph (2)(C),".

Section 4072(a) of such Act (applicable as provided by § 4072(e) of such Act, which appears as *42 USCS § 1395x* note), in subsec. (a)(8), inserted ", other than shoes pursuant to section 1861(s)(12)".

Section 4085(i)(15), (16) of such Act, in subsec. (a), in para. (1)(A), substituted "(D), or (E)" for "or (D)" and, in para. (14), substituted "a patient" for "an patient".

Section 4009(j)(6)(C) of such Act further (effective as if included in Act Oct. 21, 1986, as provided by § 4006(j)(6) of such Act, which appears as *42 USCS § 1395ww* note), amended the legislative instructions of § 9320(h)(1) of Act Oct. 21, 1986, *P.L. 99-509*, Title IX, Subtitle D, Part 2, *100 Stat. 2015* by substituting "before the semicolon" for "before the period".

1988 . Act July 1, 1988, § 202(d) (applicable to items dispensed on or after 1/1/90, as provided by § 202(m)(1) of such Act, which appears as *42 USCS § 1395u* note), in subsec. (c), designated the existing provisions as para. (1), redesignated former para. (1) as subpara. (A) and former subparas. (A)-(D) as cls. (i)-(iv), redesignated former para. (2) as subpara. (B) and, in subpara. (B) as redesignated, redesignated former subparas. (A) and (B) as cls. (i) and (ii), in cl. (i) as redesignated, substituted "subparagraph (A)" for "paragraph (1)", and added new para. (2).

Section 204(d)(2) of such Act (applicable to screening mammography performed on or after 1/1/90, as provided by § 204(e) of such Act, which appears as *42 USCS § 1395m* note), in subsec. (a), in para. (1), in subpara. (A), substituted "a succeeding subparagraph" for "subparagraph (B), (C), (D), or (E)", in subpara. (D), deleted "and"

following the concluding comma, in subpara. (E), substituted ", and" for a semicolon, and added subpara. (F); and in para. (7), inserted "or under paragraph (1)(F)".

Section 205(e)(1) of such Act (applicable to items and services furnished on or after 1/1/90, as provided by § 205(e)(2) of such Act, which appears as *42 USCS § 1395k* note), in subsec. (a), in para. (1), in subpara. (E), deleted "and" following the concluding comma, in subpara. (F), added "and" following the concluding semicolon, and added subpara. (G), and, in para. (6), inserted "and except in the case of in-home care, as is otherwise permitted under paragraph (1)(G)".

Section 411(f)(4)(D)(i) of such Act (applicable to operations performed on or after 60 days after enactment, as provided by § 411(f)(4)(D)(ii) of such Act, which appears as a note to this section), in subsec. (a)(15), inserted "(including subsequent insertion of an intraocular lens)".

Section 411(i)(4)(D) of such Act, further (effective as if included in Act Dec. 22, 1987 as provided by § 411(a)(2) of the 1988 Act, which appears as *1 USCS § 106* note), in subsec. (e), designated the existing provisions as para. (1), and in such para. redesignated former paras. (1) and (2) as subparas. (A) and (B), in such subparas., substituted "1128, 1128A, 1156, 1842(j)(2), or 1867(d)" for "section 1128 or section 1128A", transferred *42 USCS § 1395aaa* to be para. (2), and in such para., inserted "1842(j)(2)", and substituted "1866, or 1867(d)" for "or 1866".

Act Oct. 13, 1988, amended Act July 1, 1988, *P.L. 100-360*, Title IV, Subtitle B, § 411(i)(4)(D), *102 Stat. 790*, [amending this section] (effective as if included in Act July 1, 1988 as provided by § 608(g) of the later 1988 Act, which appears as *42 USCS § 704* note), in subsec. (e), in para. (1), in subparas. (A) and (B), substituted "or 1842(j)(2)" for ", 1842(j)(2), or 1867(d)", and in para. (2), by substituting "or 1866" for "1866, or 1867(d)".

1989 . Act Dec. 13, 1989 (effective 1/1/90 as provided by § 201(c) of such Act, which appears as *42 USCS § 1320a-7a*), pursuant to the repeal of §§ 201-208 of Act July 1, 1988, *P.L. 100-360*, in subsec. (a), in para. (1), substituted "subparagraph (B), (C), (D), or (E)" for "a succeeding subparagraph", in subpara. (D), added "and" following "section 1886(e)(6),", in subpara. (E), substituted the semicolon for ", and", and deleted subparas. (F) and (G) which read:

"(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(e)(2) or which does not meet the standards established under section 1834(e)(3);

"(G) in the case of in-home care for chronically dependent individuals, which is not reasonable and necessary to assure the health and condition of the individual is maintained in the individual's noninstitutional residence;".

Such Act further (effective as above), in subsec. (a), in para. (6), deleted "and except, in the case of in-home care, as is otherwise permitted under paragraph (1)(G)" following "paragraph (1)(C)", and in para. (7), deleted "or under paragraph (1)(F)" following "(1)(B)".

Such Act further (effective as above) substituted subsec. (c) for one which read:

"(c) Drug products.

(1) No payment may be made under part B for any expenses incurred for--

"(A) a drug product--

"(i) which is described in section 107(c)(3) of the Drug Amendments of 1962,

"(ii) which may be dispensed only upon prescription,

"(iii) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

"(iv) for which the Secretary has not determined there is a compelling justification for its medical need; and

"(B) any other drug product--

"(i) which is identical, related, or similar (as determined in accordance with *section 310.6 of title 21 of the Code of Federal R*egulations) to a drug product described in subparagraph (A), and

"(ii) for which the Secretary has not determined there is a compelling justification for its medical need, until such time as the Secretary withdraws such proposed order.

"(2) No payment may be made under part B for any expense incurred for a covered outpatient drug if the drug is dispensed in a quantity exceeding a supply of 30 days or such longer period of time (not to exceed 90 days, except in exceptional circumstances) as the Secretary may authorize.".

Act Dec. 19, 1989, § 6003(g)(3)(D)(xi), in subsec. (a)(14), substituted "hospital or rural primary care hospital" for "hospital" wherever appearing.

Section 6103(b)(3)(B) of such Act, in subsec. (a)(1)(E), substituted "section 1142" for "section 1875(c)".

Section 6115(b) of such Act (applicable as provided by § 6115(d) of such Act, which appears as *42 USCS § 1395x* note), in subsec. (a)(1)(F), purported to insert ", and in the case of screening pap smear, which is performed more frequently than is provided under 1861(nn)" but such amendment could not be executed pursuant to repeal of Act July 1, 1988, *P.L. 100-360*, which added (F).

Section 6202(a)(1) of such Act added subsec. (b)(5).

Section 6202(b) of such Act (applicable to items and services furnished after enactment as provided by § 6202(b)(5) of such Act, which appears as *26 USCS § 162* note), substituted subsec. (b) for one which read:

"(1) Payment under this title may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made promptly (as determined in accordance with regulations), with respect to such item or service, under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance. Any payment under this title with respect to any item or service shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been or could be made under such a law, policy, plan, or insurance. In order to recover payment made under this title for an item or service, the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a law, policy, plan, or insurance, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such law, policy, plan, or insurance, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this title for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a law, policy, plan, or insurance. The Secretary may waive the provisions of this subsection in the case of an individual claim if he determines that the probability of recovery or amount involved in such claim does not warrant the pursuing of the claim.

"(2)

(A) In the case of an individual who is entitled to benefits under part A or is eligible to enroll under Part B solely by reason of section 226A payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service furnished during the period described in subparagraph (C) to the extent that payment with respect to expenses for such item or service (i) has been made under any group health plan (as defined in *section 162(i)(2) of the Internal Revenue Code of 1954* or (ii) can reasonably be expected to be made under such a plan.

"(B) Any payment under this title with respect to any item or service furnished to an individual described in subparagraph (A) during the period described in subparagraph (C) shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been or could be made under a plan described in subparagraph (A). In order to recover

payment made under this title for an item or service, the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such plan, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this title for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a plan. The Secretary may waive the provisions of this subparagraph in the case of an individual claim if he determines that the probability of recovery or amount involved in such claim does not warrant the pursuing of the claim.

"(C) The provisions of subparagraphs (A) and (B) shall apply to an individual only during the 12-month period which begins with the earlier of--

"(i) the month in which a regular course of renal dialysis is initiated, or

"(ii) in the case of an individual who receives a kidney transplant, the first month in which he would be eligible for benefits under this title (if he had filed an application for such benefits) under the provisions of section 226A(b)(1)(B).

"(D) Where payment for an item or service under such plan is less than the amount of the charge for such item or service, payment may be made under this title (without regard to deductibles and coinsurance under this title for the remainder of such charge, but--

"(i) such payment under this title may not exceed an amount which would be payable under this title for such item or service in the absence of such group health plan; and

"(ii) such payment under this title, when combined with the amount payable under such plan, may not exceed the combined amount which would have been payable under this title and such plan if this paragraph were not in effect.

"(3)

(A)

(i) Payment under this title may not be made, except as provided in clause (ii), with respect to any item or service furnished in any month during the period described in clause (iii) to an individual (or to the spouse of such individual) who is employed at the time such item or service is furnished to the extent that payment with respect to expenses for such item or service has been made, or can reasonably be expected to be made, under a group health plan (as defined in clause (iv)) under which such individual is covered by reason of such employment.

"(ii) Any payment under this title with respect to any item or service during the period described in clause (iii) shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been or could be made under a group health plan. In order to recover payment made under this title for an item or service, the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such plan, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this title for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a plan. The Secretary may waive the provisions of this clause in the case of an individual claim if he determines that the probability of recovery or amount involved in such claim does not warrant the pursuing of the claim.

"(iii) The provisions of clauses (i) and (ii) shall apply to an individual only for the period beginning with the month in which such individual becomes entitled to benefits under this title under section 226(a) and shall not include any month for which the individual would, upon application, be entitled to benefits under section 226A.

"(iv) For purposes of this paragraph, the term "group health plan" has the meaning given to such term in *section 162(i)(2) of the Internal Revenue Code of 1954*.

"(B) Where payment for an item or service under a group health plan is less than the amount of the charge for such item or service, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but--

"(i) such payment under this title may not exceed an amount which would be payable under this title for such item or service in the absence of such group health plan; and

"(ii) such payment under this title when combined with the amount payable under such plan, may not exceed--

"(I) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this *title [42 USCS §§ 1395* et seq.] on such basis; and

"(II) in the case of an item or service for which payment is authorized under this title on another basis, the greater of--

"(a) the amount which would be payable under the group health plan (without regard to deductibles and coinsurance under such plan), or

"(b) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title.

"(4)

(A)

(i) A large group health plan may not take into account that an active individual is eligible for or receives benefits under this title under section 226(b), other than an individual who is, or would upon application be, entitled to benefits under section 226A.

"(ii) Payment may not be made under this title, except as provided in clause (iii), with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under clause (i).

"(iii) Any payment under this title with respect to any item or service to which clause (i) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this title. In order to recover payment made under this title for the item or service, the United States may bring an action against any entity which is required under this subsection (a) to pay with respect to the item or service (and may, in accordance with paragraph (5), collect double damages against that entity), or against any other entity that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service. The United States shall be subrogated (to the extent of payment made under this title for an item or service) to any right under clause (i) of an individual or any other entity to payment with respect to the item or service. The Secretary may waive (in whole or in part) the provisions of this clause in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title.

"(B) In this paragraph:

"(i) The term "large group health plan" has the meaning given such term in subsection (b) of *section 5000 of the Internal Revenue Code of 1986* without regard to subsection (d) of such section.

"(ii) The term "active individual" means an employee (as may be defined in regulations), the employer, an individual associated with the employer in a business relationship, or a member of the family of any of those persons.

"(C) The provisions of subparagraph (B) of paragraph (3) shall apply to coordination of payment under this paragraph in the case of large group health plans in the same manner as they apply to coordination of payment under paragraph (3) in the case of group health plans.

"(D) The preceding provisions of this paragraph shall only apply to items and services furnished on or after January 1, 1987, and before January 1, 1992.

"(5) There is hereby created a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a workmen's compensation law or plan, automobile or liability insurance policy or plan or no fault insurance plan, group health plan, or large group health plan which is made a primary payer under paragraph (1), (2), (3), or (4), respectively, and which fails to provide for primary payment (or appropriate reimbursement) in accordance with such respective paragraphs.".

Section 6202(e)(1) of such Act (applicable as provided by § 6202(e)(2) of such Act, which appears as a note to this section), in subsec. (b)(1), added subpara. (D).

Section 6411(d)(2) of such Act (effective 12/19/89 as provided by § 6411(d)(4) [(A)] of such Act, which appears as *42 USCS § 1320a-7* note), in subsec. (e)(1), inserted ", not including items or services furnished in an emergency room of a hospital".

1990 . Act Nov. 5, 1990, in subsec. (a)(15), designated the existing provisions as subpara. (A), and added subpara. (B).

Section 4153(b)(2)(B) of such Act (applicable to items furnished on or after 1/1/91, as provided by § 4153(b)(2)(C) of such Act, which appears as *42 USCS § 1395x* note), in subsec. (a)(7), inserted "(other than eyewear described in section 1861(s)(8))".

Section 4157(c)(1) of such Act (applicable to services furnished on or after 1/1/91, as provided by § 4157(d) of such Act, which appears as *42 USCS § 1395k* note), in subsec. (a)(14), inserted a comma and "services described by section 1861(s)(2)(K)(i), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist,", and deleted "or are services of a certified registered nurse anesthetist" preceding the concluding semicolon.

Section 4161(a)(3)(C) os such Act (applicable as provided by § 4161(a)(8) of such Act, which appears as *42 USCS § 1395k* note), in subsec. (a), in para. (2), inserted ",except in the case of Federally qualified health center services", in para. (3), inserted ", in the case of Federally qualified health center services, as defined in section 1861(aa)(3)," and added the concluding matter.

Section 4163(d)(2)(A)(i)-(iii) of such Act (applicable to screening mammography performed on or after 1/1/91, as provided by § 4163(e) of such Act, which appears as a note to *42 USCS § 13951*), in subsec. (a), in para. (1), substituted "a succeeding subparagraph" for "subparagraph (B), (C), (D), or (E)", in subpara. (D), deleted "and" after the concluding period, and, in para. (7), inserted "or under paragraph (1)(F)".

Section 4163(d)(2)(A)(iv) of Act Nov. 5, 1990 (applicable to screening pap smears performed on or after 7/1/90, as provided by § 4163(d)(3) of such Act, which appears as a note to this section), in subsec. (a)(1), added subpara. (F),

Section 4203(a)(1), (b), and (c) of such Act (effective on enactment as provided by § 4203(d) of such Act), in subsec. (b), in para. (1), in subpara. (B)(iii), substituted "October 1, 1995" for "January 1, 1992", in subpara. (C)(i), substituted "during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and" for "12-month period which begins with the earlier of--

"(I) the month in which a regular course of renal dialysis is initiated, or

"(II) in the case of an individual who receives a kidney transplant, the first month in which he would be eligible for benefits under part A [*42 USCS § 1395c* et seq.] (if he had filed an application for such benefits) under the provisions of section 226A(b)(1)(B); and",

and, in the concluding matter, added the sentence beginning "Effective for items and services . . .", and, in para. (5)(C)(iii), substituted "September 30, 1995" for "September 30, 1991".

Section 4204(g)(1) of such Act (applicable to incentives offered on or after enactment, as provided by § 4204(g)(2) of such Act, which appears as a note to this section), in subsec. (b)(3), added subpara. (C).

1993 . Act Aug. 10, 1993, in subsec. (b)(1), in subpara. (A), in cl. (i), substituted subcls. (I) and (II) for ones which read:

"(I) may not take into account, for any item or service furnished to an individual 65 years of age or older at the time the individual is covered under the plan by reason of the current employment of the individual (or the individual's spouse), that the individual is entitled to benefits under this title under section 226(a), and

"(II) shall provide that any employee age 65 or older, and any employee's spouse age 65 or older, shall be entitled to the same benefits under the plan under the same conditions as any employee, and the spouse of such employee, under age 65.",

in cl. (ii), substituted "unless the plan is a plan of, or contributed to by, an employer or employee organization that has 20 or more individuals in current employment status" for "unless the plan is sponsored by or contributed to by an employer that has 20 or more employees", in cl. (iii), substituted "by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and" for "by virtue of employment with an employer that does not have 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or" and, in cl. (iv), substituted "Subparagraph (C) shall apply instead of clause (i)" for "Clause (i) shall not apply" and inserted "(without regard to entitlement under section 226)".

Such Act further (effective as if included in the enactment of Act Dec. 19, 1989, *P.L. 101-239*, as provided by § 13561(e)(1)(D) of the 1993 Act, as amended by Act Oct. 31, 1994, § 151(c)(9)(A)), in subsec. (b)(1)(A)(v), inserted ", without regard to section 5000(d) of such Code".

Such Act further, in subsec. (b)(1), in subpara. (B), in the heading, deleted "active" following "Disabled", in cl. (i), substituted "clause (iv)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer" for "clause (iv)(II)) may not take into account that an active individual (as defined in clause (iv)(I))", in cl. (ii), substituted "Subparagraph (C) shall apply instead of clause (i)" for "Clause (i) shall not apply" and inserted "(without regard to entitlement under section 226)", and in cl. (iii), substituted "1998" for "1995".

Such Act further (effective as if included in the enactment of Act Dec. 19, 1989, *P.L. 101-239*, as provided by § 151(c)(10) of Act Oct. 31, 1994, *P.L. 103-432*), in subsec. (b)(1)(B), substituted cl. (iv) for one which read:

"(iv) Definitions. In this subparagraph:

"(I) Active individual. The term 'active individual' means an employee (as may be defined in regulations), the employer, self-employed individual (such as the employer), an individual associated with the employer in a business relationship, or a member of the family of any of such persons.

"(II) Large group health plan. The term 'large group health plan' has the meaning given such term in *section 5000(b)(2) of the Internal Revenue Code of 1986*.".

Such Act further, in subsec. (b), in para. (1)(C), in cl. (i), substituted "or eligible for benefits under this title under" for "benefits under this title solely by reason of" and, in the concluding matter, substituted "before October 1, 1998" for "on or before January 1, 1996" and substituted "or eligible for benefits under this title under" for "benefits under this title solely by reason of" and, in para. (5)(C)(iii), substituted "1998" for "1995".

Such Act further (effective 90 days after enactment, as provided by § 13561(d)(3) of such Act), in subsec. (b)(1), added the heading, introductory matter, and cl. (i) of new subpara. (E).

Such Act further, in subsec. (b)(1)(E), added cls. (ii) and (iii).

Such Act further (effective 1/1/94 as provided by § 13581(d) of such Act, which appears as a note to this section), in subsec. (b)(5), in subpara. (B), substituted "under--" and cls. (i), (ii), and the concluding matter for "under subparagraph (A) for the purposes of carrying out this subsection.", and, in subpara. (C), substituted "subparagraph (B)(i)" for "subparagraph (B)".

1994 . Act Oct. 31, 1994, § 145(c)(1) of such Act (applicable to mammography furnished by a facility on and after the first date that the certificate requirements of *42 USCS § 263b(b)* apply to such mammography conducted by such facility, as provided by § 145(d) of such Act, which appears as *42 USCS § 1395m* note), in subsec. (a)(1)(F), substituted "or which is not conducted by a facility described in section 1834(c)(1)(B)" for "or which does not meet the standards established under section 1834(c)(3)".

Section 147(e)(6) of such Act (effective as if included in the enactment of Act Nov. 5, 1990, *P.L. 101-508*, as provided by § 147(g) of the 1994 Act, which appears as *42 USCS § 1320a-3a* note), in subsec. (a)(14), substituted "1861(s)(2)(K)(i) or 1861(s)(2)(K)(iii)" for "1861(s)(2)(K)(i)".

Section 151(a)(1) of such Act, in subsec. (b), added paras. (2)(C) and (5)(D).

Section 151(a)(2)(A) of such Act (applicable as provided by § 151(a)(2)(B) of such Act, which appears as a note to this section) added subsec. (b)(6).

Section 151(b)(3)(A), (B) of such Act (applicable to payments for items and services furnished on or after enactment, as provided by § 151(b)(3)(C) of such Act, which appears as a note to this section), in subsec. (b)(2)(B)(i), substituted the heading for one which read: "Primary plans." and added the sentence beginning "If reimbursement is not made to the appropriate Trust Fund . . .".

Section 151(c)(1) of such Act (effective as if included in the enactment of Act Aug. 10, 1993, *P.L. 103-66*, as provided by § 151(c)(1) of the 1994 Act, which appears as a note to this section), in subsec. (b)(1)(A), in cl. (i)(II), substituted "older (and the spouse age 65 or older of any individual) who has current employment status with an employer" for "over (and the individual's spouse age 65 or older) who is covered under the plan by virtue of the individual's current employment status with an employer", and, in cl. (ii), substituted "that has 20 or more employees" for "or employee organization that has 20 or more individuals in current employment status".

Section 151(c)(4) of such Act (effective as if included in the enactment of Act Nov. 5, 1990, *P.L. 101-508*, as provided by § 151(c)(4) of the 1994 Act, which appears as a note to this section), in subsec. (b)(1)(C), in the concluding matter, substituted "this subparagraph" for "clauses (i) and (ii)".

Section 151(c)(5) of such Act (effective as if included in the enactment of Dec. 19, 1989, *P.L. 101-238*, as provided by § 151(c)(5) of the 1994 Act, which appears as a note to this section), in subsec. (b)(1)(C), in the concluding matter, substituted "paying benefits secondary to this title when" for "taking into account that".

Section 151(c)(6) of such Act (effective as if included in the enactment of Dec. 19, 1989, *P.L. 101-238*, as provided by § 151(c)(6) of the 1994 Act, which appears as a note to this section), in subsec. (b)(5)(C)(i), substituted "6103(l)(12)(E)(iii)" for "6103(l)(12)(D)(iii)".

Section 151(c)(9) of such Act (effective as if included in the enactment of Act Aug. 10, 1993, *P.L. 103-66*, as provided by § 151(c)(9) of the 1994 Act), inserted an effective date provision in, and amended the directory language of § 13561(e)(1)(D) of Act Aug. 10, 1993, without affecting the text of this section.

Section 156(a)(2)(D) of such Act (applicable to services provided on or after enactment, as provided by § 156(a)(3) of such Act, which appears as *42 USCS § 1320c-3* note), in subsec. (a), in para. (14), inserted "or" after the concluding semicolon, in para. (15)(B), substituted a period for "; and", and deleted para. (16), which read: "furnished in connection with a surgical procedure for which a second opinion is required under section 1164(c)(2) and has not been obtained.".

Section 157(b)(7) of such Act (effective as if included in the enactment of Act Nov. 5, 1990, *P.L. 101-508*, as provided by § 157(b)(8) of the 1994 Act, which appears as a note to this section), in subsec. (b)(3)(C), in the heading, substituted "plan or a large group health plan" for "plan", and in the text, substituted "group health plan or a large group health plan" for "group health plan", deleted ", unless such incentive is also offered to all individuals who are eligible for coverage under the plan" following "paragraph (2)(A)", and substituted "subsections (a) and (b)" for "the first sentence of subsection (a) and other than subsection (b)".

1996 . Act Oct. 2, 1996, *P.L. 104-224*, deleted subsec. (h), which read:

"(h) Registry of cardiac pacemaker devices and leads; testing of devices and leads; withholding of payment.

(1)

(A) The Secretary shall, through the Commissioner of the Food and Drug Administration, provide for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title.

"(B) Such registry shall include the manufacturer, model, and serial number of each such device or lead, the name of the recipient of such device or lead, the date and location of the implantation or removal of the device or lead, the name of the physician implanting or removing such device or lead, the name of the hospital or other provider billing for such procedure, any express or implied warranties associated with such device or lead under contract or State law (and any amount paid to a provider under any such warranty), and such other information as the Secretary deems to be appropriate.

"(C) Each physician and provider of services performing the implantation or replacement of pacemaker devices and leads for which payment is made or requested to be made under this title shall, in accordance with regulations of the Secretary, submit information respecting such implantation or replacement for the registry.

"(D) Such registry shall be for the purposes of assisting the Secretary in determining when payments may properly be made under this title, in tracing the performance of cardiac pacemaker devices and leads, in determining when inspection by the manufacturer of such a device or lead may be necessary under paragraph (3), in determining the amount subject to repayment under paragraph (2)(C), and in carrying out studies with respect to the use of such devices and leads. In carrying out any such study, the Secretary may not reveal any specific information which identifies any pacemaker device or lead recipient by name (or which would otherwise identify a specific recipient).

"(E) Any person or organization may provide information to the registry with respect to cardiac pacemaker devices and leads other than those for which payment is made under this title.

"(2) The Secretary may, by regulation, require each provider of services--

"(A) to return, to the manufacturer of the device or lead for testing under paragraph (3), any cardiac pacemaker device or lead which is removed from a patient and payment for the implantation or replacement of which was made or requested by such provider under this title,

"(B) not to charge any beneficiary for replacement of such a device or lead if the device or lead has not been returned in accordance with subparagraph (A), and

"(C) to make repayment to the Secretary of amounts paid under this title to the provider with respect to any cardiac pacemaker device or lead which has been replaced by the manufacturer, or for which the manufacturer has made payment to the provider, under an express or implied warranty.

"(3) The Secretary may, by regulation, require the manufacturer of a cardiac pacemaker device or lead (A) to test or analyze each pacemaker device or lead for which payment is made or requested under this title and which is returned to the manufacturer by a provider of services under paragraph (2), and (B) to provide the results of such test or analysis to that provider, together with information and documentation with respect to any warranties covering such device or lead. In any case where the Secretary has reason to believe, based upon information in the pacemaker registry or otherwise available to him, that replacement of a cardiac pacemaker device or lead for which

payment is or may be requested under this title is related to the malfunction of a device or lead, the Secretary may require that personnel of the Food and Drug Administration be present at the testing of such device by the manufacturer, to determine whether such device was functioning properly.

"(4) The Secretary may deny payment under this title, in whole or in part and for such period of time as the Secretary determines to be appropriate, with respect to the implantation or replacement of a pacemaker device or lead of a manufacturer performed by a physician and provider of services after the Secretary determines (in accordance with the procedures established under subsections (c), (f), and (g) of section 1128) that--

"(A) the physician or provider of services has failed to submit information to the registry as required under paragraph (1)(C),

"(B) the provider of services has failed to return devices and leads as required under paragraph (2)(A), has improperly charged beneficiaries as prohibited under paragraph (2)(B), or has failed to make repayment to the Secretary as required under paragraph (2)(C),

"(C) the manufacturer of the device or lead has failed to perform and to report on the testing of devices and leads returned to it as required under paragraph (3).".

Act Oct. 2, 1986, *P.L. 104-226*, in subsec. (b)(5), in subpara. (B), substituted "subparagraph (A) for purposes of carrying out this subsection." for "--

"(i) subparagraph (A), and

"(ii) section 1144,

for purposes of carrying out this subsection."

and, in subpara. (C)(i), substituted "subparagraph (B)" for "subparagraph (B)(i)".

1997 . Act April 30, 1997 (effective applicable as provided by § 11 of such Act, which appears as *42 USCS § 14401* note), in subsec. (a), in para. (14), deleted "or" after the concluding semicolon, in para. (15)(B), substituted "; or" for a concluding period, and added para. (16).

Act Aug. 5, 1997, in subsec. (a), in para. (15), deleted "or" after the concluding semicolon, in para. (16), substituted "; or" for a concluding period, and added para. (17); and, in subsec. (b), in para. (1), in subpara. (B), in cl. (i), substituted "clause (iii)" for "clause (iv)", deleted cl. (iii), which read: "(iii) Sunset. Clause (i) shall only apply to items and services furnished on or after January 1, 1987, and before October 1, 1998.", and redesignated cl. (iv) as cl. (iii), in subpara. (C), substituted "the date of enactment of the Balanced Budget Act of 1997" for "October 1, 1998" and added the sentence beginning "Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997 . . .", and, in para. (5)(C), deleted cl. (iii), which read: "(iii) Sunset on requirement. Clause (ii) shall not apply to inquiries made after September 30, 1998.".

Section 4022(b)(1)(B) of such Act (effective 11/1/97 pursuant to § 4022(c)(2) of such Act, which appears as *42 USCS § 1395b-6* note), in subsecs. (a)(1)(D) and (i), substituted "Medicare Payment Advisory Commission" for "Prospective Payment Assessment Commission"

Section 4102(c) of such Act (applicable to items and services furnished on or after 1/1/98, as provided by § 4102(e) of such Act, which appears as *42 USCS § 1395l* note), in subsec. (a)(1)(F), inserted "and screening pelvic exam".

Section 4103(c) of such Act (applicable to items and services furnished on or after 1/1/2000, as provided by § 4103(e), which appears as *42 USCS § 1395l* note), in subsec. (a), in para. (1), in subpara. (E), deleted "and" after the concluding semicolon, in subpara. (F), substituted ", and" for a concluding semicolon, and added subpara. (G) and, in para. (7), substituted "subparagraphs (B), (F), or (G) of paragraph (1)" for "paragraph (1)(B) or under paragraph (1)(F)".

Section 4104(c)(3) of such Act (applicable to items and services furnished on or after 1/1/98, as provided by § 4104(e), which appears as 42 USCS § 1395l note), in subsec. (a), in para. (1), in subpara. (F), deleted "and" after the concluding comma, in subpara. (G), substituted ", and" for a concluding semicolon, and added subpara. (H) and, in para. (7), substituted "(G), or (H)" for "or (G)".

Section 4201(c)(1) of such Act (applicable to services furnished on or after 10/1/97, as provided by § 4201(d) of such Act, which appears as 42 USCS § 1395f note), in subsec. (a)(14), substituted "critical access" for "rural primary care".

Section 4432(b)(1) of such Act (applicable to items and services furnished on or after 7/1/98, as provided by § 4432(d) of such Act, which appears as 42 USCS § 1395i-3 note), in subsec. (a), deleted "or" after the concluding semicolon, in para. (17), substituted "; or" for a concluding period, and added para. (18).

Section 4507(a)(2)(B) of such Act (applicable with respect to contracts entered into on and after 1/1/98, as provided by § 4507(c) of such Act, which appears as 42 USCS § 1395a note), in para. (17), deleted "or" after the concluding semicolon, in para. (18), substituted "; or" for a concluding period, and added para. (19).

Section 4511(a)(2)(C) of such Act (applicable with respect to services furnished and supplies provided on and after 1/1/98, as provided by § 4511(e) of such Act, which appears as 42 USCS § 1395k note), in subsec. (a)(14), substituted "section 1861(s)(2)(K)" for "section 1861(s)(2)(K)(i) or 1861(s)(2)(K)(iii)".

Section 4541(b) of such Act (applicable to services furnished on or after 1/1/98, including portions of cost reporting periods occurring on or after such date, as provided by § 4541(e) of such Act, which appears as 42 USCS § 1395l note), in subsec. (a), in para. (18), deleted "or" after the concluding semicolon, in para. (19), substituted "; or" for a concluding period, and added para. (20).

Section 4603(c)(2)(C) of such Act (applicable to cost reporting periods beginning on or after 10/1/99, as provided by 4603(d) of such Act, which appears as 42 USCS § 1395fff note), in subsec. (a), in para. (19), deleted "or" after the concluding semicolon, in para. (20), substituted "; or" for a concluding period, and added para. (21),

Section 4614(a) of such Act (applicable to services furnished on or after 10/1/97, as provided by § 4614(c) of such Act, which appears as a note to this section), in subsec. (a)(1), in subpara. (G), deleted "and" after the concluding comma, in subpara. (H), inserted ", and", and added subpara. (I).

Section 4632(a) of such Act (applicable to items and services furnished on or after enactment, as provided by 4632(b) of such Act, which appears as a note to this section), in subsec. (b)(2)(B), added cl. (v).

Section 4633(a), (b) of such Act (applicable to items and services furnished on or after enactment, as provided by § 4633(c) of such Act, which appears as a note to this section), in subsec. (b), in para. (1), added subpara. (F) and, in para. (2)(B)(ii), substituted "(directly, as a third-party administrator, or otherwise) to make payment" for "under this subsection to pay" and added the sentence beginning "The United States may not recover from a third-party administrator . . .".

1999 . Act Nov. 29, 1999 (applicable as provided by § 305(c) of H.R. 3426, as enacted into law by such Act, which appears as 42 USCS § 1395u note), in subsec. (a)(21), inserted "(including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section)".

Such Act further (effective as if included in the enactment of Act Aug. 5, 1997, as provided by § 321(m) of H.R. 3426, as enacted into law by Act Nov. 29, 1999, which appears as 42 USCS § 1395d note), in subsec. (a)(7), substituted "subparagraph" for "subparagraphs".

2000 . Act Dec. 21, 2000, enacting into law § 102(c) of H.R. 5661 (applicable as provided by § 102(d) of H.R. 5661, which appears as 42 USCS § 1395x note), in subsec. (a)(1)(F), deleted "and," following "section 1834(c)(1)(B)", and inserted "and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu),".

Such Act further, enacting into law § 313(a) of H.R. 5661 (applicable as provided by § 313(c) of H.R. 5661, which

appears as 42 USCS § 1395u note), in subsec. (a)(18), substituted "during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), which are furnished to such an individual without regard to such period)," for "or of a part of a facility that includes a skilled nursing facility (as determined under regulations),".

Such Act further, enacting into law § 432(b)(1) of H.R. 5661 (applicable as provided by § 432(c) of H.R. 5661, which appears as 42 USCS § 1395u note), in subsec. (a)(3), deleted a second comma following "1861(aa)(1),", and inserted "in the case of services for which payment may be made under section 1880(e),".

Such Act further, enacting into law § 522(b) of H.R. 5661 (applicable as provided by § 522(d) of H.R. 5661, which appears as 42 USCS § 1314 note), in subsec. (a), in the concluding matter, added the sentence beginning "In making a national coverage determination . . .".

2001 . Act Dec. 27, 2001 (applicable to claims submitted on or after 10/16/2003, as provided by § 3(b), which appears as a note to this section), in subsec. (a), in para. (20), deleted "or" following the concluding semicolon, in para. (21), substituted "; or" for a concluding period, and added para. (22); and added subsec. (h).

2003 . Act Dec. 8, 2003, in subsec. (a)(1), in subpara. (H), deleted "and" following the concluding comma, in subpara. (I), substituted ", and" for a concluding semicolon, and added subpara. (J); and, in subsec. (b)(5)(A)(ii), substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

Section 301(a) of such Act (effective as if included in the enactment of Title III of Act July 18, 1984, as provided by § 301(d)(1) of Act Dec. 8, 2003, which appears as a note to this section), in subsec. (b)(2), in subpara. (A)(ii), deleted "promptly (as determined in accordance with regulations)" following "to be made", and, in subpara. (B), redesignated cls. (i)-(v) as cls. (ii)-(vi), respectively, and inserted new cl. (i).

Section 301(b) and (c) of such Act (effective as if included in the enactment of § 953 of Act Dec. 5, 1980, as provided by § 301(d)(2) of Act Dec. 8, 2003, which appears as a note to this section), in subsec. (b), in para. (1)(A), made a technical correction which did not affect the text, in para. (2), in subpara. (A), in the concluding matter, added the sentence beginning "An entity that engages . . .", and, in subpara. (B), in cl. (ii) as redesignated, substituted the sentences beginning "A primary plan, . . ." and "A primary plan's responsibility . . ." for "Any payment under this title with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been or could be made under such subparagraph.", and substituted "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received" for "on the date such notice or other information is received", and, in cl. (iii) as redesignated, substituted the sentences beginning "In order to recover . . .", "The United States may, . . .", and "In addition, the United States . . ." for "In order to recover payment under this title for such an item or service, the United States may bring an action against any entity which is required or responsible (directly, as a third-party administrator, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service.", and, in para. (3)(A) deleted "such" before "paragraphs".

Section 611(d)(1) of such Act (applicable to services furnished on or after 1/1/2005, but only for individuals whose coverage period under part B (42 USCS §§ 1395j et seq.) begins on or after such date, as provided by § 611(e) of such Act, which appears as 42 USCS § 1395w-4 note), in subsec. (a), in para. (1), in subpara. (I), deleted "and" following the concluding comma, in subpara. (J), substituted ", and" for a concluding semicolon, and added subpara. (K), and, in para. (7), substituted "(H), or (K)" for "or (H)".

Section 612(c) of such Act (applicable to tests furnished on or after 1/1/2005, as provided by § 612(d) of such Act, which appears as 42 USCS § 1395x note), in subsec. (a), in para. (1), in subpara. (J), deleted "and" following the concluding comma, in subpara. (K), substituted ", and" for a concluding semicolon, and added subpara. (L).

Section 613(c) of such Act (applicable to tests furnished on or after 1/1/2005, as provided by § 613(d) of such Act, which appears as 42 USCS § 1395x note), in subsec. (a), in para. (1), in subpara. (K), deleted "and" following the concluding comma, in subpara. (L), substituted ", and" for a concluding semicolon, and added subpara. (M).

Section 731(a)(1) of such Act (applicable as provided by § 731(a)(2) of such Act, which appears as a note to this section), in subsec. (a), in the concluding matter, inserted "consistent with subsection (l)"; and added subsec. (l).

Section 731(b)(1) of such Act (applicable as provided by § 731(b)(2) of such Act, which appears as a note to this section), added subsec. (m).

Section 944(a)(1) of such Act (applicable to items and services furnished on or after 1/1/2004, as provided by § 944(a)(2) of such Act, which appears as a note to this section), inserted subsec. (d).

Section 948(a) of such Act (effective as if included in the enactment of Act Dec. 21, 2000, as provided by § 948(e) of such Act, which appears as 42 USCS § 1314 note), in subsec. (a), deleted "established under section 1114(f)" following "advisory committees"; and transferred subsec. (i) of 42 USCS § 1314 to this section and redesignated it as subsec. (j), and, in such subsection, deleted "under subsection (f)" following "appointed", and substituted "subsection (a)(1) for "section 1862(a)(1)".

Section 950(a) of such Act (effective 60 days after enactment, as provided by § 950(b) of such Act, which appears as a note to this section), inserted subsec. (k).

2006 . Act Feb. 8, 2006 (applicable to services furnished on or after 1/1/2007, as provided by § 5112(f) of such Act, which appears 42 USCS § 1395l note), in subsec. (a)(1), in subpara. (L), deleted "and" following the concluding comma, in subpara. (M), substituted ", and" for a concluding semicolon, and added subpara. (N).

2007 . Act Dec. 29, 2007, in subsec. (b), added paras. (7) and (8).

2008 . Act July 15, 2008 (applicable to services furnished on or after 1/1/2009, as provided by § 101(c) of such Act, which appears as 42 USCS § 1395l note), in subsec. (a)(1), in subpara. (A), inserted "or additional preventive services (as described in section 1861(ddd)(1))", and in subpara. (K), substituted "more" for "not later" and "1 year" for "6 months".

Such Act further (applicable to advanced diagnostic imaging services furnished on or after 1/1/2012, as provided by § 135(a)(2)(B) of such Act, which appears as a note to this section, in subsec. (a), in para. (21), deleted "or" following the concluding semicolon, in para. (22), substituted "; or" for a concluding period, and added para. (23).

Such Act further (applicable to services furnished on or after 7/1/2009, as provided by § 143(c) of such Act, which appears as 42 USCS § 1395k note), in subsec. (a)(20), substituted "outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services" for "outpatient occupational therapy services or outpatient physical therapy services" and "subsection (g) or (ll)(2) of section 1861" for "section 1861(g)".

Such Act further (applicable to services furnished on or after 1/1/2010, as provided by § 152(b)(2) of such Act, which appears as 42 USCS § 1395w-4 note), in subsec. (a)(1), in subpara. (M), deleted "and" following the concluding comma, in subpara. (N), substituted ", and" for a concluding semicolon, and added subpara. (O).

Such Act further, in subsec. (a), in para. (22), deleted "or" following the concluding semicolon, in para. (23), substituted "; or" for a concluding period, and added para. (24).

2010 . Act March 23, 2010 (effective on enactment, as provided by § 1105 of such Act, which appears as 42 USCS § 1320d note), in subsec. (a), in para. (23), deleted "or" following the concluding semicolon, in para. (24), substituted "; or" for a concluding period, and added para. (25).

Such Act further added subsecs. (n) and (o).

Such Act further (applicable to services furnished on or after 1/1/2011, as provided by § 4103(e) of such Act, which appears as 42 USCS § 1395l note), in subsec. (a), in para. (1), in subpara. (N), deleted "and" following the

concluding comma, in subpara. (O), substituted ", and" for a concluding semicolon, and added subpara. (P), and in para. (7), substituted "(K), or (P)" for "or (K)".

2011 . Act Oct. 21, 2011 (applicable to contracts entered into or renewed on or after 1/1/2012, as provided by § 261(e) of such Act, which appears as *42 USCS § 1320c* note), in subsec. (a)(15)(A), and in the heading and text of subsec. (g), substituted "quality improvement" for "utilization and quality control peer review".

2013 . Act Jan. 10, 2013, in subsec. (b), in para. (2)(B), added cls. (vii) and (viii), and in para. (8), in subpara. (B), added the concluding matter, in subpara. (E)(i), substituted "may be subject to a civil money penalty of up to $ 1,000 for each day of noncompliance with respect to each claimant." for "shall be subject to a civil money penalty of $ 1,000 for each day of noncompliance with respect to each claimant.", and added subpara. (I).

Such Act further (applicable to years beginning with 2014, as provided by § 202(b) of such Act, which appears as a note to this section), in subsec. (b), in para. (2)(B)(ii), substituted "Subject to paragraph (9), a primary plan" for "A primary plan", and added para. (9).

Such Act further (applicable to actions brought and penalties sought on or after 6 months after the date of enactment, as provided by § 205(b) of such Act, which appears as a note to this section), in subsec. (b)(2)(B)(iii), added the sentence beginning "An action may not be brought . . .".

2014 . Act Nov. 26, 2014, in subsec. (b)(9)(B)(i), substituted "for 2014" for "for a year".

2015 . Act April 16, 2015 (effective on the date of enactment and applicable to information required to be provided on or after 1/1/2016, as provided by § 516(b) of such Act, which appears as a note to this section), in subsec. (b)(5), added subpara. (E).

2016 . Act Dec. 13, 2016 (applicable as provided by § 4009(b) of such Act, which appears as a note to this section), in subsec. (l)(5), added subpara. (D).

2018 . Act Oct. 24, 2018 (applicable with respect to plan years beginning on or after 1/1/2020, as provided by § 2008(e) of such Act, which appears as *42 USCS § 1395w-27* note), added subsec. (o)(4).

Such Act further, in subsec. (b)(7)(A), substituted cl. (i) for one which read: "(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this title; and".

Redesignation:

Act Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle A, Ch 1, Subch A, § 4001, *111 Stat. 275*, redesignated Part C of Title XVIII of Act Aug. 14, 1935, ch 531, as Part D of such Title.

Act Dec. 8, 2003, *P.L. 108-173*, Title I, § 101(a)(1), *117 Stat. 2071*, redesignated Part D of Title XVIII of Act Aug. 14, 1935, ch 531, as Part E of such Title.

Other provisions:

Report to Congressional Committees on implementation of certification requirements relating to modification of health benefits plan or program; failure to submit report. Act Oct. 26, 1974, *P.L. 93-480*, § 4(b), *88 Stat. 1454*, provided that the Civil Service Commission and the Secretary of Health, Education, and Welfare should submit to the Committee on Post Office and Civil Service and the Committee on Ways and Means of the House of Representatives, and to the Committee on Post Office and Civil Service and the Committee on Finance of the Senate, on or before March 1, 1975, a report on the steps which have been taken, and the steps which are planned, to enable the Secretary of Health, Education, and Welfare to make the determination and certification referred to in former subsec. (c) of this section and that if such report was not submitted to such committees on or before March 1, 1975, the date specified in such former subsec. (c) was to be deemed to be July 1, 1975, rather than January 1, 1976.

Effective date of amendments made by § 13 of Act Oct. 25, 1977. Act Oct. 25, 1977, *P.L. 95-142*, § 13(c), *91 Stat. 1198*, provided: "The amendments made by this section [amending subsec. (d) of this section, former *42*

USCS § 1320c-6, and 42 USCS § 1395cc] shall take effect on the date of the enactment of this Act [enacted Oct. 25, 1977].".

Applicability of amendment made by § 939 of Act Dec. 5, 1980. Act Dec. 5, 1980, P.L. 96-499, Title IX, Part B, Subpart I, § 939(b), 94 Stat. 2640, provided: "The amendment made by subsection (a) [amending subsec. (a)(13)(C) of this section] shall apply with respect to services furnished on or after July 1, 1981.".

Applicability of Dec. 28, 1980 amendments. Act Dec. 28, 1980, P.L. 96-611, § 2 in part, 94 Stat. 3567, which appears as 42 USCS § 1395l note, provided that the amendments made to this section by such Act are applicable to services furnished on or after July 1, 1981.

Applicability of amendments made by § 2103 of Act Aug. 13, 1981. Act Aug. 13, 1981, *P.L. 97-35*, Title XXI, Subtitle A, Ch 1, § 2103(a)(2), 95 Stat. 787, provided: "The amendments made by paragraph (1) [adding subsec. (c)] shall apply with respect to expenses incurred on or after October 1, 1981.".

Effective date of amendments made by § 2146 of Act Aug. 13, 1981. Act Aug. 13, 1981, *P.L. 97-35*, Title XXI, Subtitle B, Ch 3, § 2146(c)(1), 95 Stat. 801, provided: "The amendments made by subsection (a) [designating existing subsec. (b) as (b)(1) and adding (b)(2) of this section] shall become effective on October 1, 1981.".

Establishment and implementation of home health services guidelines. Act Aug. 13, 1981, *P.L. 97-35*, Title XXI, Subtitle B, Ch 4, § 2152(b), 95 Stat. 802, provided that The Secretary of Health and Human Services should establish, and provide for the implementation of, the guidelines described in subsec. (f) of this section not later than October 1, 1981.

Prohibition of payment for ineffective drugs. Act Sept. 3, 1982, P.L. 97-248, Title I, Subtitle A, Part I, Subpart B, § 115(b), *96 Stat. 353*, provided: "No provision of law limiting the use of funds for purposes of enforcing or implementing section 1862(c) or section 1903(i)(5) of the Social Security Act [subsec. (c) of this section or 42 USCS § 1396b(i)(5)], section 2103 of the Omnibus Budget Reconciliation Act of 1981 [adding subsec. (c) and note to this section and 42 USCS § 1396b(i)(5) and note], or any rule or regulation issued pursuant to any such section (including any provision contained in, or incorporated by reference into, any appropriation Act or resolution making continuing appropriations) shall apply to any period after September 30, 1982, unless such provision of law is enacted after the date of the enactment of this Act [enacted Sept. 3, 1982] and specifically states that such provision is to supersede this section.".

Waiver of requirements of subsec. (a)(14) and of *42 USCS § 1395cc(a)(1)(H)*. Act April 20, 1983, P.L. 98-21, Title VI, § 602(k), 97 Stat. 165; April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 1, Subpart A, § 9112(a), *100 Stat. 163*, applicable as provided by § 9112(b) of such Act provides:

"(1) The Secretary of Health and Human Services may, for any cost reporting period beginning prior to October 1, 1986, waive the requirements of sections 1862(a)(14) and 1866(a)(1)(H) of the Social Security Act [subsec. (a)(14) of this section and 42 USCS § 1395cc(a)(1)(H)] in the case of a hospital which has followed a practice, since prior to October 1, 1982, of allowing direct billing under part B of title XVIII of such Act [42 USCS §§ 1395j et seq.] for services (other than physicians' services) so extensively, that immediate compliance with those requirements would threaten the stability of patient care. Any such waiver shall provide that such billing may continue to be made under part B of such title [42 USCS §§ 1395j et seq.] but that the payments to such hospital under part A of such title [42 USCS §§ 1395c et seq.] shall be reduced by the amount of the billings for such services under part B of such title [42 USCS §§ 1395j et seq.]. If such a waiver is granted, at the end of the waiver period the Secretary may provide for such methods of payments under part A [42 USCS §§ 1395c et seq.] as is appropriate, given the organizational structure of the institution.

"(2) [applicable to cost reporting periods beginning on or after Jan. 1, 1986, as provided by § 9112(b)(1)] In the case of a hospital which is receiving payments pursuant to a waiver under paragraph (1), payment of the adjustment for indirect costs of approved educational activities shall be made as if the hospital were receiving under

part A of title XVIII of the Social Security Act [*42 USCS §§ 1395c* et seq.] all the payments which are made under part B of such *title [42 USCS §§ 1395j* et seq.] solely by reason of such waiver.

"(3) [applicable to items and services furnished after the end of the 10-day period beginning on enactment on April 7, 1986, as provided by § 9112(b)(2)] Any waiver granted under paragraph (1) shall provide that, with respect to those items and services billed under part B of title XVIII of the Social Security Act [*42 USCS §§ 1395j* et seq.] solely by reason of such waiver--

"(A) payment under such part shall be equal to 100 percent of the reasonable charge or other applicable payment base for the items and services; and

"(B) the entity furnishing the items and services must agree to accept the amount paid pursuant to subparagraph (A) as the full charge for the items and services.".

Applicability of amendments made by § 2301 of Act July 18, 1984. Act July 18, 1984, *P.L. 98-369*, Division B, Title III, Subtitle A, Part I, § 2301(c)(1), *98 Stat. 1063*, provided: "The amendment made by subsection (a) [amending subsec. (b)(3)(A)(i) of this section] shall be effective with respect to items and services furnished on or after January 1, 1985.".

Promulgation of regulations; applicability of amendments made by § 2304 of Act July 18, 1984. Act July 18, 1984, *P.L. 98-369*, Division B, Title III, Subtitle A, Part I, § 2304(d), *98 Stat. 1069*, provided: "The Secretary of Health and Human Services shall promulgate final regulations to carry out this section and the amendment made by this section [adding subsec. (h) of this section, this note, and *42 USCS § 1395l* note] prior to January 1, 1985, and the amendment made by subsection (c) [adding subsec. (h) to this section] shall apply to pacemaker devices and leads implanted or removed on or after the effective date of such regulations.".

Effective date of amendments made by § 2313 of Act July 18, 1984. Act July 18, 1984, *P.L. 98-369*, Division B, Title III, Subtitle A, Part I, § 2313(e), *98 Stat. 1079*, provided: "The amendments made by this section [adding subsec. (i) of this section and amending *42 USCS § 1395ww*] shall become effective on the date of the enactment of this Act [enacted July 18, 1984].".

Payment for debridement of mycotic toenails. Act July 18, 1984, *P.L. 98-369*, Division B, Title III, Subtitle A, Part I, § 2325, *98 Stat. 1087*, provided: "The Secretary shall provide, pursuant to section 1862(a) of the Social Security Act [subsec. (a) of this section] that payment will not be made under part B of title XVIII of such Act [*42 USCS §§ 1395j* et seq.] for a physician's debridement of mycotic toenails to the extent such debridement is performed for a patient more frequently than once every 60 days, unless the medical necessity for more frequent treatment is documented by the billing physician.".

Applicability of amendments made by § 2344 of Act July 18, 1984. Act July 18, 1984, *P.L. 98-369*, Division B, Title III, Subtitle A, Part II, § 2344(d), *98 Stat. 1096*, provided: "The amendments made by this section [amending subsec. (b) of this section] shall apply to items and services furnished on or after the date of the enactment of this Act [enacted July 18, 1984].".

Reinstatement of waiver of liability presumption. Act April 7, 1986, *P.L. 99-272*, Title IX, Subtitle A, Part 2, Subpart B, § 9126(c), *100 Stat. 170*; July 1, 1988, *P.L. 100-360*, Title IV, Subtitle C, § 426(b), *102 Stat. 814*; Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 1, § 4008(a)(1), *104 Stat. 1388*-44, effective on enactment as provided by § 4008(a)(3) of such Act, provides: "The Secretary of Health and Human Services shall, for purposes of determining whether payments to a skilled nursing facility should be denied pursuant to section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], apply the same presumption of compliance (5 percent) as in effect under regulations as of July 1, 1985. Such presumption shall apply for the period beginning with the first month beginning after the date of the enactment of this Act and ending on December 31, 1995.".

Applicability of amendments made by § 9201 of Act April 7, 1986. Act April 7, 1986, *P.L. 99-272*, Title IX, Subtitle A, Part 2, Subpart A, § 9201(d)(1), *100 Stat. 171*, provides: "(1) The amendments made by subsection (a)

[amending subsec. (b)(3)(A) of this section] shall apply with respect to items and services furnished on or after May 1, 1986.".

Home health waiver of liability. Act April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 2, Subpart A, § 9205, *100 Stat. 178*; July 1, 1988, *P.L. 100-360*, Title IV, Subtitle C, § 426(d), *102 Stat. 814*; Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 158(b)(1), *108 Stat. 4442* (effective as if included in the enactment of Act Nov. 5, 1990, *P.L. 101-508*, as provided by § 158(b)(2) of the 1994 Act), provides: "The Secretary of Health and Human Services shall, for purposes of determining whether payments to a home health agency should be denied pursuant to section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], apply a presumption of compliance (2.5 percent) in the same manner as under the regulations in effect as of July 1, 1985. Such presumption shall apply until December 31, 1995.".

Extension of prohibition to other procedures. Act April 7, 1986, P.L. 99-272, Title IX, Subtitle A, Part 3, Subpart A, § 9307(d), *100 Stat. 194*, provides: "The Secretary of Health and Human Services, after consultation with the Physician Payment Review Commission, shall develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery is generally not medically necessary and the circumstances under which the use of an assistant at surgery is generally appropriate but should be subject to prior approval of an appropriate entity. The Secretary shall report to Congress, not later than January 1, 1987, on these recommendations and guidelines.".

Extension of waiver of liability provisions to Hospice programs. Act Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 1, § 9305(f), *100 Stat. 1991*; July 1, 1988, *P.L. 100-360*, Title IV, Subtitle C, § 426(a), *102 Stat. 814*; Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 1, § 4008(a)(2), *104 Stat. 1388*-44, effective on enactment as provided by § 4008(a)(3) of such Act, provides:

"(1) In general. The Secretary of Health and Human Services shall, for purposes of determining whether payments to a hospice program should be denied pursuant to section 1862(a)(1)(C) of the Social Security Act [subsec. (a)(1)(C) of this section], apply (under section 1879(a) of such Act [*42 USCS § 1395pp(a)*]) a presumption of compliance of 2.5 percent (based on the number of days of hospice care billed) in a manner substantially similar to that provided to home health agencies under policies in effect as of July 1, 1985.

"(2) Effective date. Paragraph (1) shall apply to hospice care furnished on or after the first day of the first month that begins at least 6 months after the date of the enactment of this Act and before December 31, 1995.".

Study of impact of amendments on disabled beneficiaries and family. Act Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9319(e), *100 Stat. 2012*, effective as to items and services furnished on or after Jan. 1, 1987, as provided by § 9319(f) of such Act, which appears as a note to this section, provides:

"(e) The Comptroller General shall study and report to Congress, by not later than March 1, 1990, the impact of the amendments made by this section on access of disabled individuals and members of their family to employment and health insurance. The report shall include information relating to--

"(1) the number of disabled medicare beneficiaries for whom medicare has become secondary, either through their employment or the employment of a family member;

"(2) the amount of savings to the medicare program achieved annually through this provision; and

"(3) the effect on employment, and employment-based health coverage, of disabled individuals and family members.".

Effective date and applicability of Oct. 21, 1986 amendments. Act Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9319(f), *100 Stat. 2013*, provides:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending *42 USCS § 1395y(b)(4)*, (5), and note and *26 USCS § 5000*] shall apply to items and services furnished on or after January 1, 1987.

"(2) The amendments made by subsection (c) shall apply to enrollments occurring on or after January 1, 1987.".

Effective date and application of subsec. (e)(2). For the effective date and application of subsec. (e)(2), see Act Aug. 18, 1987, *P.L. 100-93*, § 15, *101 Stat. 698*, which appears as *42 USCS § 1320a-7* note.

Carrier approval of use of surgical assistant. Act Oct. 22, 1986, *P.L. 99-514*, Title XVIII, Subtitle C, Ch 1, § 1895(b)(16)(C), *100 Stat. 2934*, effective as if included in Act April 7, 1986 as provided by § 1895(e), which appears as *26 USCS § 162* note provides: "For purposes of section 1862(a)(15) of the Social Security Act (*42 U.S.C. 1395y(a)(15)*), added by section 9307(a)(3) of COBRA, and for surgical procedures performed during the period beginning on April 1, 1986, and ending on December 15, 1986, a carrier is deemed to have approved the use of an assistant in a surgical procedure, before the surgery is performed, based on the existence of a complicating medical condition if the carrier determines after the surgery is performed that the use of the assistant in the procedure was appropriate based on the existence of a complicating medical condition before or during the surgery.".

Designation of pediatric hospitals as meeting certification as heart transplant facility. Act Dec. 22, 1987, *P.L. 100-203*, Title IV, Subtitle A, Part 1, § 4009(b), *101 Stat. 1330*-57, provides:

"For purposes of determining whether a pediatric hospital that performs pediatric heart transplants meets the criteria established by the Secretary of Health and Human Services for facilities in which the heart transplants performed will be considered to meet the requirement of section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], the Secretary shall treat such a hospital as meeting such criteria if--

"(1) the hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that meets such criteria,

"(2) the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria), and

"(3) the hospital demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.".

Effective date of amendment made by § 4034 of Act Dec. 22, 1987. Act Dec. 22, 1987, *P.L. 100-203*, Title IV, Subtitle A, Part 2, Subpart C, § 4034(b), *101 Stat. 1330*-77, provides: "The amendment made by subsection (a) [amending subsec. (b)(4)(B)(i) of this section] shall be effective as if included in the enactment of section 9319(a) of the Omnibus Budget Reconciliation Act of 1986 [adding subsec. (b)(4) to this section].".

Applicability of amendment made by § 4036 of Act Dec. 22, 1987. Act Dec. 22, 1987, *P.L. 100-203*, Title IV, Subtitle A, Part 2, Subpart C, § 4036(a)(2), *101 Stat. 1330*-79, provides: "The amendment made by paragraph (1) [amending subsec. (b)(2)(A)(ii) of this section] shall apply with respect to items and services furnished on or after 30 days after the date of the enactment of this Act.".

Effective date of amendment made by § 4039 of Act Dec. 22, 1987. Act Dec. 22, 1987, *P.L. 100-203*, Title IV, Subtitle A, Part 2, Subpart C, § 4039(c)(2), *101 Stat. 1330*-82, provides: "The amendments made by paragraph (1) [amending subsec. (h) of this section] shall become effective on January 1, 1988.".

Contingent effective date of amendments made by § 4072 of Act Dec. 22, 1987. For contingent effective date of amendments made by § 4072 of Act Dec. 22, 1987, *P.L. 100-203*, amending subsec. (a)(8), among other things [for full classification, consult USCS Tables volumes], see Act Dec. 22, 1987, *P.L. 100-203*, Title IV, Subtitle A, Part 3, Subpart C, § 4072(e), *101 Stat. 1330*-117, which appears as *42 USCS § 1395x* note.

Applicability of July 1, 1988 amendment. Act July 1, 1988, *P.L. 100-360*, Title IV, Subtitle B, § 411(f)(4)(D)(ii), *102 Stat. 778*, provides: "The amendment made by clause (i) [amending subsec. (a)(15) of this section] shall apply to operations performed on or after 60 days after the date of the enactment of this Act.".

Deadline for transmittals and requests for disclosure of information by Secretary. Act Dec. 19, 1989, *P.L. 101-239*, Title VI, Subtitle A, Part 3, Subpart A, § 6202(a)(2)(B), *103 Stat. 2229*, provides:

"The Commissioner of Social Security shall first--

"(i) transmit to the Secretary of the Treasury information under paragraph (5)(A)(i) of section 1862(b) of the Social Security Act [subsec. (b)(5)(A)(i) of this section] (as inserted by subparagraph (A)), and

"(ii) request from the Secretary disclosure of information described in *section 6013 (l)(12)(A) of the Internal Revenue Code of 1986* [*26 USCS § 6013(l)(12)(A)*], by not later than 14 days after the date of the enactment of this Act.".

Applicability of Dec. 19, 1989 amendment. Act Dec. 19, 1989, *P.L. 101-239*, Title VI, Subtitle A, Part 3, Subpart A, § 6202(e)(2), *103 Stat. 2235*, provides: "The amendment made by paragraph (1) [adding subsec. (b)(1)(D) of this section] shall apply to items and services furnished on or after October 1, 1989.".

Applicability of subsec. (a)(1)(F), as added by Act Nov. 5, 1990. Act Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 2, Subpart B, § 4163(d)(3), as added by Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle B, Part III, § 147(f)(5)(A), *108 Stat. 4431* (effective as if included in the enactment of Act Nov. 5, 1990, as provided by § 147(g) of the 1994 Act, which appears as *42 USCS § 1320a-3a* note), provides: "The amendment made by paragraph (2)(A)(iv) [adding subsec. (a)(1)(F) of this section] shall apply to screening pap smears performed on or after July 1, 1990.".

GAO study of extension of secondary payer period. Act Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 2, Subpart B, § 4203(c)(2), *104 Stat. 1388*-108; Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(7), *108 Stat. 4436* (effective as if included in the enactment of Act Nov. 5, 1990, *P.L. 101-508*, as provided by § 151(c)(7) of the 1994 Act), provides:

"(A) The Comptroller General shall conduct a study of the impact of the second sentence of section 1862(b)(1)(C) of the Social Security Act [subsec. (b)(1)(C) of this section], and shall include in such report information relating to--

"(i) the number (and geographic distribution) of such individuals for whom medicare is secondary;

"(ii) the amount of savings to the medicare program achieved annually by reason of the application of such sentence;

"(iii) the effect on access to employment, and employment-based health insurance, for such individuals and their family members (including coverage by employment-based health insurance of cost-sharing requirements under medicare after such employment-based insurance becomes secondary);

"(iv) the effect on the amount paid for each dialysis treatment under employment-based health insurance;

"(v) the effect on cost-sharing requirements under employment-based health insurance (and on out-of-pocket expenses of such individuals) during the period for which medicare is secondary; and

"(vi) the appropriateness of applying the provisions of section 1862(b)(1)(C) of such Act [subsec. (b)(1)(C) of this section] to all group health plans, without regard to the number of employees covered by such plans.

"(B) The Comptroller General shall submit a preliminary report on the study conducted under subparagraph (A) to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate not later than January 1, 1993, and a final report on such study not later than January 1, 1995.".

Applicability of Nov. 5, 1990 amendment. Act Nov. 5, 1990, *P.L. 101-508*, Title IV, Subtitle A, Part 2, Subpart B, § 4204(g)(2), *104 Stat. 1388*-112, provides: "The amendment made by paragraph (1) [adding subsec. (b)(3)(C) of this section] shall apply to incentives offered on or after the date of the enactment of this Act.".

Effective date of amendment made by § 13561(e)(1)(D) of Act Aug. 10, 1993. Act Aug. 10, 1993, *P.L. 103-66*, Title XIII, Ch 2, Subch A, Part III, § 13561(e)(1)(D), *107 Stat. 595*; Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(9), *108 Stat. 4436* (effective as if included in the enactment of Act Aug. 10, 1993, as provided by § 151(c)(9) of the 1994 Act), provides that the amendment made to subsec. (b)(1)(A)(v) by § 13561(e)(1)(D) of the 1993 Act is "effective as if included in the enactment of OBRA-1989 [Act Dec. 19, 1989, *P.L. 101-239*, *103 Stat. 2106*; for full classification, consult USCS Tables volumes]".

Retroactive exemption for certain situations involving religious orders. Act Aug. 10, 1993, *P.L. 103-66*, Title XIII, Ch 2, Subch A, Part III, § 13561(f), *107 Stat. 595*, provides: "Section 1862(b)(1)(D) of the Social Security Act [subsec. (b)(1)(D) of this section] applies, with respect to items and services furnished before October 1, 1989, to any claims that the Secretary of Health and Human Services had not identified as of that date as subject to the provisions of section 1862(b) of such Act [subsec. (b) of this section].".

Effective date of amendments made by § 13581 of Act Aug. 10, 1993. Act Aug. 10, 1993, *P.L. 103-66*, Title XIII, Ch 2, Subch A, Part V, § 13581(d), *107 Stat. 611*, provides: "The amendments made by this section shall take effect on January 1, 1994.".

Distribution of questionnaire by contractor. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(a)(1)(B), *108 Stat. 4433*, provides: "The Secretary of Health and Human Services shall enter into an agreement with an entity not later than 60 days after the date of the enactment of the Social Security Act Amendments of 1994 [enacted Oct. 31, 1994], to distribute the questionnaire described in section 1862(b)(5)(D) of the Social Security Act [subsec. (b)(5)(D) of this section] (as added by subparagraph (A)).".

Applicability of subsec. (b)(6), as added by Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(a)(2)(B), *108 Stat. 4433*, provides: "The amendment made by subparagraph (A) [adding subsec. (b)(6) of this section] shall apply with respect to items and services furnished on or after the expiration of the 120-day period beginning on the date of the enactment of this Act.".

Applicability of amendments made by § 151(b)(3) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(b)(3)(C), *108 Stat. 4433*, provides: "The amendments made by this paragraph [amending subsec. (b)(2)(B) of this section] shall apply to payments for items and services furnished on or after the date of the enactment of this Act.".

Effective date of amendments made by § 151(c)(1) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(1), *108 Stat. 4435*, provides that the amendments made to subsec. (b)(1)(A) of this section by § 151(c)(1) of such Act are effective "as if included in the enactment of OBRA-1993 [Act Aug. 10, 1993, *P.L. 103-66*, *107 Stat. 312*; for full classification, consult USCS Tables volumes]".

Effective date of amendments made by § 151(c)(4) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(4), *108 Stat. 4435*, provides that the amendments made to subsec. (b)(1)(C) of this section by § 151(c)(4) of such Act are effective "as if included in the enactment of OBRA-1990 [Act Nov. 5, 1990, *P.L. 101-508*, *104 Stat. 1388*-1; for full classification, consult USCS Tables volumes]".

Effective date of amendments made by § 151(c)(5) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(5), *108 Stat. 4436*, provides that the amendments made to subsec. (b)(1)(C) of this section by § 151(c)(5) of such Act are effective "as if included in the enactment of OBRA-1989 [Act Dec. 19, 1989, *P.L. 101-239*, *103 Stat. 2106*; for full classification, consult USCS Tables volumes.]".

Effective date of amendments made by § 151(c)(6) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(6), *108 Stat. 4436*, provides that the amendments made to subsec. (b)(5)(C)(i) of this section by § 151(c)(6) of such Act are effective "as if included in the enactment of OBRA-1989 [Act Dec. 19, 1989, *P.L. 101-239*, *103 Stat. 2106*; for full classification, consult USCS Tables volumes.]".

Retroactive applicability of Aug. 10, 1993 amendment of subsec. (b)(1)(B)(iv). Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 151(c)(10), *108 Stat. 4436*, provides: "The amendment made by section 13561(e)(1)(G) of

OBRA-1993 [amending subsec. (b)(1)(B)(iv) of this section], to the extent it relates to the definition of large group health plan, shall be effective as if included in the enactment of OBRA-1989 [Act Dec. 19, 1989, *P.L. 101-239*, *103 Stat. 2106*; for full classification, consult USCS Tables volumes].".

Effective date of amendments made by § 157(b) of Act Oct. 31, 1994. Act Oct. 31, 1994, *P.L. 103-432*, Title I, Subtitle C, § 157(b)(8), *108 Stat. 4442*, provides: "The amendments made by this subsection [amending this section and *42 USCS § 1395mm* and notes] shall take effect as if included in the enactment of OBRA-1990 [Act Nov. 5, 1990, *P., L. 101-508*, *104 Stat. 1388*-1; for full classification, consult USCS Tables volumes].".

Notification of home health visits exceeding threshold. Act Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle G, Ch 1, Subch B, § 4614(b), *111 Stat. 474*, provides: "The Secretary of Health and Human Services may establish a process for notifying a physician in cases in which the number of home health visits, furnished under title XVIII of the Social Security Act [*42 USCS §§ 1395* et seq.] pursuant to a prescription or certification of the physician, significantly exceeds such threshold (or thresholds) as the Secretary specifies. The Secretary may adjust such threshold to reflect demonstrated differences in the need for home health services among different beneficiaries.".

Applicability of amendments made by § 4614 of Act Aug. 5, 1997. Act Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle G, Ch 1, Subch B, § 4614(c), *111 Stat. 474*, provides: "The amendments made by this section [amending subsec. (a)(1) of this section] apply to services furnished on or after October 1, 1997.".

Applicability of amendments made by § 4632 of Act Aug. 5, 1997. Act Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle G, Ch 3, § 4632(b), *111 Stat. 486*, provides: "The amendments made by this section [adding subsec. (b)(2)(B)(v) of this section] apply to items and services furnished on or after the date of the enactment of this Act.".

Applicability of amendments made by § 4633 of Act Aug. 5, 1997. Act Aug. 5, 1997, *P.L. 105-33*, Title IV, Subtitle G, Ch 3, § 4633(c), *111 Stat. 487*, provides: "The amendments made by this section [amending subsec. (b) of this section] apply to items and services furnished on or after the date of the enactment of this Act.".

Applicability of Dec. 27, 2001 amendments. Act Dec. 27, 2001, *P.L. 107-105*, § 3(b), *115 Stat. 1007*, provides: "The amendments made by subsection (a) [adding subsecs. (a)(22) and (h) of this section] shall apply to claims submitted on or after October 16, 2003.".

Effective date of amendments made by § 301 of Act Dec. 8, 2003. Act Dec. 8, 2003, *P.L. 108-173*, Title III, § 301(d), *117 Stat. 2222*, provides:

"The amendments made by this section shall be effective--

"(1) in the case of subsection (a) [amending subsec. (b)(2) of this section], as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (*Public Law 98-369*) [Act July 18, 1984; for full classification, consult USCS Tables volumes]; and

"(2) in the case of subsections (b) and (c) [amending subsec. (b)(1)-(3) of this section], as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980 (*Public Law 96-499*; *94 Stat. 2647*) [Act Dec. 5, 1980; amending subsec. (b) of this section].".

Applicability of amendments made by § 731(a) of Act Dec. 8, 2003. Act Dec. 8, 2003, *P.L. 108-173*, Title VII, Subtitle D, § 731(a)(2), *117 Stat. 2351*, provides: "The amendments made by paragraph (1) [amending subsec. (a) and adding subsec. (l) of this section] shall apply to national coverage determinations as of January 1, 2004, and section 1862(l)(5) of the Social Security Act [subsec. (l)(5) of this section], as added by such paragraph, shall apply to local coverage determinations made on or after July 1, 2004.".

Applicability of amendments made by § 731(b) of Act Dec. 8, 2003. Act Dec. 8, 2003, *P.L. 108-173*, Title VII, Subtitle D, § 731(b)(2), *117 Stat. 2351*, provides: "The amendment made by paragraph (1) [adding subsec. (m) of this section] shall apply to routine costs incurred on and after January 1, 2005, and, as of such date, *section*

411.15(o) of title 42, Code of Federal Regulations, is superseded to the extent inconsistent with section 1862(m) of the Social Security Act, as added by such paragraph.".

Subsec. (m); rule of construction. Act Dec. 8, 2003, *P.L. 108-173*, Title VII, Subtitle D, § 731(b)(3), *117 Stat. 2351*, provides: "Nothing in the amendment made by paragraph (1) [adding subsec. (m) of this section] shall be construed as applying to, or affecting, coverage or payment for a nonexperimental/investigational (category B) device.".

Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions. Act Dec. 8, 2003, *P.L. 108-173*, Title IX, Subtitle E, § 943, *117 Stat. 2422*, provides:

"(a) In general. The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act [subsec. (b) of this section] (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

"(b) Reference laboratory services described. Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A [42 USCS §§ 1395c et seq.] or enrolled under part B [42 USCS §§ 1395j et seq.], or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.".

Applicability of amendment made by § 944 of Act Dec. 8, 2003. Act Dec. 8, 2003, *P.L. 108-173*, Title IX, Subtitle E, § 944(a)(2), *117 Stat. 2423*, provides: "The amendment made by paragraph (1) [adding subsec. (d) of this section] shall apply to items and services furnished on or after January 1, 2004.".

Effective date of amendment made by § 950(a) of Act Dec. 8, 2003. Act Dec. 8, 2003, *P.L. 108-173*, Title IX, Subtitle E, § 950(b), *117 Stat. 2427*, provides: "The amendment made by subsection (a) [adding subsec. (k) of this section] shall take effect on the date that is 60 days after the date of the enactment of this Act.".

Annual publication of list of national coverage determinations. Act Dec. 8, 2003, *P.L. 108-173*, Title IX, Subtitle E, § 953(b), *117 Stat. 2428*, provides: "The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act [42 USCS §§ 1395 et seq.] in the previous year and information on how to get more information with respect to such determinations.".

Act Dec. 29, 2007 amendments; rule of construction. Act Dec. 29, 2007, *P.L. 110-173*, Title I, § 111(b), *121 Stat. 2499*, provides: "Nothing in the amendments made by this section [adding subsec. (b)(7) and (8) of this section] shall be construed to limit the authority of the Secretary of Health and Human Services to collect information to carry out Medicare secondary payer provisions under title XVIII of the Social Security Act [42 USCS §§ 1395 et seq.], including under parts C and D of such title [42 USCS §§ 1395w-21 et seq. and 1395w-101 et seq.].".

Application of amendments made by § 135(a)(2) of Act July 15, 2008. Act July 15, 2008, *P.L. 110-275*, Title I, Subtitle C, Part I, § 135(a)(2)(B), *122 Stat. 2535*, provides: "The amendments made by this paragraph [amending subsec. (a) of this section] shall apply to advanced diagnostic imaging services furnished on or after January 1, 2012.".

Application of amendments made by § 202 of Act Jan. 10, 2013. Act Jan. 10, 2013, *P.L. 112-242*, Title II, § 202(b), *126 Stat. 2380*, provides: "The amendments made by subsection (a) [amending subsec. (b) of this section] shall apply to years beginning with 2014.".

Application of amendments made by § 205 of Act Jan. 10, 2013. Act Jan. 10, 2013, *P.L. 112-242*, Title II, § 205(b), *126 Stat. 2381*, provides: "The amendment made by subsection (a) [amending subsec. (b)(2)(B)(iii) of this

section] shall apply with respect to actions brought and penalties sought on or after 6 months after the date of the enactment of this Act.".

Effective date and application of amendment made by § 516(a) of Act April 16, 2015. Act April 16, 2015, *P.L. 114-10*, Title V, Subtitle A, § 516(b), *129 Stat. 175*, provides: "The amendment made by subsection (a) [adding subsec. (b)(5)(E) of this section] shall take effect on the date of the enactment of this Act and shall apply to information required to be provided on or after January 1, 2016.".

Application of amendment made by § 4009(a) of Act Dec. 13, 2016. Act Dec. 13, 2016, *P.L. 114-255*, Div A, Title IV, § 4009(b), *130 Stat. 1185*, provides: "The amendment made by subsection (a) [adding subsec. (l)(5)(D)] shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of enactment of this Act.".

Case Notes

I. IN GENERAL

1. Generally

Department of Health and Human Services is not required to reduce pro rata its recovery of conditional Medicare payments (*42 USCS § 1395y(b)*) when beneficiary's liability settlement is less than his or her total damages; thus, Department is entitled to recover up to full amount of its conditional Medicare payments when beneficiary receives discounted settlement from third party. *Zinman v Shalala (1995, CA9 Cal) 67 F3d 841, 49* Soc Sec Rep Serv 128,

95 CDOS 7840, 95 Daily Journal DAR 13435 (criticized in In re Dow Corning Corp. (2000, BC ED Mich) 250 BR 298, 55 Fed Rules Evid Serv 118).

Department of Health and Human Services is entitled to recover full amount of its conditional Medicare payments when beneficiary receives discounted settlement from third party; HHS is not required to reduce its recovery proportionately to amount by which settlement is discounted. Zinman v Shalala (1995, CA9 Cal) 67 F3d 841, 49 Soc Sec Rep Serv 128, 95 CDOS 7840, 95 Daily Journal DAR 13435 (criticized in In re Dow Corning Corp. (2000, BC ED Mich) 250 BR 298, 55 Fed Rules Evid Serv 118).

42 USCS § 1395y(b)(2)(A)(ii), which prohibits Medicare payments to beneficiary for medical expenses if payment has been made, or can reasonably be expected to be made promptly, under automobile or liability insurance policy or plan or under no-fault insurance, preempts those sections of Rhode Island Insurers' Insolvency Fund Act (R.I. Gen. Laws §§ 27-34-5(8)(ii)(C) and 27-34-12(b)) which purport to shift financial responsibility for primary insurance coverage from Rhode Island Insurers' Insolvency Fund to federal Medicare program. United States v Rhode Island Insurers' Insolvency Fund (1996, CA1 RI) 80 F3d 616, 50 Soc Sec Rep Serv 492 (criticized in Sabo v Metropolitan Life Ins. Co. (1998, CA3 Pa) 137 F3d 185, RICO Bus Disp Guide (CCH) P 9440).

42 USCS § 1395y(b) has no impact on priority as between solely private insurers and does not trump plan language adopted by private insurers as to priority; additionally, statute does not affect contractual regulations under which one insurer's coverage is secondary to that of another when no claim is being asserted against Medicare. Harris Corp. v Humana Health Ins. Co. of Fla. (2001, CA11 Fla) 253 F3d 598, 14 FLW Fed C 798.

Because 42 USCS § 1395y(a)(1)(A) expressly prohibits Medicare payment if provider fails to comply with its terms, provider's submission of reimbursement claim form implicitly certifies compliance with its provision for purposes of liability under False Claims Act (31 USCS §§ 3729 et seq.). United States ex. rel. Mikes v Straus (2001, CA2 NY) 274 F3d 687.

Medicare Secondary Payer Statute, 42 USCS § 1395y(b), did not preempt state law that required workers' compensation claimant to obtain preauthorization from relevant carrier before incurring certain medical expenses; Tex. Lab. Code Ann. § 413.014(c), (d), 28 Tex. Admin. Code § 134.600. Caldera v Ins. Co. of Pa. (2013, CA5 Tex) 716 F3d 861.

Congress intended Medicare Secondary Payer Statute, 42 USCS § 1395y(b), to complement, not supplant, state workers' compensation rules; this included preauthorization requirement that claimant failed to meet before he filed suit. Congress did not intend to override primary payer's ability to impose medical necessity requirements in accordance with state law. Caldera v Ins. Co. of Pa. (2013, CA5 Tex) 716 F3d 861.

Under Medicare Secondary Payer Statute (MSP), 42 USCS § 1395y(b), if claimant fails to file proper claim in accordance with state-law requirements and, therefore, cannot recover benefits from primary payer, so be it. Medicare can refuse to make conditional payment, or it can seek reimbursement from claimant himself; in any event, claimant cannot succeed under MSP. Caldera v Ins. Co. of Pa. (2013, CA5 Tex) 716 F3d 861.

In accordance with Medicare as Secondary Payer Act, fact of settlement alone, if it releases tortfeasor from claims for medical expenses, is sufficient to demonstrate beneficiary's obligation to reimburse Medicare. Taransky v Sec'y of United States HHS (2014, CA3 NJ) 760 F3d 307.

For purpose of determining coverage of inpatient rehabilitative services, HCFA Ruling 85-2 (which lists eight specific criteria which patient in need of inpatient rehabilitation should meet in order for services to be considered reasonable and necessary) applies, because in determining whether services are reasonable and necessary, Secretary should consider whether services were provided in most cost-effective setting. Probstein v Sullivan (1993, DC Conn) CCH Medicare & Medicaid Guide P 41423.

Calculation of interest by Secretary of United States Department of Health and Human Services when reimbursement claim is in dispute is permitted. Haro v Sebelius (2011, DC Ariz) 789 F Supp 2d 1179.

Secretary of United States Department of Health and Human Services may not collect disputed reimbursement claims from beneficiaries or their attorneys pending resolution of waiver requests and appeals, and she may not preclude attorneys from disbursing undisputed portions of settlement proceeds to their beneficiary clients. *Haro v Sebelius (2011, DC Ariz) 789 F Supp 2d 1179.*

42 USCS § 1395y(b) does not prohibit private insurer from terminating coverage under health insurance policy due to insured's eligibility for Medicare, but rather, merely excludes from payment by Medicare medical expenses that are already paid by other insurance. *Mote v State Farm Mut. Auto. Ins. Co. (1990, Ind App) 550 NE2d 1354.*

2. Construction, generally

With respect to "personal comfort items," secretary should have first chance to apply language specifically to particular items by gradual process of inclusion and exclusion as cases presented for decision shall require; judicial interpretation of statute would not be satisfactory method of determining what facilities, appliances and equipment are ordinarily furnished by hospitals and which are personal comfort items. *Fairview Deaconess Hospital v Heckler (1984, CA8 Minn) 749 F2d 1256.*

Secretary's decision as to whether particular category or type of medical service is not reasonable and necessary, and therefore not covered by Medicare, and means by which Secretary implements decision, whether by promulgating generally applicable rule or by allowing individual adjudication on case-by-case basis, is clearly matter of discretion under § 1395y(a)(1); thus, Secretary may rely on HCFA Ruling 80-2 to deny Medicare benefits for bilateral carotid body resection surgery notwithstanding showing that surgery has relieved pain in particular case. *Wilkins v Sullivan (1989, CA7 Ill) 889 F2d 135.*

42 USCS § 1395y(b) has no impact on priority as between solely private insurers and does not trump plan language adopted by private insurers as to priority; additionally, statute does not affect contractual regulations under which one insurer's coverage is secondary to that of another when no claim is being asserted against *Medicare. Harris Corp. v Humana Health Ins. Co. of Fla. (2001, CA11 Fla) 253 F3d 598, 14 FLW Fed C 798.*

Because *42 USCS § 1395y(a)(1)(A)* contains express condition of payment, it explicitly links each Medicare payment to requirement that particular item or service be reasonable and necessary. *United States ex. rel. Mikes v Straus (2001, CA2 NY) 274 F3d 687.*

Reading statute as whole and comparing it with Medicare Secondary Payer statute, *42 USCS § 1395y(b)*--which used mandatory rather than permissive language--made it clear that *42 USCS § 1395mm(e)(4)* was intended to permit Medicare-substitute HMOs to create right of reimbursement for themselves in context of their own insurance agreements with Medicare insureds; statute did not confer any affirmative rights to reimbursement enforceable in federal court, and contained no implied private right of action. *Care Choices HMO v Engstrom (2003, CA6 Mich) 330 F3d 786, 2003 FED App 162P.*

By its plain terms, *42 USCS § 1395y(b)* and Health Care Financing Administration regulations predicate reimbursement liability on existence of primary insurance plan. *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

Medicare payments are conditional and subject to recoupment under *42 USCS § 1395y(b)* regardless of whether another insurer can be expected to render prompt primary payment. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

Where manufacturers of silicone breast implants paid into fund settling claims for implant injuries out of their own earnings, then submitted claims to their liability carriers for partial reimbursement, manufacturers were entities that received payment from primary plans within meaning of *42 USCS § 1395y(b)(2)(B)(ii)*, rather than mere

intermediaries between their insurance companies and claimants. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

It is sufficient, for purposes of subrogation under *42 USCS § 1395y(b)(2)(B)(iii)*, that tortfeasors have constructive knowledge that they were paying tort claimants whose medical expenses were already paid by Medicare; actual knowledge of Medicare payments is not required and tortfeasor that willfully blinds itself to such payments can be charged with constructive knowledge of payments. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

Court-appointed escrow agent of settlement fund in class action was not liable entity which received payment from primary plan within meaning of *42 USCS § 1395y(b)(2)(B)(ii)*; agent acted in purely ministerial role serving district court and did not receive payment under claim of right or entitlement to retain it. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

Medicare as Secondary Payer statute's requirement of existence of primary plan connotes some type of formal arrangement by which entity consciously undertakes to set aside funds to cover potential future liabilities and formal procedure for processing claims made against that fund pursuant to terms of plan. *Mason v Am. Tobacco Co. (2003, CA2 NY) 346 F3d 36,* cert den, motion gr *(2004) 541 US 1057, 158 L Ed 2d 757, 124 S Ct 2163.*

Where Medicare benefits recipient obtained settlement in medical malpractice action after she received reimbursement from Secretary of Department of Health and Human Services for these medical services, Secretary was entitled to reimbursement of such payments from recipient's settlement because, under clear language of Medicare Secondary Payer Provisions (MSP), *42 USCS § 1395y(b)(2)*, as amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), *Pub. L. No. 108-173*, § 301, *117 Stat. 2066*, 2221, such reimbursement was required; MMA did not constitute substantive change in law, but merely clarified existing law, and recipient's settlement was funded from self-insured plan that satisfied definition of primary plan under *MSP. Brown v Thompson (2004, CA4 Va) 374 F3d 253.*

Plaintiff did not demand that it pay for only 10 percent of medical expenses that he incurred as result of his accident (he demanded that it pay for all of them); that choice had consequences, one of which was that plaintiff had to reimburse Medicare for those same expenses. *Hadden v United States (2011, CA6 Ky) 661 F3d 298, 2011 FED App 293P,* reh den, reh, en banc, den (2012, CA6) *2012 US App LEXIS 486.*

Under *42 USCS § 1395y(b)(2)(B)(ii)* as amended, if beneficiary made claim against primary plan, and later received "payment" from plan in return for "release" as to that claim, then plan was deemed responsible for payment of items or services included in claim. *Hadden v United States (2011, CA6 Ky) 661 F3d 298, 2011 FED App 293P,* reh den, reh, en banc, den (2012, CA6) *2012 US App LEXIS 486.*

Medicare Advantage Organization (MAO) must make secondary payment any time Secretary of Health & Human Services would do so; Congress empowered, and perhaps obligated, MAOs to make secondary payments under same circumstances as *Secretary. Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Medicare Secondary Payer Act (MSP) private cause of action permits Medicare Advantage Organization (MAO) to sue primary plan that fails to reimburse MAO's secondary payment; subsection (b)(3)(A) is broadly available in case of primary plan which fails to provide for primary payment (or appropriate reimbursement), and neither MSP nor our case law places any other restriction on class of plaintiffs to whom MSP private cause of action is available. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Medicare Secondary Payer Act (MSP) applies to Medicare Advantage Organizations (MAO), and MAO has statutory right to charge primary plan when MAO payment is made secondary pursuant to MSP; in such case, primary plan's failure to make primary payment or to reimburse MAO causes MAO injury in fact, and thus, MAO may avail itself of MSP private cause of action when primary plan fails to make primary payment or to reimburse MAO's secondary payment. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Although subsection (b)(2)(A) does not expressly obligate primary plans to make payments, defined term "primary plan" presupposes existing obligation, whether by statute or contract, to pay for covered items or services; therefore, primary plan fails to provide for primary payment, or appropriate reimbursement when it fails to honor underlying statutory or contractual obligation, and thus, subsections (b)(2)(A), (2)(B), and (3)(A), work together to establish comprehensive scheme. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Subsection (b)(2)(A) unambiguously refers to all Medicare payments, which include both traditional Medicare and Medicare Advantage plans, and Medicare Advantage Organization (MAO) right-to-charge provision parenthetically refers to circumstances under which MAO payments are made secondary pursuant to subsection (b)(2). *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Plain reading of subsection (b)(2)(A) and Medicare Advantage Organization (MAO) right-to-charge provision reveals that MAO payments are made secondary to primary payments pursuant to Medicare Secondary Payer Act (MSP), not MAO right-to-charge provision, and MSP does not limit private cause of action to cases in which traditional Medicare is secondary payer. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Subsection (b)(2)(A) establishes secondary payer status for all Medicare and defines "primary plan" with reference to pre-existing obligations; thus, primary plan that fails to make primary payment has failed to do so in accordance with subsections (b)(1) and (2)(A), regardless of whether secondary payer is Secretary of Health & *Human Services or Medicare Advantage Organization. Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

ALJ who, in denying coverage of inpatient rehabilitation services pursuant to reasonable and necessary standard of *42 USCS § 1395y(a)(1)(A)*, apparently did not consider HCFA Ruling 85-2, which lists eight specific criteria which a patient in need of inpatient rehabilitation should meet in order for services to be considered reasonable and necessary, committed error, because when rule sets forth specific criteria, ALJ's reasonable and necessary determination must contain application of criteria to particular facts of case. Probstein v Sullivan (1993, DC Conn) CCH Medicare & Medicaid Guide P 41423.

In construing Medicare secondary payer (MSP) statute (*42 USCS § 1395y*), one District Court, in class action dealing with Medicare beneficiaries who were injured in accidents in which Medicare paid for medical expenses for which it was later determined that private insurance policies were obligated to pay, held that Medicare does not have to proportionately reduce its reimbursement demand when beneficiary's settlement award does not fully cover medical expenses; notices of MSP recovery claims should be sent directly to beneficiaries, rather than to personal injury attorneys retained to represent beneficiaries in tort actions arising out of accidents; Medicare should utilize uniform notice which advises beneficiaries of their rights to seek waiver of recovery and to appeal denial of waiver requests; Medicare does not have lien on settlement awards, so that term cannot be used to describe MSP recovery claims in communications with beneficiaries and their attorneys; and Secretary must develop written guidelines as to waiver requests reviewed under equity and good conscience (*20 CFR § 404.509*). *Zinman v Shalala (1993, ND Cal) 835 F Supp 1163, 42* Soc Sec Rep Serv 655, 93 Daily Journal DAR 14349, affd (1995, CA9 Cal) *67 F3d 841, 49* Soc Sec Rep Serv 128, *95 CDOS 7840, 95* Daily Journal DAR 13435 (criticized in *In re Dow Corning Corp. (2000, BC ED Mich) 250 BR 298, 55 Fed Rules Evid Serv 118).*

Medicare as Secondary Payor (MSP), *42 USCS § 1395y(b)(3)(A)*, as construed by proposed class action plaintiffs would have distorted federal-state substantive tort balance by creating harsh, double recovery, shadow federal tort action in any case where Medicare payments were made on behalf of any person injured by delict; tobacco companies were not self-insured plans or insurance companies, and had no apparent agreement or policy to be self-insured plans covering general tort claims, and MSP statute did not require each individual covered by Medicare to bring suit, but instead it simply authorized civil proceeding similar to qui tam action where anyone could bring claim on behalf of United States government and receive bounty. *Mason v Am. Tobacco Co. (2002, ED NY) 212 F Supp 2d 88,* affd (2003, CA2 NY) *346 F3d 36,* cert den, motion gr *(2004) 541 US 1057, 158 L Ed 2d 757, 124 S Ct 2163.*

Subparagraph A of *42 USCS § 1395y(b)(2)* tells Secretary of Department of Health and Human Services not to make Medicare payments where primary plan or payer exists. *Brown v Thompson (2003, ED Va) 252 F Supp 2d 312,* affd (2004, CA4 Va) *374 F3d 253* and (criticized in *Timmerman v Thompson (2004, DC Minn) 2004 US Dist LEXIS 15120).*

Subparagraph B of *42 USCS § 1395y(b)(2)* authorizes Secretary of Health and Human Services to obtain reimbursement for Medicare payments that have been made for certain medical services where existence of primary plan to cover those services becomes known after, indeed even well after, Medicare payment is made. *Brown v Thompson (2003, ED Va) 252 F Supp 2d 312,* affd (2004, CA4 Va) *374 F3d 253* and (criticized in *Timmerman v Thompson (2004, DC Minn) 2004 US Dist LEXIS 15120).*

Taken literally, language of *42 USCS § 1395y(b)(A)(B)(i)* and (ii) simply says, in respect to Medicare subscriber with private source of insurance, that Medicare will not pay if it is reasonably certain that insurance company will pay, but if it is not certain that company will pay, Medicare will do so; if, however, company pays after Medicare pays, subscriber must reimburse *Medicare. Estate of Urso v Thompson (2004, DC Conn) 309 F Supp 2d 253.*

Statutory and legislative history convinced court that language in *42 USCS § 1395y(a)(7)* was, as illuminated by statutory and legislative history, clear and unambiguous; term "eyeglasses" in § 1395y(a)(7) referred to eyewear, not to video monitors used to aid sight; although administrative law judge addressed these issues, Medicare Appeals Council had not, thus, court exercised its discretion under *42 USCS § 405(g)* and remanded matter to Secretary of Health and Human Services for further proceedings. *Currier v Thompson (2005, DC Me) 369 F Supp 2d 65.*

Medicare contractors erred when they issued local coverage determinations for inhalation drug that was used to treat Chronic Obstructive Pulmonary Disease and provided combination of albuterol and ipratropium bromide in one dose, and declared that reimbursement for drug would be based on payment allowance for separate doses of albuterol and ipratropium bromide; *42 USCS § 1395w-3a* set reimbursement rate for drug in question, and *42 USCS § 1395y(a)* did not authorize Secretary of U.S. Department of Health and Human Services or contractors, acting on Secretary's behalf, to set reimbursement rate that differed from rate set by § 1395w-3a. *Hays v Leavitt (2008, DC Dist Col) 583 F Supp 2d 62.*

In case in which kidney dialysis center operator, which was assignee of retiree health care benefits of now-deceased patient, sued health and welfare fund to recover unpaid benefits due under fund's group health plan pursuant to *29 USCS § 1132(a)(1)(B)*, fund unsuccessfully asserted that meaning of *42 USCS § 1395y(b)(1)(C)(ii)* was that plan could neither treat end stage renal disease (ESRD) patients less favorably nor more favorably than non-ESRD patients; *42 CFR § 411.161(b)(2)(i)*-(v) was regulation that interpreted § 1395y(b)(1)(C)(ii)'s nondifferentiation requirement, and that regulation offered nonexhaustive sampling of actions that constituted differentiation in plan benefits; without exception, listed examples are of actions that negatively impacted ESRD patients, none of listed circumstances treated ESRD patients more favorably than persons not suffering from that condition. *Bio-Medial Applications of Tenn., Inc. v Central States Southeast and Southwest Areas Health and Welfare Fund (2009, ED Tenn) 648 F Supp 2d 988, 47 EBC 2203.*

In case in which kidney dialysis center operator, which was assignee of retiree health care benefits of now-deceased patient, sued health and welfare fund to recover unpaid benefits due under fund's group health plan pursuant to *29 USCS § 1132(a)(1)(B)*, fund's long-term reliance on Blue Cross Texas decision's benefits/coverage distinction was misplaced; insurance at issue in present case was not continuation coverage, and there was no relevant contrary statute at issue in case, such as Consolidated Omnibus Budget Reconciliation Act, containing specific provision that overrode *42 USCS § 1395y(b)*. *Bio-Medial Applications of Tenn., Inc. v Central States Southeast and Southwest Areas Health and Welfare Fund (2009, ED Tenn) 648 F Supp 2d 988, 47 EBC 2203.*

Given that purpose of private cause of action is to save government money by giving private citizens incentive to recover funds erroneously paid by Medicare, double damages claim pursuant to *42 USCS § 1395y(b)(3)(A)* may be maintained only where Medicare has, in fact, paid claims that primary insurer should have, but refused, to pay. *Bio-Medical Applications of Ga., Inc. v City of Dalton (2009, ND Ga) 685 F Supp 2d 1321.*

Medicare set aside amount from pre-petition workers' compensation settlement was not exempt; however, it was not subject to administration by trustee because it was not property of bankruptcy estate, as settlement agreement with respect to this portion established trust for benefit of medical providers. *Carr v Arellano (In re Arellano) (2015, BC MD Pa) 524 BR 615, 72 CBC2d 1545.*

3. --Self-insurance plan

Under language of *42 USCS § 1395y(b)(2)(B)(i)*, which expressly cross-references § 1395y(b)(2)(A)(i)-(ii), absent expectation of prompt payment, government has no cause of action to collect from "self-insured plan," or from any of other primary plans enumerated in § 1395y(b)(2)(A)(ii). *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

Term "self-insurance plan," as used in *42 USCS § 1395y(b)*, is not only clear in its meaning, it plainly does not apply automatically to alleged tortfeasors who settle with plaintiffs, and thus, court agreed with other district courts that have concluded that alleged tortfeasor who settles with plaintiff is not, ipso facto, "self-insurer" under statute; term "self-insurance plan" is predicated on term "primary plan," and statute's reimbursement provisions are not triggered unless Medicare recipient's source of recovery meets definition of "primary plan," regardless of whether that source is group healthcare plan, workman's compensation, liability insurance, or self-insurance plan. *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

In sense used in *42 USCS § 1395y(b)*, "primary plan" of "self-insurance" requires entity's ex ante adoption, for itself, of arrangement for (1) source of funds and (2) procedures for disbursing these funds when claims are made against entity; according to ordinary meaning of terms of statute, it is wrong for one to contend that entity's negotiating of single settlement with individual plaintiff is sufficient, in and of itself, for such entity to be deemed as having "self-insurance plan." *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

42 USCS § 1395y(b) explicitly speaks in terms of insurance plans that provide primary medical coverage, and nowhere does statute mention or even suggest that alleged tortfeasor who settles single claim with single plaintiff falls within ambit of statute's category of self-insurance plan; failure of Congress to include in statute right of action for reimbursement of medical expenditures against tortfeasors indicates that this statute plainly intends to allow recovery only from insurer, and express inclusion of recovery from tortfeasors in Medical Care Recovery Act, *42 USCS §§ 2651*-53, supports conclusion that Congress's omission of tortfeasors from list of those potentially liable under *42 USCS § 1395y(b)* was knowing and intentional. *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

"Self-insured plan," as that term is understood in *42 USCS § 1395y(b)(2)(A)(iii)*, connotes some type of ex ante arrangement to assume legal liability for medical expenses; thus, tortfeasor's mere payment, without more, would not constitute plan of self-insurance and mere absence of insurance does not necessarily constitute plan of self-insurance. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

Where manufacturers of silicone breast implants had plans or arrangements to assume legal liability existing before claims were asserted for conditions traceable to implants, which may have included combination of self-insurance with respect to certain amounts and purchase of insurance policies as to other amounts, U.S. properly alleged that manufactures were self-insured within meaning of *42 USCS § 1395y(b)(2)(A)(iii)*. *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098,* cert den (2004, US) *159 L Ed 2d 828, 124 S Ct 2907.*

Plaintiffs' action to recover under Medicare as Secondary Payer statute was properly dismissed because defendants' status as accused tortfeasors, standing alone, did not convert them into primary plans or self-insured plans for Medicare beneficiaries injured by using their products; complaint did not allege, even in conclusory fashion, that defendants, alone or collectively, had actually established any concerted plan to pay anyone's healthcare expenses beyond having made decision to set aside funds to cover potential future tort liability. *Mason v Am. Tobacco Co. (2003, CA2 NY) 346 F3d 36,* cert den, motion gr *(2004) 541 US 1057, 158 L Ed 2d 757, 124 S Ct 2163.*

4. Bedside telephones

Expenses incurred by private hospital in providing bedside telephones to Medicare beneficiaries are not reasonable costs of Medicare and are thus not reimbursable under *42 USCS § 1395x*. *St. Mary of Nazareth Hospital Center v Department of Health & Human Services (1983, CA7 Ill) 698 F2d 1337,* cert den *(1983) 464 US 830, 78 L Ed 2d 110, 104 S Ct 107.*

Cost of providing Medicare patient with bedside telephone is not reimbursable under Medicare program. *Arlington Hospital v Heckler (1984, CA4 Va) 731 F2d 171.*

Secretary's regulation (42 CFR § 405.310(j)) disallowing reimbursement to hospitals for bedside telephone supplied to Medicare patients has rational basis and is consistent with Congressional intent and legislative history of *42 USCS § 1395y(a)(6)*. *St. Joseph Hospital v Heckler (1983, ND Ind) 570 F Supp 434.*

Secretary did not act outside her statutory authority in determining that patient telephone services are personal comfort items unnecessary for treatment of illness and injury and thus not reimbursable expenses. *Bedford County General Hospital v Heckler (1983, ED Tenn) 574 F Supp 943,* affd (1985, CA6 Tenn) *757 F2d 87.*

Although Congress has substantially amended *42 USCS § 1395y(a)(6)* on several occasions, it has not amended personal comfort exclusion or altered Secretary's implementation of patient-telephone regulations. *Greater Cleveland Hospital Asso. Group Appeal v Schweiker (1984, ND Ohio) 599 F Supp 1000.*

5. Community services

District courts erred in dismissing claims filed by assignees of health maintenance organization (HMO) against primary plans for double damages under Medicare Secondary Payer Act because assignees had standing where their claims were not claims on HMO's contract with government, Act's private cause of action did not require any sort of relationship (contractual or otherwise) with government (or anyone else) as prerequisite to suit, *42 CFR § 411.22(b)* specifically referenced contractual obligations, and judgment or settlement from separate proceeding was not necessary. *MSP Recovery, LLC v Allstate Ins. Co. (2016, CA11 Fla) 835 F3d 1351, 26 FLW Fed C 738,* magistrate's recommendation (2017, SD Fla) *2017 US Dist LEXIS 34711* and magistrate's recommendation (2017, SD Fla) *2017 US Dist LEXIS 41424.*

Hospital is not entitled to reimbursement for use of Tel-Med system since such system is available to community at large, and not restricted to care of Medicare beneficiaries; hospital cannot be reimbursed for telephone service where there is operation of nurse-signalling system in hospital, and therefore telephones are provided for patients'

personal comfort; interest expense on loans taken to refinance existing debt is unnecessary and nonallowable for Medicare reimbursement. *St. Francis Hospital, Inc. v Califano (1979, DC Dist Col) 479 F Supp 761.*

6. Dental treatment

Exception in dental exclusion in Medicare statute for underlying medical condition applies only to claims under Part A of the statute. *Chipman v Shalala (1996, CA10 Kan) 90 F3d 421, 51* Soc Sec Rep Serv 294.

Characterization of porcelain veneer crowns as medically necessary, without further authority or basis for exception from general dental services exclusion, did not support assertion that payment for claimant's crowns should have been covered by *Medicare. Chipman v Shalala (1996, CA10 Kan) 90 F3d 421, 51* Soc Sec Rep Serv 294.

Secretary of Department of Health and Human Services properly denied claims for Medicare Part B beneficiaries' dental services under *42 USCS § 1395y(a)(12)*, because although § 1395y(a)(12) was ambiguous, Secretary's interpretation that primary dental services that were not provided on inpatient basis were excluded from coverage was entitled to Chevron deference and was reasonable, and Secretary's policy did not violate equal protection guarantee under *U.S. Const. amend. V*. *Fournier v Sebelius (2013, CA9 Ariz) 718 F3d 1110.*

Claim for reimbursement of dental expenses, denied as fully within exclusion of *42 USCS § 1395y(a)(12)*, was entitled to review under *42 USCS § 1395ff*. *Bohlen v Richardson (1972, ED Pa) 345 F Supp 124,* affd (1973, CA3 Pa) *483 F2d 918.*

Claimant, who suffered from atrophy of maxilla and mandible with resulting inability to wear dentures, was entitled to reimbursement under Medicare Part B for endosteal bone augmentation surgery that he underwent, but was not entitled to reimbursement for cost of porcelain veneer crowns that were implanted in his mandible and maxilla following such surgery, despite fact that two physicians had indicated that it was medically necessary for claimant to have dental implant procedure due to his history of peptic ulcer disease which required proper nutrition and properly chewed food, because porcelain crowns were dental services, and as such were not covered services pursuant to *42 USCS § 1395y(a)(12)*; nothing in medical record indicated that dental implant procedure was necessary part of bone augmentation surgery, or that bone augmentation would be beneficial only if claimant would later receive dental implants. *Chipman v Shalala (1995, DC Kan) 894 F Supp 392, 48* Soc Sec Rep Serv 392, affd (1996, CA10 Kan) *90 F3d 421, 51* Soc Sec Rep Serv 294.

Dental services received by claimant, which involved root canals to repair damage to claimant's mouth as result of radiation treatments to his head and neck for metastatic squamous cell carcinoma, and to prevent radiation osteonecrosis, did not qualify for exception to general exclusion of such services (*42 USCS § 1395y(a)(12)*), because dental services were neither incident to, nor integral part of, covered radiation treatments, as dental services were not performed by same physician who had administered radiation treatments, were not provided at same location as radiation treatments, and were performed over four years after claimant had received his radiation treatments; and physician who had administered radiation treatments did not diagnose radiation osteonecrosis that would eventually lead to loss of teeth and infection to jaw bone, but merely predicted it if claimant failed to have recommended treatment. Bick v Secretary of Health and Human Services (1996, CD Cal) CCH Medicare & Medicaid Guide P 44440.

Evidence did not support Medicare Appeals Council's determination under *42 USCS § 1395y(a)(12)* that dental services provided to claimant were intended to address dental problem and were not incidental to or an integral part of covered service, where evidence showed that dental services were medically necessary and directly related to claimant's treatment for leukemia and thrombocytopenia. *Maggio v Shalala (1999, WD NY) 40 F Supp 2d 137, 61* Soc Sec Rep Serv 243.

Under *42 USCS § 1395y(a)(12)*, Medicare Part B did not provide reimbursement for outpatient extraction of teeth, even where medically necessary for preparation for heart valve replacement surgery. *Wood v Shalala (2000, WD*

Wis) 94 F Supp 2d 1024, 69 Soc Sec Rep Serv 298, affd sub nom *Wood v Thompson (2001, CA7 Wis) 246 F3d 1026, 73* Soc Sec Rep Serv 263.

Secretary of Health and Human Services was entitled, as secondary payer, to reimbursement from proceeds of deceased's settlement with supermarket's liability insurer where Secretary's interpretation of Medicare's secondary payer (MSP) provisions, *42 USCS § 1395y(b)(A)(B)(i)* and (ii), which required that reimbursement for hospital bill's paid by Medicare be recovered from deceased's settlement, was consistent with history and purpose of MSP provisions. *Estate of Urso v Thompson (2004, DC Conn) 309 F Supp 2d 253.*

Although Medicare patients' dental problems were caused by their diseases, Sjogren's syndrome and graft versus host disease from leukemia treatments, which caused them to lose salivary functions and their teeth to consequently decay and break off, dental work was primary procedure and was excluded under *42 USCS § 1395y(a)(12)*. *Fournier v Sebelius (2012, DC Ariz) 839 F Supp 2d 1077.*

Finding that plaintiff's mandible reconstruction and bone grafts were not covered services under Medicare Part B was supported by substantial evidence because medical records established that her procedures were performed in connection with treatment of her teeth and teeth supporting structures; pursuant to *42 USCS § 1395y(a)(12)*, procedures were not covered. *Born v Sebelius (2013, DC Colo) 968 F Supp 2d 1109.*

Where Part A beneficiary incurs hospital expenses for oral surgery to remove bone growth in his lower mouth, payment for said expenses is not precluded by "dental exclusion" in *42 USCS § 1395y(a)(12)* when surgery was not performed primarily for care of structures directly supporting teeth nor for purpose of preparing his mouth for false teeth. SSR 69-32 (1969).

Unpublished Opinions

Unpublished: Medicare Secondary Payer Act actions are rooted in restitution or unjust enrichment theory and are subject to six-year statute of limitations. *United States v Weinberg (2002, ED Pa) 2002 US Dist LEXIS 12289.*

Unpublished: Medicare was entitled to reimbursement from third-party action by Medicare recipient of value of Medicare benefits provided to recipient. *United States v Weinberg (2002, ED Pa) 2002 US Dist LEXIS 12289.*

7. Litigation claims

In hospital's action against health benefits fund that sought declaratory judgment and damages under *28 USCS § 2201*, *42 USCS §§ 1395* and 1935y(b), and *29 USCS § 1101* et seq., for fund's refusal to pay for hospital services provided to dependent of fund beneficiary, summary judgment in favor of fund was warranted because there were no genuine issues of material fact. *Baptist Mem'l Hosp. v Marsaw (2000, CA6 Tenn) 24 EBC 2637.*

District court properly dismissed government's action for reimbursement under Medicare Secondary Provider statute, *42 USCS § 1395y(b)*, against manufacturer of artificial hip, which had been sued for product liability and had paid settlement to patient and her attorney, because statute and related regulations predicated reimbursement liability on existence of primary insurance plan, and government's complaint failed to allege existence of any elements of primary plan; furthermore, statutory requirement that primary insurance plan pay within 120 days of medical care claim precluded holding that manufacturer was liable as self-insurer under statute. *Thompson v Goetzmann (2002, CA5 Tex) 315 F3d 457* (criticized in *Brown v Thompson (2003, ED Va) 252 F Supp 2d 312)* and op withdrawn, substituted op (2003, CA5 Tex) *337 F3d 489* and (criticized in *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098).*

District court properly granted patient and her attorney summary judgment in government's action for reimbursement of Medicare expenditures for patient's treatment, where prosthesis manufacturer that paid patient settlement in her products liability action was not self-insurer, and patient and her attorney therefore were not liable for reimbursement. *Thompson v Goetzmann (2002, CA5 Tex) 315 F3d 457* (criticized in *Brown v Thompson (2003,*

ED Va) 252 F Supp 2d 312) and op withdrawn, substituted op (2003, CA5 Tex) *337 F3d 489* and (criticized in *United States v Baxter Int'l, Inc. (2003, CA11 Ala) 345 F3d 866, CCH Prod Liab Rep P 16742, 57 FR Serv 3d 410, 16 FLW Fed C 1098).*

Action under Medicare Act by Medicare Advantage Organization (MAO) that sought reimbursement against survivors for decedent's medical expenses out of proceeds of automobile insurance policy failed to state claim because *42 USCS § 1395w-22(a)(4)* did not grant MAO private right of action, and *42 USCS § 1395y(b)(3)(A)* did not apply since there was no claim against primary plan, and primary plan did not fail to provide for payment. *Parra v Pacificare of Ariz., Inc. (2013, CA9 Ariz) 715 F3d 1146.*

Medicare as Secondary Payer Act authorized Government to seek reimbursement from plaintiff's court-approved settlement with tortfeasor because she received funds from primary plan under statute that had responsibility for her medical expenses. *Taransky v Sec'y of United States HHS (2014, CA3 NJ) 760 F3d 307.*

Medicare need not pay anything liability insurer, as result of litigation, can be expected to pay; patient may be required to turn over settlement from tortfeasor's insurer to satisfy subrogation rights of Medicare program, even though settlement did not make patient whole because of tortfeasor's filing for bankruptcy. *St. Agnes Hospital v Jaeckel (1985, ED Wis) 616 F Supp 426.*

Private plaintiffs' action against tobacco companies, alleging that companies had responsibility to reimburse Medicare for medical costs of Medicare beneficiaries' smoking related diseases, was dismissed because Medicare Secondary Payer statute, *42 USCS § 1395y(b)*, as amended in 2003, did not permit such action where underlying tort liability was unresolved and companies' responsibility to pay Medicare had not been established by judgment, settlement, or other means of like kind. *Glover v Philip Morris USA (2005, MD Fla) 380 F Supp 2d 1279, 18 FLW Fed D 865.*

Medicare beneficiary was not given standing under *42 USCS § 1395y(b)(3)(A)* to bring class claims against defendants, manufacturers and distributors of allegedly defective pacemakers and implantable cardioverter defibrillators, as beneficiary could not show that Medicare Secondary Payer (MSP) statute granted beneficiary standing as assignee of U.S.; unlike False Claims Act, MSP does not unambiguously indicate that Congress, expressly or by implication, has assigned any individual right to bring suit on behalf of all Medicare beneficiaries; even if beneficiary had been able to show standing, claims would have failed because defendants' responsibility to reimburse Medicare had not been determined. *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig. (2007, DC Minn) 484 F Supp 2d 973.*

Because plaintiff's settlement agreement and release included compensation for medical expenses already paid for by Medicare with conditional payments, substantial evidence existed that plaintiff received payment from primary plan responsible for payment of her medical expenses that had been covered by Medicare, and plaintiff was required to reimburse Medicare $ 10,121.15 pursuant to Medicare as Secondary Payer statute. *Taransky v Sebelius (2013, DC NJ) 956 F Supp 2d 563.*

Conditional Medicare benefits subject to reimbursement are not collateral source under New Jersey Collateral Source Statute (NJCSS), and NJCSS does not apply to exclude conditional Medicare benefits from tort settlement or judgment. *Taransky v Sebelius (2013, DC NJ) 956 F Supp 2d 563.*

Where award under Federal Tort Claims Act for damages suffered by Part A beneficiary included amounts to reimburse him for hospital and medical expenses also covered under *42 USCS §§ 1395* et seq., (1) payments under Federal Tort Claims Act do not constitute payments by "governmental entity" for purposes of exclusion in *42 USCS § 1395y(a)(3)*, (2) Social Security Administration is given no right to recover such amounts (i.e., right of subrogation) or any other form of reimbursement from third-party tortfeasors by §§ 1395 et seq., and (3) beneficiary is permitted reimbursement under both §§ 1395 et seq. and Federal Tort Claims Act, since there is nothing inconsistent with simultaneous reimbursement under program and from other sources (with sole exception of

priority of workmen's compensation payments), since §§ 1395 et seq. is in nature of social insurance. SSR 69-8 (1969).

Where compromise settlement in disputed workmen's compensation claim has been reached and, in accordance with state statutory requirement, has been approved by workmen's compensation board or commission, to extent settlement could reasonably be deemed reimbursement of medical expenses, payment may not be made under *42 USCS §§ 1395* et seq. by virtue of *42 USCS § 1395y(b)*. SSR 70-38 (1970).

8. Services covered by automobile insurance

Neither statutory nor constitutional rights of insurance company are violated by regulations prohibiting Medicare payments for services covered by automobile insurance policy, even though policy states that its benefits are secondary to Medicare, despite contention that retroactive effect of regulations will require insurance company to make unanticipated payments on claims arising under previously issued policies since (1) regulations are not contrary to intent of Congress or language of implementing statute (*42 USCS § 1395y(b)(1)*), (2) insurer which freely chose to tie its coverage to Medicare provisions has no vested rights in maintenance of statutory status quo and (3) in view of 2 1/2 year interval between enactment of § 1395y(b)(1) and issuance of regulations, insurer cannot contend that regulations upset any justified expectations. *Colonial Penn Ins. Co. v Heckler (1983, CA3 Pa) 721 F2d 431.*

Hospital could not recover from former auto accident patient who later recovered lump-sum from negligent driver, difference between what Medicare paid hospital and amount hospital actually spent caring for patient. *Rybicki v Hartley (1986, CA1 NH) 792 F2d 260.*

Secretary did not act arbitrarily, capriciously, or in excess of statutory authority in promulgating regulation which provides that Medicare payments will no longer be made for services covered by any auto insurance policy (including no-fault), even if policy itself and/or state law states that benefits under policy are secondary to Medicare. *Abrams v Heckler (1984, SD NY) 582 F Supp 1155.*

Section 1395y(b)(1), under which Medicare is secondary source of recovery for expenses which are covered by private automobile liability insurer, preempts Florida's collateral source rule which permits automobile liability insurers to become secondary sources of recovery behind Medicare; therefore, automobile insurer cannot rely on Florida rule to withhold from arbitration award owed to Medicare claimant amount paid by Medicare for services covered by award. Smith v Midwestern Indemnity Company (1989, MD Fl) CCH Medicare and Medicaid Guide P 38328.

Since text and legislative history of *42 USCS § 1395y(b)(1)* require private automobile liability insurers to be beneficiary's primary source of recovery, and Medicare secondary source, state collateral source rule that permits automobile liability insurers to become secondary source of recovery is preempted by federal Medicare statute; accordingly, federal law applied where United States sought reimbursement from beneficiary who was covered by private insurers but whose bills from automobile accident had been paid by Medicare; as to private insurer who compensated beneficiary for same services that Medicare had already paid for, United States could use conditional Medicare payment provision of § 1395y(b)(1) to recover from beneficiary; however, United States could not use conditional reimbursement provision to recover for liability of two underinsured motorist insurers who refused to pay beneficiary full amount of arbitration award. *Smith v Travelers Indem. Co. (1989, MD Fla) 763 F Supp 554.*

By virtue of *42 USCS § 1395y(b)(2)(B)*, claim by United States for reimbursement for services paid for by Medicare is paramount to all other claims; therefore, United States has paramount right to insurance proceeds where pedestrian struck by automobile sustained serious injuries, and incurred medical expenses as result of accident, where medical expenses were paid for by Medicare; however, government's right can only be exercised if motorist's insurer's liability is established. Casualty Reciprocal Exchange v Johnson, et al. (1992, ED La) CCH Medicare & Medicaid Guide P 40955.

By virtue of *42 USCS § 1395y(b)(2)(B)*, claim by United States for reimbursement for services paid for by Medicare is paramount to all other claims; thus, United States has paramount right to insurance proceeds in case involving pedestrian who was struck by automobile, sustained serious injuries, and incurred medical expenses as result of accident, where medical expenses were paid for by Medicare; however, government's right can only be exercised if motorist's insurer's liability is established. Casualty Reciprocal Exchange v Johnson, et al. (1992, ED La) CCH Medicare & Medicaid Guide P 40955.

Medicare, as secondary payer to automobile insurance, is not entitled, under *42 USCS § 1395y(b)(2)(B)(ii)* or (iii), to reimbursement to full extent of individual recovery potentially available under insurance policy, but rather is limited to individual's right to payment under primary plan; thus, if individual's right to payment under primary plan is limited by terms of plan or by operation of state law, then Medicare's subrogation claim is equally limited. Waters, et al. v Farmers Texas County Mutual Insurance Company (1993, SD Tex) 5 MMLR P 53.

Department of Health and Human Services was entitled to receive $ 10,070 from underinsured motorist provisions of decedent's automobile insurance policy for medical expenses it paid for decedent following his accident because Department was using its right of direct action under *42 USCS § 1395y(b)(2)(B)(iii)* and because Department's construction of Medicare Secondary Payer (MSP) was rational and consistent with statute; Department's construction was consistent with legislative purposes of MSP and with plain language reading of statute, and it provided practical and economical way for Department to recover its conditional payments. *Farmers Ins. Exch. v Forkey (2010, DC Nev) 764 F Supp 2d 1205.*

Although Medicare was primary insurer of medication expenses of insured, secondary insurer which paid expenses as required by state no-fault automobile insurance law was not entitled to reimbursement of expenses from government since Medicare Secondary Payer Act allowed reimbursement to government from primary insurer when government was secondary insurer, but statute granted no reciprocal right of reimbursement to secondary insurer. Auto Club Ins; ass'n v *United States (2012) 103 Fed Cl 268.*

9. Services rendered outside United States

Where beneficiary is furnished items and services by foreign physician in connection with injury suffered while he was temporarily outside United States, reimbursement for items and services furnished in foreign country is precluded by *42 USCS § 1395y(a)(4)* even though one of items of medical equipment furnished was ordered from firm in United States. SSR 69-64 (1969).

10. Services rendered to relatives

Plain language of *42 USCS § 1395y(b)(3)(A)(i)* makes it clear that self-employed individuals are included in category of employed for purpose of determining when Medicare is secondary, rather than primary, payer; thus, ALJ properly determined that claimant, who was covered under group health plan that her husband had obtained from company that he worked for as independent contractor, was not entitled to Medicare reimbursement for costs associated with surgery that had been performed on her foot, because payment for surgery could have reasonably been expected to be made under claimant's husband's group health plan. Therkelsen v Shalala (1993, DC Minn) 5 MMLR P 54.

Where physician furnished services to his stepmother, Part B enrollee, after death of his natural father, payment for such services is precluded by *42 USCS § 1395y(a)(11)*; steprelationship did not terminate with death of physician's father, person through whom relationship was originally created. SSR 69-66 (1969).

11. Other expenses or services

Denial of Medicare reimbursement was affirmed because *42 USCS § 1395m(j)(2)* did not preclude Secretary of Health and Human Services from requiring additional evidence, beyond certificate of medical necessity, to establish medical necessity for equipment supplied and Secretary had duty imposed by *42 USCS § 1395y(a)* to ensure that no payment was made for items that were not medically necessary; also, company could not avail itself of liability-limiting provisions of *42 USCS § 1395pp(a)(2)* because it was deemed to have constructive notice of manual issuances, bulletins, and other written guidelines and directives that indicated that certain items of durable medical equipment would not be covered by *Medicare. Maximum Comfort v Sec'y of HHS (2007, CA9 Cal) 512 F3d 1081.*

Nurse practitioner's fraud allegations regarding propriety of mental health clinic's four-person evaluation process, mandatory drug screenings, and policies on prescription refills and appointments in her qui tam action under False Claims Act and Wisconsin False Claims Act did not suffice because she provided no medical, technical, or scientific context in her complaint that would enable reader of complaint to understand why clinic's alleged actions amounted to unnecessary care forbidden by statute; moreover, each of allegations depended entirely on nurse practitioner's personal estimation that was not supported in any concrete manner. *United States v Acacia Mental Health Clinic, LLC (2016, CA7 Wis) 836 F3d 770, 95 FR Serv 3d 1041.*

Government had authority pursuant to *42 USCS § 1395y* to recover medical payments that were inadvertently paid by Medicare from employer when employer voluntarily sponsored and contributed to group health plan for benefit of its employees. *Telecare Corp. v Leavitt (2005, CA FC) 409 F3d 1345.*

Medicare Part B beneficiary was improperly denied full reimbursement for prescribed inhalation drug because, under *42 USCS § 1395y(a)*, Secretary of Department of Health and Human Services was permitted to determine only whether prescribed drug was reasonable and necessary; if so, Medicare was required to fully reimburse based on 106 percent formula in *42 USCS § 1395w-3a*. By reimbursing beneficiary's prescribed drug at 106 percent of average sales price of its two component drugs, which had different billing and payment codes, Secretary fundamentally altered statutory scheme. *Hays v Sebelius (2009, App DC) 589 F3d 1279.*

Use in 42 CFR § 405.451(b)(2) of term "related to the care of beneficiaries" must be considered in light of *42 USCS § 1395y(a)(1)*, therefore Medicare will not reimburse provider of Medicare services for expenses stemming from inability of provider's majority and minority investors to agree upon appropriate corporate course of action. *Doctors Hospital, Inc. v Califano (1978, DC Dist Col) 459 F Supp 201.*

Term "custodial care" must be interpreted in light of benevolent congressional purpose underlying *42 USCS § 1395y(a)(9)* using nontechnical approach, common sense meaning, and consideration of needs and underlying condition of claimant as whole. *Kuebler v Secretary of United States Dep't of Health & Human Services (1984, ED NY) 579 F Supp 1436.*

Claimant, who was 66 years old and suffered from cardiovascular accident, hypertension, diabetes and hemorrhoids, was entitled to be reimbursed for intermittent home health visits for two-month period, since services provided, which included diabetic foot care, and instructions on medications and diet, and which were part of overall management of treatment plan, constituted skilled services. Follond, o/b/o Smith v Sullivan (1992, DC Vt) CCH Medicare & Medicaid Guide P 40738.

Tobacco companies were not self-insured entities within meaning of *42 USCS § 1395y(b)(2)(A)*, where federal government sued tobacco companies and others to recover health-care expenditures that government paid or will pay for injuries allegedly caused by defendants' tortious conduct, but there were no allegations that tobacco companies engaged in same sorts of underwriting procedures that insurance companies employ, or that they maintained fund or reserve to cover possible losses or had procedure for considering claims and for managing reserve. *United States v Philip Morris, Inc. (2001, DC Dist Col) 156 F Supp 2d 1.*

Under Medicare Secondary Payer statute (MSP) and regulations promulgated thereunder, Medicare is barred from providing payments to eligible beneficiaries when primary plan is obligated to cover same medical expenses; in other words, Medicare must be secondary payor in those circumstances. *In re RJF Int'l Corp. (2004, DC RI) 332 F*

Supp 2d 458, 2005 AMC 354, motion gr, in part, motion den, in part, costs/fees proceeding, request den (2004, DC RI) *334 F Supp 2d 109.*

Where question was whether Medicare supplanted maintenance and cure as payor of first resort when seaman became Medicare eligible, court found that vessel owner's yacht insurance policy was type of liability insurance policy covered by Medicare Secondary Payer (MSP) statute; consequently, MSP statute barred vessel owner from shifting financial burden of its cure obligation for injured seaman's medical expenses to Medicare system. *In re RJF Int'l Corp. (2004, DC RI) 332 F Supp 2d 458, 2005 AMC 354,* motion gr, in part, motion den, in part, costs/fees proceeding, request den (2004, DC RI) *334 F Supp 2d 109.*

Group of athletic trainers had prudential standing under *5 USCS § 702* to bring suit that challenged new Medicare regulation that rendered certain physician ordered therapies ineligible for reimbursement because trainers had been deemed by HHS to adequately perform therapy services in manner that met appropriate standards and quality required by *42 USCS § 1395y(a)(20)*; therefore, they could be expected to police physicians' interests protected by statute and, as result, satisfied prudential standing requirement. *Nat'l Ath. Trainers' Ass'n v United States HHS (2005, ND Tex) 394 F Supp 2d 883.*

District court did not have jurisdiction over suit challenging new Medicare rule that rendered certain physician-ordered therapies ineligible for reimbursement because administrative remedies had not been exhausted as required by *42 USCS § 405(g)* and (h); while athletic trainers who filed suit did not have route for administrative review, physicians who submitted claims for reimbursement could challenge rule and had incentive to raise issue of who could provide therapy services incident to their own professional services. *Nat'l Ath. Trainers' Ass'n v United States HHS (2005, ND Tex) 394 F Supp 2d 883.*

ALJ who determined that home health services that were provided to patient were not reasonable and necessary as required by *42 USCS § 1395y(a)(1)(A)* for Medicare Part coverage improperly focused on individual services provided by non-skilled caregiver rather than patient's condition as whole; nurse's role in managing and evaluating care was vital, and ALJ's failure to consider that function was in error. *Exec. Dir. ex rel. Carey v Sebelius (2009, DC Vt) 698 F Supp 2d 436,* adopted, motion gr, motion den, remanded (2010, DC Vt) *698 F Supp 2d 436.*

Relator stated claim under False Claims Act, *31 USCS §§ 3729* et seq., where she alleged that drug companies knowingly provided false information regarding efficacy of drug compared to cheaper alternatives, which caused physicians and pharmacists to either expressly or impliedly make false certifications about drug's efficacy or necessity for patient's treatment, and caused submission of false claims for payment by government payors since Medicare Act required that item be reasonable and necessary under *42 USCS § 1395y(a)(1)(A)* as prerequisite for reimbursement. *United States ex rel. Dickson (2013, SD Ill) 289 FRD 271.*

Relator stated claim under False Claims Act, *31 USCS §§ 3729* et seq., as she alleged false or fraudulent claim, even though drug was United States Food and Drug Administration (FDA)-approved, as: (1) fact that drug was FDA approved did not mean that it was reasonable and necessary for *42 USCS § 1395u(a)(1)(A)* purposes in every instance in which it was prescribed; (2) relator alleged that drug companies instructed their sales force to present various data and studies in manner designed to confuse physicians and make them believe that drug was more effective than cheaper alternatives, and that companies' misrepresentations caused physicians to feel that drug was essentially their only option; and (3) relator alleged that companies specifically instructed their sales force to focus sales calls on physicians who wrote significant numbers of prescriptions for patients covered by certain government payors. *United States ex rel. Dickson (2013, SD Ill) 289 FRD 271.*

Where participating hospital has policy of limiting its charges to extent of patient's coverage under commercial health insurance or health insurance under *42 USCS §§ 1395* et seq. and waiving collection of all its charges in case of indigent patients who have no such insurance coverage, *42 USCS § 1395y(a)(2)* does not bar payment on behalf of beneficiary for covered services furnished by such hospital, since such services are not services for which beneficiary has no legal obligation to pay and which no other person has legal obligation to pay for or provide. SSR 68-40 (1968).

Exclusion for routine foot care contained in *42 USCS § 1395y(a)(13)(C)* was found to be inapplicable to treatments that claimant received for plantar keratoses, based upon statement from orthopedic specialist, which indicated that claimant's condition was worst that he had ever seen, and affidavit, signed by 18 unaffiliated medical specialists, including podiatrists and orthopedic specialists, which supplied same opinion. In re Joseph P. Gerardi and The Travelers Insurance Co. (1995, Appeals Council Decision) CCH Medicare & Medicaid Guide P 43187.

Where insurer cut its reimbursement for out-of-network renal dialysis by 88 percent to levels below customary charges, cause of action did not arise under *42 USCS § 1395y(b)(3)(A)*, because Medicare as Second Payer Act was not intended to force insurers to subsidize dialysis treatment for patients in underserved areas; court found it significant that benefits granted to Medicare enrollees were not altered by cut in reimbursement, and insurer did not reimburse for dialysis of non-end-stage renal disease (ESRD) patients differently than for ESRD patients. *Nat'l Renal Alliance, LLC v Blue Cross & Blue Shield of Ga., Inc. (2009, ND Ga) 598 F Supp 2d 1344.*

Unpublished Opinions

Unpublished: Medical provider that failed to follow drug label instructions limiting dosage of drug to one dose per vial, but instead treated up to three patients from single vial by extracting three doses into three separate syringes, was not entitled to reimbursement from Medicare for each dose. *Vitreo Retinal Consultants of Palm Beaches v United States HHS (2016, CA11 Fla) 649 Fed Appx 684,* cert den (2017, US) *85 USLW 3453.*

Unpublished: Where ALJ found that optometrist's services were excluded from coverage by *42 USCS § 1395y(a)(7)* and *42 CFR § 411.15(c)* because optometrist's consultation notes established that she performed services that were statutorily excluded from payment, and that decision remained unchallenged, appellate court affirmed. *Baba v Leavitt (2008, CA9 Cal) 2008 US App LEXIS 12040.*

II. CUSTODIAL CARE EXCLUSION

12. Generally

Opinion of claimant's physician with regard to necessity of skilled medical care is not of controlling weight, but may properly be weighed against all other evidence. *Rendzio v Secretary of Health, Education & Welfare (1975, ED Mich) 403 F Supp 917.*

Medicaid Act is given liberal construction and exclusions from coverage for custodial care are to be narrowly interpreted; custodial care is kind of care which does not rise to level of care constituting inpatient hospital services or extended care services, even if such care occurs in hospital; custodial care has no significant relationship to medical care of any type and can be administered by laymen. *Monmouth Medical Center v Harris (1980, DC NJ) 494 F Supp 590,* affd (1981, CA3 NJ) *646 F2d 74.*

"Three hour rule" (rehabilitative hospital patient's need for and receipt of at least 3 hours of physical and/or occupational therapy per day is major factor in determining whether patient's stay in hospital is covered by Medicare) is intended as screening criterion only and does not create irrebuttable presumption of noncoverage for patient who does not require or cannot tolerate such therapy every day, but who nonetheless needs to be treated in such rehabilitative setting. Hooper v Sullivan (1989, DC Conn) CCH Medicare & Medicaid Guide P 37985.

13. Consideration of totality of condition, generally

In determining whether care being received by recipient of Medicaid came under exception of "custodial care" there must be consideration of patient's condition as whole, not merely consideration of course of treatment administered. *Ridgely v Secretary of HEW (1972, DC Md) 345 F Supp 983,* affd (1973, CA4 Md) *475 F2d 1222.*

It would have been impossible to conclude that treatment received by plaintiff, a victim of strokes and heart attacks, who also suffered from arthritis and many other ailments, was "custodial" under *42 USCS § 1395y*, had Secretary of HEW [now HHS] considered overall medical history of plaintiff. *Schoultz v Weinberger (1974, ED Wis) 375 F Supp 929.*

Care received by person admitted to skilled nursing facility does not come within exclusion for custodial care where, although taken singly patient's ailments might not seem to require skilled nursing care, taken together they make patient chronically ill, disabled person in need of monitoring and care by skilled personnel in order to maintain what health patient has left and to prevent any further injury. *Kuebler v Secretary of United States Dep't of Health & Human Services (1984, ED NY) 579 F Supp 1436.*

Complete nature of nursing home patient's condition was consistent with ALJ's finding that services provided to patient were custodial in nature, and therefore not covered by Medicare, where patient was transferred to nursing home following hospitalization for pain and swelling of left knee, received physical therapy twice/week, required assistance in activities of daily living, was placed on medication for anxiety and pain, and did not require constant monitoring of medication. *Aurora v Secretary of United States Dep't of Health & Human Services (1989, ED NY) 715 F Supp 466.*

14. --Deteriorated condition

Finding that only supportive care is necessary, in contradistinction to professional supervision, will be reversed in view of patient's debilitated condition. *Ridgely v Secretary of Dep't of Health, Education & Welfare (1973, CA4 Md) 475 F2d 1222.*

Treatment given to decedent in nursing home which was necessary to help her deteriorating physical condition was not "custodial care." *Sowell v Richardson (1970, DC SC) 319 F Supp 689.*

Secretary failed to apply proper legal standards in considering claim for in-patient hospital services in finding that services rendered to claimant were "primarily supportive in nature" was not supported by substantial evidence where no consideration was given to petitioner's acutely debilitated condition on admission and necessity that petitioner have attention of skilled medical personnel attending her on daily basis to administer treatment. *Westgard v Weinberger (1975, DC ND) 391 F Supp 1011.*

15. Hospital vs. lesser care facility, generally

In view of clear and plain language of *42 USCS § 1395y(a)(1)* excluding from coverage only those services that are not reasonable and necessary to treatment or diagnosis of patient's ailments, construction of *42 USCS § 1395y(a)(1)* by Secretary of HEW [now HHS] to mean that services that are admittedly reasonable and necessary for treatment and diagnosis of patient's ailments are nonetheless excluded from coverage if Secretary determines that it was not reasonable and necessary to render those services in hospital as opposed to lesser care facility could not be sustained. *Hultzman v Weinberger (1974, CA3 Pa) 495 F2d 1276.*

Medicare does not cover costs for services rendered in acute care facility when, despite patient's need for continued reimbursable medical services, attending physician and hospital's utilization review committee both certified that skilled nursing facility could provide required services. *Lerum v Heckler (1985, CA7 Ill) 774 F2d 210.*

Exclusions for expenses which are not reasonable and necessary for diagnosis or treatment of illness or injury or to improve functioning of malformed body member does not exclude coverage for such services merely because those services could have been provided in a lesser care facility, care provided in lesser care facility is not synonymous with "custodial care" as used in *42 USCS § 1395y*, but may also be subject to Medicare coverage under *42 USCS § 1395d(a)(2)*. *Torphy v Weinberger (1974, ED Wis) 384 F Supp 1117.*

16. --Nursing home

Where 89-year old woman suffered broken hip, was taken to hospital where she remained for nine days and then, because she refused surgical treatment on religious grounds, was transferred to geriatrics center, care she received at center is not "custodial care" within meaning of *42 USCS § 1395y(a)(9)*, and she is therefore entitled to post-hospital extended care insurance benefits under *42 USCS § 1395x(h)*. *Reading v Richardson (1972, ED Mo) 339 F Supp 295.*

88-year-old woman who, after having been treated in hospital for 18 days for arteriosclerotic heart disease with congestive failure and degenerative arthritis, was removed to nursing home to make hospital space available for acutely ill patient, and who received essentially same treatment in nursing home, her physicians agreeing that she continued to require skilled nursing, care did not come within custodial care exclusion despite lack of daily nursing entries at nursing home; Appeals Council took improperly broad view of custodial care exception where it included all care which need not necessarily be administered by trained medical personnel. *Harris v Richardson (1973, ED Va) 357 F Supp 242.*

70-year-old Medicare claimant who was confined to nursing home after surgery for cancer of bladder received "skilled nursing care" and not custodial care, and thereby qualified for reimbursement for expenses under Medicare Act. *Allen v Richardson (1973, ED Mich) 366 F Supp 516.*

Skilled nursing home facilities were entitled only to Medicare reimbursement for routine maintenance services, under *42 USCS § 1395y(a)(1)* and its regulations and interpretative manuals, where facilities failed to establish that physical therapy met criteria for separate reimbursement as auxiliary cost. *Brae Loch Manor Health Care Facility v Thompson (2003, WD NY) 287 F Supp 2d 191,* affd (2004, CA2 NY) *102 Fed Appx 221.*

17. Miscellaneous

Hospital's use of antipsychotic drugs and physical restraints in response to patient's episodes of agitation, confusion, and wandering constituted skilled, not custodial, services where complete nature of patient's condition was such as to require close observation and monitoring of patient's acute psychological symptoms, and drugs and restraints were used as coordinated responses to particular episodes of agitated behavior, not as part of prescribed routine. *Hurley v Bowen (1988, CA2 NY) 857 F2d 907.*

A 73-year-old petitioner who suffered from broken arm, obesity, and other infirmities associated with old age, whose physician decided that she required hospital care in order to mend properly received medical care rather than "custodial care" and was eligible for benefits for such care under Social Security Act. *Samuels v Weinberger (1973, SD Ohio) 379 F Supp 120.*

Finding that care was merely custodial (*42 USCS § 1395y*) was not supported by substantial evidence, where patient, in addition to other medical needs, was hospitalized for primary purpose of continuing intensive physical therapy program with goal of becoming ambulatory; such treatments are within definition of "skilled nursing care". *Whitman v Weinberger (1974, ED Va) 382 F Supp 256.*

Secretary's decision, that payment not be made to petitioner for in-patient hospital expenses incurred as result of dizziness, hypertension, subsequent fall and broken bones, was not supported by substantial evidence where record showed necessity for continuous observation by skilled medical personnel to determine possibilities of nervous system diseases which may have caused fall. *Sheeran v Weinberger (1975, SD Ohio) 392 F Supp 106.*

Services received by 95-year-old claimant in skilled nursing facility could be found not to be at skilled level of care for purposes of Medicare reimbursement where vast majority of services provided to claimant were custodial in nature, and although claimant participated in physical therapy program, there was no evidence that such care could

not be administered by health provider visiting claimant at home. Perales v Bowen (1989, ED NY) CCH Medicare & Medicaid Guide P 37667, No. CV-86-2132.

Medicare claimant's terminal condition was not basis for finding that claimant did not require or receive skilled nursing care where claimant's condition required regular monitoring and intervention from date on which claimant was discharged from hospital until date of claimant's death. *Stearns v Sullivan (1989, DC Mass) 1989 US Dist LEXIS 14185.*

Although Medicare beneficiary, who was hospitalized on May 6, 1986, for liver cancer, needed great deal of support and supervision that neither she nor her husband could handle themselves, care she received in hospital after May 13, 1986, did not rise to skilled level of inpatient hospital care for purposes of Medicare coverage and was therefore excludible custodial care; after May 13, 1986, care afforded to beneficiary could only be described as custodial in that it consisted of assistance in getting in and out of bed, routine administering of medications, frequent positioning in bed when she was no longer able to do this for herself, and general care of Foley catheter; moreover, her treating physician stated that she required only custodial care after May 13, 1986, although her husband refused to have her moved from hospital. Harris v Secretary of HHS (1990, ND NY) Medicare & Medicaid Guide P 38830.

Assistance in improving ambulation and bowel and bladder training provided to nursing home patient do not constitute skilled care for purpose of entitlement to Medicare benefits where ambulatory therapy is prescribed to increase patient's walking range and strength, not to teach patient to walk, and is overseen by physical therapy aide, not by or under the supervision of trained physical therapist, and bowel and bladder training consists of providing periodic use of a bed pan and assisting patient to toilet as patient's strength and mobility increases. *Bryan v United States Secretary of HHS (1990, ED NC) 758 F Supp 1092.*

Because conclusion of defendant Secretary of U.S. Department of Health and Human Services that Medicare claimant could not reasonably have been expected to reach higher level of function from further skilled therapy, was in direct conflict with evidence that her physical capacity had improved subsequent to her stay at skilled nursing facility, it was appropriate to remand with instructions to award her benefits; only possible conclusion that could have been reached was that claimant would have benefited from continued skilled nursing care during relevant time because she had not reached her peak functional capacity. *Papciak v Sebelius (2010, WD Pa) 742 F Supp 2d 765.*

III. PRACTICE AND PROCEDURE

18. Generally

42 USCS § 1395y(b)(3)(A) does not create qui tam action, but rather merely enables private party to bring action to recover from private insurer only where that private party has itself suffered injury because primary plan has failed to make required payment to or on its behalf. *Woods v Empire Health Choice, Inc. (2009, CA2 NY) 574 F3d 92.*

Secretary acted arbitrarily and capriciously in promulgating secondary payment regulations implementing *42 USCS § 1395y(b)(2)(A)*, under which employer group health plans are primary payer of benefits for patient's initial 12 months of eligibility for End-Stage Renal Disease program benefits, and under which intermediary or carrier is to pay conditional primary benefits only if it knows from experience or ascertains that employer plan's payments are substantially less prompt than Medicare's, since statute expressly directs Secretary not to pay program benefits to extent that she determines that employer plan payments will be as prompt as Medicare payments. *National Asso. of Patients on Hemodialysis & Transplantation, Inc. v Heckler (1984, DC Dist Col) 588 F Supp 1108.*

19. Notice

Denial of Medicare coverage for beneficiary's stay in hospital was in error where hospital failed to comply with requirement of 42 CFR § 405.334(b) that written notice be given to or on behalf of Medicare beneficiary informing

beneficiary or someone acting on beneficiary's behalf that stay in hospital was excluded from Medicare coverage, where hospital gave no notice to beneficiary herself because she was acknowledged by hospital to be mentally incompetent; written notice given to patient's son did not suffice because hospital was aware that son was severe schizophrenic, and was therefore incompetent himself; and telephone notice given to friend of beneficiary who was in process of being officially appointed as beneficiary's conservator was inadequate because no written follow-up notice was given, as required by Intermediary Manual § 3440.1. Carpenter v Secretary of Health & Human Services (1990, DC Conn) CCH Medicare & Medicaid Guide P 38621.

Remand was ordered where ALJ's determination of amount of reimbursement required under Medicare's secondary payer provisions, *42 USCS § 1395y(b)(A)(B)(i)* and (ii), was not supported by substantial evidence under *42 USCS § 405(g)* and where ALJ erred as matter of law in placing ultimate burden of proof on plaintiff to prove that items for which Secretary sought reimbursement were unrelated to Medicare covered injuries plaintiff sustained in slip and fall accident. *Estate of Urso v Thompson (2004, DC Conn) 309 F Supp 2d 253.*

20. Decision by Secretary

Decision of secretary that decedent, who had suffered broken hip, needed only custodial care was not supported by substantial evidence where careful review of record disclosed that secretary's determination was based solely on records of extended care facility, and court found that hearing examiner had been unduly selective in his reliance upon only those portions of facility's records dealing with treatment of decedent and disregarded other portions which indicated that her condition was such that more than custodial care was required. *Ridgely v Secretary of Dep't of Health, Education & Welfare (1973, CA4 Md) 475 F2d 1222.*

Congress delegated broad authority under *42 USCS § 1395ff* to Secretary of Health and Human Services to determine when durable medical device was reasonable and necessary under *42 USCS § 1395y*, and broad authority to select procedures used for making that determination and decisions of local Medicare contractors could not deprive her of that discretion. *Almy v Sebelius (2012, CA4 Md) 679 F3d 297, 56 BCD 100.*

Because plaintiff medical device supplier's studies were authored or sponsored by manufacturer, studies' objectivity was questionable, and, studies on regenerating cartilage were not conducted on humans; thus, Medicare Appeals Council's finding that studies failed to show device was "reasonable and necessary" under *42 USCS § 1395y(a)(1)(A)* was not arbitrary, capricious, or unsupported by substantial evidence under *5 USCS § 706*, *42 USCS § 405(g)*. *Int'l Rehabilitative Scis., Inc. v Sebelius (2012, CA9 Wash) 688 F3d 994.*

Secretary's interpretation of secondary payer provisions was reasonable where there was no statutory basis to distinguish between entities that received payment from primary plan and end-point recipients and 2003 amendments indicated Congress intended broad construction of "entity that received payment from primary plan." *Haro v Sebelius (2014, CA9 Ariz) 747 F3d 1099.*

Failure of utilization review committee to timely review case or promptly to notify claimant of its finding that further inpatient hospital services are not medically necessary will not defeat or preclude determination by Secretary, based on all pertinent evidence, that services received by claimant were custodial and thus excluded from coverage under *42 USCS § 1395y(a)(9)*. SSR 71-37 (1971).

Unpublished Opinions

Unpublished: Claims that Department of Health and Human Services (DHHS) was not entitled to reimbursement from settlement proceeds was properly dismissed under *28 USCS § 1331* or *1346* because claim required interpretation of *42 USCS § 1395y(b)(2)* and was not subject to judicial review under *42 USCS § 405(g)* until final decision by DHHS secretary even where claimant did not seek Medicare benefits; *5 USCS §§ 701(a)* and *704* did not provide basis for jurisdiction until claim had gone through agency process, which was not futile even though DHHS had previously found that it was entitled to reimbursement for Medicare benefits paid on behalf of claimants who later obtained tort settlements. *Johnson v United States HHS (2005, CA5 Miss) 142 Fed Appx 803.*

21. Suspension of reimbursement

Complaint affirmatively and explicitly denying that Secretary of HEW [now HHS] was authorized by *42 USCS § 1395g* to suspend Medicare payments to provider of services for purpose of recouping allegedly erroneous payments made prior to effective date of 1972 amendments to *42 USCS § 1320c*, and citing *42 USCS § 1395y(a)(1)* as imposing contrary duty, sufficiently invokes officer suit exception to doctrine of sovereign immunity to demand inquiry into merits. *Mt. Sinai Hospital, Inc. v Weinberger (1974, SD Fla) 376 F Supp 1099,* revd on other grounds (1975, CA5 Fla) *517 F2d 329,* mod and reh den (1975, CA5 Fla) *522 F2d 179,* cert den *(1976) 425 US 935, 48 L Ed 2d 176, 96 S Ct 1665.*

Medicare equipment supplier to whom reimbursement had been suspended on grounds that supplier had presented false claims was entitled to administrative hearing on charges where court concluded that provisions of *42 USCS § 1395y* were not intended to operate to deny supplier post-termination hearing for over two years during which time supplier was placed in limbo awaiting Secretary's determination of amount alleged to have been overpaid. *Eisenberg v Mathews (1976, ED Pa) 420 F Supp 1274.*

Physician whose Medicare payments were suspended was not entitled to administrative hearing prior to suspension under former *42 USCS § 1395y(d)(3)*, where payments were not suspended pursuant to § 1395y(d)(1), and Secretary has made no such determination in physician's case and has not suspended him from future participation in program. *Krebsbach v Heckler (1985, DC Neb) 617 F Supp 548* (superseded by statute as stated in *Diagnostic Cardioline Monitoring of N.Y., Inc. v Shalala (2000, ED NY) 2000 US Dist LEXIS 13443).*

22. Judicial review

Courts have jurisdiction to review construction secretary chooses to give to statutory term; review is limited to insuring that secretary did not exceed statutory authority and that regulation is not arbitrary, capricious, or abuse of discretion under *5 USCS § 706*. *Holy Cross Hospital-Mission Hills v Heckler (1984, CA9 Cal) 749 F2d 1340.*

District Court does not have jurisdiction under *42 USCS § 1395y(b)* over action by Medicare provider whose payments were suspended for alleged fraud or misrepresentation in cost reports, based upon allegations of provider that it was denied due process by failure of Secretary to issue regulations providing for hearing in case of suspension for fraud or willful misrepresentation and also in denying provider post-suspension hearing, since provider voluntarily left Medicare program in 1977 and its payments were suspended in 1979. *Homewood Professional Care Center, Ltd. v Heckler (1985, CA7 Ill) 764 F2d 1242.*

Doctor's allegations of deprivation of liberty by suspension of reimbursement sought to be preliminarily enjoined were sufficiently colorable to confer jurisdiction, despite lack of exhaustion of administrative remedies, but pre-termination evidentiary hearing was not required. *Koerpel v Heckler (1986, CA10 Utah) 797 F2d 858.*

District court erred in concluding that it had federal question jurisdiction under *28 USCS § 1331* over class action complaint, which sought to enjoin Government from obtaining Medicare reimbursement pursuant to *42 USCS § 1395y(b)(2)(B)(i)* from settlement trust established in products liability action that arose from defective orthopedic bone screws; claim that Government was not entitled to reimbursement from settlement trust fund was "claim arising under" Medicare Act, *42 USCS §§ 1395-1395zz*, and therefore *42 USCS § 405(h)*, part of Social Security Act, made applicable to Medicare Act by *42 USCS § 1395ii*, precluded district court from having federal question jurisdiction over class action complaint. *Fanning v United States (2003, CA3 Pa) 346 F3d 386,* cert den (2004, US) *159 L Ed 2d 776, 124 S Ct 2872.*

Because doctors could submit claims for athletic trainers' services as incident to physician's professional service under *42 USCS § 1395x(s)(1)*, (2), disclose they were not Medicare benefit under *42 USCS §§ 1395x(p)*,

1395y(a)(20), and appeal denial, exception to *42 USCS § 405(h)* did not apply, and dismissal of plaintiff athletic trainers' association's claim challenging defendant Secretary of Department of Health and Human Services' new Medicare Part B rule, *69 Fed. Reg. 66,236, 66,352* (Nov. 15, 2004), for lack of subject matter jurisdiction was affirmed. *Nat'l Ath. Trainers' Ass'n v United States HHS (2006, CA5 Tex) 455 F3d 500.*

Where doctors and patients, pursuant to *28 USCS § 1331*, challenged administrative regulation implementing *42 USCS § 1395y(a)(20)* that limited Medicare Part B, *42 USCS § 1395j*, reimbursement for physical therapy services provided "incident-to" physician's professional service as set out in *42 USCS § 1395x(s)(2)(A)*, their suit was properly dismissed pursuant to *42 USCS §§ 1395ii*, *405(h)* because they had not exhausted administrative remedies pursuant to *42 USCS §§ 1395ff(b)(a)(A)*, *405(h)*; review was not being precluded-merely postponed-until claim was denied. *Puerto Rican Ass'n of Physical Med. & Rehab., Inc. v United States (2008, CA1 Puerto Rico) 521 F3d 46.*

Court of appeals reviews de novo district court's interpretation of working aged provision of statute (*42 USCS § 1395y(b)(1)(A)(i)*), because such is question of law over which appellate court's review is plenary. *New York Life Ins. Co. v United States (1999, CA FC) 190 F3d 1372, 64 Soc Sec Rep Serv 1, 24 EBC 1329,* CCH Unemployment Ins Rep P 16321B.

Reference in *42 USCS § 1395ff(b)(1)(A)*, affording judicial review to application dissatisfied over Secretary's determination of eligibility under "conditions of § 426," is to subd (a) of *42 USCS § 426*, setting two criteria for eligibility for disability benefits not contested herein, and not to subd (c) thereof, alluding to "limitations of Part A [*42 USCS §§ 1395c*-*1395i-2*]"; finding that hospital care is "custodial," and therefore excluded from Medicare coverage by *42 USCS § 1395y(a)(9)*, is not subject to judicial review under § 1395ff(b)(1)(A), nor is judicial review available under the Administrative Procedure Act where jurisdictional amount of *42 USCS § 1395ff(b)(1)(C)* is not met; moreover, jurisdiction does not lie under the Mandamus and Venue Act of 1962 absent showing that Secretary has breached any clear duty owing to plaintiff. *Giove v Weinberger (1974, DC Md) 380 F Supp 364.*

Court's review of Secretary's denial of Medicare benefits for skilled nursing facility care is not limited to substantial evidence standard, but extends to review of Secretary's interpretation of law; correct legal standard for determining Medicare coverage is consideration of patient's condition as whole; where there is no directly conflicting evidence, treating physician's opinion must be given great weight. *Kuebler v Secretary of United States Dep't of Health & Human Services (1984, ED NY) 579 F Supp 1436.*

Estate of deceased Medicare beneficiary has no standing to appeal denial of Medicare decision excluding coverage of home health care services provided to beneficiary as "custodial" services where decision also states that beneficiary is not liable for cost of services and that liability for costs falls solely on supplier of services. Lake v Secretary of Health and Human Services (1989, DC NH) CCH Medicare and Medicaid Guide P 38348.

Court lacked subject matter jurisdiction over plaintiff's action against Secretary of Health and Human Services in which plaintiff, on behalf of patient, alleged that Secretary violated Due Process Clause of Fifth Amendment when he invoked Medicare Secondary Payer Act (MSPA), *42 USCS § 1395y*, to seek and obtain reimbursement from patient for certain Medicare payments that Secretary had made on patient's behalf because *28 USCS § 1331* jurisdiction was precluded by *42 USCS § 405(h)* and *42 USCS § 1395ii* where action arose under Medicare Act, and plaintiff failed to exhaust administrative remedies before filing action; because plaintiff was challenging constitutionality of Secretary's actions and not MSPA itself, plaintiff had to exhaust administrative remedies before filing suit. *Maresh v Thompson (2003, ND Tex) 290 F Supp 2d 737,* affd (2004, CA5 Tex) *114 Fed Appx 152.*

Allegations, that insurer was aware of applicable regulations regarding primary/secondary payment and knew that it was not accurately processing claims under Medicare Secondary Payer Statute, *42 USCS § 1395y(b)(2)(B)(ii)*, and that insurer actually obtained information relevant to making accurate decisions but ignored it, were sufficient to meet knowledge element of prima facie case under *31 USCS § 3729(a)(1)* for purposes of avoiding dismissal under *Fed. R. Civ. P. 12(b)(6)*. *United States ex rel. Drescher v Highmark, Inc. (2004, ED Pa) 305 F Supp 2d 451.*

Remand was ordered concerning ALJ's denial of deceased's request for waiver under *42 USCS § 1395y(b)(2)* because reviewing court found no indication that ALJ considered fact that, had Secretary made determination of deceased's waiver request while she was living, she undoubtedly would have been entitled to waiver. *Estate of Urso v Thompson (2004, DC Conn) 309 F Supp 2d 253.*

Where healthcare provider's multiple myeloma treatment involved high and potentially lethal dose of chemotherapy to treat cancer, and subsequent stem cell transplant to ameliorate harsh effects of chemotherapy, denial of Medicare coverage for transplantation was properly denied, but chemotherapy was reasonable and necessary treatment for multiple myeloma and thus denial of coverage for chemotherapy was abuse of discretion and not supported by substantial evidence. *Bd. of Trs. v Sec'y of HHS (2005, ED Ark) 354 F Supp 2d 924.*

U.S. Department of Health and Human Services was granted summary judgment in suit challenging denial of Medicare coverage for medical device of bankruptcy debtor because Secretary's final decisions in eight cases that device was not reasonable and necessary were supported by substantial evidence and were not arbitrary or capricious. *Almy v Sebelius (2010, DC Md) 749 F Supp 2d 315.*

Secretary of Health and Human Services (HHS) was entitled to *Fed. R. Civ. P. 12(b)(1)* dismissal of Medicare beneficiary's action seeking declaration requiring HHS to pay medical bills arising from motor vehicle accident, under *42 USCS § 1395y(b)*; beneficiary had not initiated--let alone exhausted--his administrative remedies as required under *42 USCS §§ 405(g)*, (h) and 1395ff(b)(1)(A). *Wright v Sebelius (2011, DC Neb) 818 F Supp 2d 1153.*

In case dealing with plaintiff's obligation to reimburse federal Medicare program for its payments of her medical expenses related to injuries that she sustained during trip-and-fall accident, because plaintiff's due process claim arose under Medicare Act, defendants' motion to dismiss that claim for lack of jurisdiction was granted as she failed to administratively exhaust that claim. *Taransky v Sebelius (2013, DC NJ) 956 F Supp 2d 563.*

Unpublished Opinions

Unpublished: Employee's appeal from dismissal of his action alleging that his employer, its insurance carrier, and United States Department of Health and Human Services (HHS), violated *42 USCS § 1395y* was dismissed as moot because employee obtained all relief he sought as he received assurance from United States Department of Health and Human Services that amount set aside from his workers' compensation settlement was sufficient to cover future injury-related medical expenses and he received replacement check from his employer and its insurer. *Coryell v Liberty Mut. Ins. Co. (2009, CA7 Ill) 2009 US App LEXIS 10364.*

23. Miscellaneous

Employees of HFCA, regional and statewide peer review groups, and two state officials involved in excluding doctor from eligibility for Medicare payments for 10 years, which exclusion was later reversed for procedural and substantive errors, were absolutely immune from common-law tort and constitutional law claims by doctor. *Kwoun v Southeast Missouri Professional Standards Review Organization (1987, CA8 Mo) 811 F2d 401,* cert den *(1988) 486 US 1022, 100 L Ed 2d 226, 108 S Ct 1994,* reh den *(1988) 488 US 880, 102 L Ed 2d 169, 109 S Ct 200.*

Pharmaceutical company does not have standing to challenge Medicare drug reimbursement policy. *TAP Pharms. v United States HHS (1998, CA4 SC) 163 F3d 199, 59* Soc Sec Rep Serv 532.

Six-year statute of limitations applicable to private rights of action under False Claims Act (*31 USCS § 3731(b)(1)*) should be applied to private rights of action under Medicare Secondary Payer Act (*42 USCS § 1395y(b)*). *Manning v Utils. Mut. Ins. Co. (2001, CA2 NY) 254 F3d 387.*

Because neither attorney nor insured individual received monies from entity that distributed funds under "primary plan," but instead received monies from manufacturer, who did not act under primary self-insurance plan, in

connection with individual's action for personal injury damages, neither attorney nor individual could be required to reimburse government under Medicare Secondary Provider statute, *42 USCS § 1395y(b)*; thus, trial court properly dismissed claims against manufacturer pursuant to *Fed. R. Civ. P. 12(b)(6)* and granted attorney and individual summary judgment under *Fed. R. Civ. P. 56*. *Thompson v Goetzmann (2003, CA5 Tex) 337 F3d 489.*

Where Medicare benefits recipient obtained settlement in medical malpractice action after she received reimbursement from Secretary of Department of Health and Human Services for same services, Secretary was entitled to reimbursement of such payments from recipient's settlement because, under clear language of Medicare Secondary Payer Provisions (MSP), *42 USCS § 1395y(b)(2)*, as amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), *Pub. L. No. 108-173*, § 301, *117 Stat. 2066*, 2221 (2003), such reimbursement was required; MMA did not constitute substantive change in law, but merely clarified existing law, and recipient's settlement was funded from self-insured plan that satisfied definition of primary plan under *MSP. Brown v Thompson (2004, CA4 Va) 374 F3d 253.*

Plaintiffs failed to state private cause of action under Medicare Secondary Payer statute, *42 USCS § 1395y(b)(3)*, because they alleged cigarette manufacturers' responsibility for payment of Medicare beneficiaries' medical costs for smoking related diseases but allegations had not been proven or taken to judgment in order for responsibility to be "demonstrated," condition precedent for such private cause of action. *Glover v Liggett Group, Inc. (2006, CA11 Fla) 459 F3d 1304, 19 FLW Fed C 974.*

Nonprofit taxpayer advocacy group lacked U.S. Const. art. III standing to file private cause of action pursuant to Medicare Secondary Payer Statute (MSP), *42 USCS § 1395y(b)(3)(A)*, to force tobacco companies to reimburse Medicare expenditures on smoking-related illnesses as there was no Congressional intent to create qui tam action in MSP and none of its members were beneficiaries who had so suffered. Unlike False Claims Act (FCA), *31 USCS §§ 3729* et seq., in which qui tam action had been explicitly created, MSP, which was created in same month, differed; moreover, also unlike FCA, MSP did not contemplate that plaintiff share with Government in any monetary judgment, and it failed to include any of procedural mechanisms typical of qui tam statutes, which were predicated on recognition that Government was "real party in interest" in any qui tam prosecution. *United Seniors Ass'n v Philip Morris USA (2007, CA1 Mass) 500 F3d 19.*

Medicare Secondary Payer Statute's private right of action, *42 USCS § 1395y(b)(3)(A)*, provision does not transform MSP into qui tam statute; therefore because MSP was not qui tam statute, private attorney general did not have U.S. Const. art. III standing to assert his claims. *Stalley v Methodist Healthcare (2008, CA6 Tenn) 517 F3d 911, 2008 FED App 97P.*

Because Medicare Secondary Payer Act, *42 USCS § 1395y(b)(3)(A)*, was not qui tam statute, dismissal of plaintiff relator's action was affirmed, but remand for dismissal without prejudice was required for lack of U.S. Const. art. III, § 2, standing since he did not allege he was treated by defendant health care provider or allege he was injured by provider, and thus, court had lacked subject matter jurisdiction. *Stalley v Orlando Reg'l Healthcare Sys. (2008, CA11 Fla) 524 F3d 1229, 21 FLW Fed C 588.*

US Court of Appeals for Eleventh Circuit rejects contention that Medicare Secondary Payer Act, *42 USCS § 1395y(b)(3)(A)*, is qui tam statute. *Stalley v Orlando Reg'l Healthcare Sys. (2008, CA11 Fla) 524 F3d 1229, 21 FLW Fed C 588.*

Secretary of Department of Health and Human Services was properly granted summary judgment in appellants' declaratory judgment action, in which appellants argued that Missouri wrongful death statute did not provide for recovery of medical expenses, and therefore, they had no duty to reimburse Medicare, because settlement in appellants' wrongful death action under *Mo. Rev. Stat. § 537.080* resolved their claim for medical expenses for their decedent under *Mo. Rev. Stat. § 537.090*, so Medicare had right to reimbursement under *42 USCS § 1395y*. *Mathis v Leavitt (2009, CA8 Mo) 554 F3d 731.*

Because *42 USCS § 1395y(b)(3)(A)* did not create qui tam action and because plaintiff, resident of New York, did not suffer particularized injury from insurer's failure to make payments on behalf of other individuals, plaintiff lacked standing to bring action under § 1395y(b)(3)(A) to recover amounts paid from Medicare funds for which insurer was primarily responsible. *Woods v Empire Health Choice, Inc. (2009, CA2 NY) 574 F3d 92.*

Only decedent's estate's allocated share of settlement proceeds was subject to province of Secretary of Department of Health and Human Services because settlement involved medical expenses and costs recovered by estate (and subject to Medicare Secondary Payer statute), along with plaintiffs' non-medical, tort property claims for lost parental companionship under state law (and not subject to Medicare Secondary Payer statute); under Florida Wrongful Death Act any claim of estate was separate and distinct from claim of survivor; plaintiffs' loss of parental companionship claims did not include decedent's medical expenses, as claim for medical expenses belonged only to estate. *Bradley v Sebelius (2010, CA11 Fla) 621 F3d 1330, 22 FLW Fed C 1463.*

Secretary of Department of Health and Human Services' ipse dixit contained in field manual did not control law. *Bradley v Sebelius (2010, CA11 Fla) 621 F3d 1330, 22 FLW Fed C 1463.*

In case in which individual, law firm, and attorney appealed district court's imposition of more than $ 276,000.00 in sanctions, legal conclusion that *42 USCS § 1395y(b)* was qui tam statute had no legal foundation, and they were on notice of frivolous nature of individual's multiple filings from inception of filings. *Stalley v Mt. States Health Alliance (2011, CA6 Tenn) 644 F3d 349, 2011 FED App 182P.*

Secretary of Health and Human Services' interpretation of secondary payer provisions, *42 USCS § 1395y(b)(2)(B)(ii)* and (iii), i.e., that attorneys who received settlement proceeds had to reimburse Medicare before disbursing those proceeds to their clients, was reasonable and consistent with general purpose of secondary payer provisions. *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

District court lacked subject matter jurisdiction over Medicare beneficiaries' claims challenging Secretary of Health and Human Services' practice of demanding up front reimbursement for secondary payments from beneficiaries who appealed reimbursement determination or sought waiver of reimbursement obligation because federal question jurisdiction was precluded, and jurisdictional presentment requirement was not met as beneficiaries' claim had not been presented to agency. *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

District court had subject matter jurisdiction over claim of Medicare beneficiary's attorney that Secretary of Health and Human Services' practice of demanding that attorneys withhold settlement proceeds from beneficiary-clients until Medicare was reimbursed was inconsistent with secondary-payer provisions because attorney's claim was excepted from channeling requirement, and district court had federal question jurisdiction to adjudicate his claim. *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

Medicare beneficiary had U.S. Const. art. III standing on behalf of class to challenge Secretary of Health and Human Services' practice of demanding up front reimbursement for secondary payments from beneficiaries who appealed reimbursement determination or sought waiver of reimbursement obligation as she was direct object of Secretary's collection practice, she had suffered fiscal injury that was directly traceable to Secretary, and properly framed injunction would have redressed her injury *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

Expiration of named Medicare beneficiary's personal stake in injunctive relief did not moot class beneficiaries' claim seeking to enjoin Secretary of Health and Human Services' practice of demanding up front reimbursement for secondary payments from beneficiaries who appealed reimbursement determination or sought waiver of

reimbursement obligation *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

Medicare beneficiary's attorney had U.S. Const. art. III standing to raise his claim that Secretary of Health and Human Services' practice of demanding that attorneys withhold settlement proceeds from beneficiary-clients until Medicare was reimbursed was inconsistent with secondary payer provision because regulation subjected attorney to individual liability *Haro v Sebelius (2013, CA9 Ariz) 729 F3d 993, 78 Cal Comp Cases 956,* amd, reh den, reh, en banc, den (2014, CA9 Ariz) *2014 US App LEXIS 60* and reprinted as amd (2014, CA9 Ariz) *2014 US App LEXIS 61.*

Medicare Advantage Organization (MAO) could bring its claim against insurer regarding its obligation to reimburse MAO for Medicare benefits that MAO paid on behalf of insurer's Medicare Advantage plan enrollee because Medicare Secondary Payer Act private cause of action, permitted MAO to sue primary plan that failed to reimburse MAO's secondary payment. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

District court correctly ordered insurer to reimburse Medicare Advantage Organization for double amount to which it was otherwise entitled; double damages are required by statute, and unlike Government's cause of action, private cause of action uses mandatory language "shall" to describe damages amount. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

District court properly granted Medicare Advantage Organization (MAO) summary judgment in its action against insurer to recover damages for its failure to reimburse MAO for Medicare benefits it paid on behalf of insurer's Medicare Advantage plan enrollee because insurer was primary plan since it was liability insurer that paid enrollee for covered medical expenses, it had constructive knowledge of MAO's Medicare payment, and it failed to provide reimbursement. *Humana Med. Plan, Inc. v Western Heritage Ins. Co. (2016, CA11 Fla) 832 F3d 1229, 26 FLW Fed C 591.*

Where 67-year-old woman was admitted to hospital for sprained right ankle and remained in hospital nearly 2 months on advice of her attending physician, only to learn some 4 months after she left hospital that hospital's utilization review committee considered her last 25 days in hospital to be custodial care and not reimbursable under 42 USCS § 1375y, Social Security Administration could deny woman reimbursement, even though its own regulations were not followed, since effect of hospital's failure to provide timely review is not to make nonreimbursable expenses reimbursable, but to preclude or limit hospital from participating as provider of services under Act. *Low v Richardson (1973, ND Ill) 360 F Supp 499.*

United States, in case involving individual who had received Medicare benefits following automobile accident, and who had brought state court action for negligence and settled for $ 25,000.00, was entitled to reimbursement of $ 15,066.68 for conditional Medicare payments under *42 USCS § 1395y(b)(2)* from settlement proceeds, despite fact that default judgment had been entered against two state fiscal intermediaries named as nominal defendants in state action, because intermediaries were private entities, not federal agencies, and neither United States nor any of its federal agencies or officers had been named in state action; furthermore, government is not equitably estopped from pursuing its Medicare lien, based on defendant's claim that despite government's actual notice of state action, it did nothing, because neither government, its officers nor its agencies were named as nominal defendants in state action, and defendant did not notify government of default of named nominal defendants or subsequent entry of judgment in state action until some time after judgment had been entered. United States of America v Henry L. Sosnowski, et al. (1993, WD Wisc) 3 MMLR P 185.

For purpose of *42 USCS § 1395y(b)(1)*, which provides for Medicare's secondary payer status relative to beneficiaries who are working aged, disabled active individuals and individuals with end stage renal disease, who are covered by designated group health plans, disabled individual is "active" when he or she is participating spouse of active employee covered by large group health plan, such that spouse's health plan would be primary payer relative to Medicare; a disabled individual is also "active" when he can be classified as employee and participates in

his employer's group health plan; however, when disabled individual is retiree, his former employer's health plan is not primary payer relative to Medicare, since Congress did not intend to include retired individuals in category of "active" individuals Perry v Metropolitan Life Insurance Company, et al. (1994, MD Tenn) CCH Medicare & Medicaid Guide P 42774.

Reimbursement may be had with regard to any conditional payments made for services Medicare covered regardless of whether payment is made to estate or to heirs of recipient, because *42 USCS § 1395y(b)(2)* does not differentiate as to recipient of payment, and *42 CFR § 411.24(g)* provides that reimbursement may be had from any entity; consequently, fact that under state law, settlement proceeds from wrongful death claim are property of recipient's heirs, rather than his estate, does not bar reimbursement; furthermore, fact that state law places limit on amount that creditors of estate can reach in wrongful death recovery, does not limit Medicare reimbursement, since any such state law is preempted by federal law. *Cox v Shalala (1995, MD NC) 1995 US Dist LEXIS 10817,* affd (1997, CA4 NC) *112 F3d 151, 53* Soc Sec Rep Serv 190 (criticized in *In re Dow Corning Corp. (2000, BC ED Mich) 250 BR 298, 55 Fed Rules Evid Serv 118).*

Evidence of medical bills is admissible in tort case arising out of motor vehicle collision, to extent that bills were paid under Medicare program, even though state law purports to exclude such evidence from trial, because *42 USCS § 1395y*, providing that Medicare payments are subject to reimbursement, preempts state law. *Klinefelter v Faultersak (1998, ED Pa) 31 F Supp 2d 457, 60* Soc Sec Rep Serv 21.

Subrogation rights of U.S. under *42 USCS § 1395y(b)(2)(B)(ii)* to settlement paid to deceased Medicare beneficiary in medical malpractice action had priority over state's rights arising from Medicaid payments on beneficiary's behalf, even though malpractice award was paid directly to trust created to ensure that beneficiary retained his Medicaid eligibility, since trust received third-party payment to which U.S. was entitled. *Filippi v United States HHS (2001, SD NY) 138 F Supp 2d 545, 74* Soc Sec Rep Serv 106.

In multi-district mass tort litigation, states which agreed to resolution of Medicare and Medicaid liens, pursuant to *42 USCS §§ 1395y(b)(2)(B)(ii)*<F>(iv), 1396a, by means of global or traditional-holdback methods and sought to recover disbursements from settling plaintiffs were to pay share of relevant attorneys' fees and costs, with total amount of fees capped, thus reflecting equitable sharing of burdens of litigation. *In re Zyprexa Prods. Liab. Litig. (2006, ED NY) 451 F Supp 2d 458,* CCH Prod Liab Rep P 17534.

Medicare Under Medicare Secondary Payer statute, *42 USCS § 1395y(b)* is not qui tam statute conferring on private party right to bring action on behalf of United States against Medicare providers and their insurers for allegedly improper billings to Medicare; qui tam plaintiff lacked standing to bring private claim. *Stalley ex rel. United States v Catholic Health Initiatives (2006, ED Ark) 458 F Supp 2d 958.*

City's motion to dismiss firefighter's action under Medicare Secondary Payer (MSP) statute, *42 USCS § 1395y(b)(3)(A)*, was denied because firefighter's allegations sufficiently alleged injury in fact (the complaint averred that MSP statute rendered city responsible as primary payer for firefighter's medical expenses and that its refusal to fulfill that obligation had forced Medicare to make all illness-related payments on firefighter's behalf), and MSP statute's citizen suit provision existed to redress exactly that type of injury. *O'Connor v Mayor of Baltimore (2007, DC Md) 494 F Supp 2d 372.*

Plaintiff, dialysis services provider, was not entitled to go to trial on its claim against defendant city under *42 USCS § 1395y(b)* because Medicare had made no payments on behalf of plaintiff's patient, and plaintiff could not demonstrate that city was obligated to make payments under its employee health benefit plan. *Bio-Medical Applications of Ga., Inc. v City of Dalton (2009, ND Ga) 685 F Supp 2d 1321.*

Plaintiff, dialysis services provider, was not entitled to double damages pursuant to *42 USCS § 1395y(b)(3)(A)* because Medicare had made no conditional payments on behalf of plaintiff's patient. *Bio-Medical Applications of Ga., Inc. v City of Dalton (2009, ND Ga) 685 F Supp 2d 1321.*

Plaintiff, dialysis services provider, was not entitled to go to trial on its claim against defendant city under *42 USCS § 1395y(b)* because plaintiff had not demonstrated by any of means contemplated by *42 USCS § 1395y(b)(2)(B)(ii)* that defendant city was obligated to make payments under its employee health benefit plan. *Bio-Medical Applications of Ga., Inc. v City of Dalton (2009, ND Ga) 685 F Supp 2d 1321.*

Where patient's treating physician certified pursuant to *42 USCS § 1395n(a)(2)(A)* that patient required skilled nursing care, ALJ reviewing whether home health services were reasonable and necessary as required by *42 USCS § 1395y(a)(1)(A)* for Medicare Part coverage should have either given extra weight to treating physician's certifications or supplied reasoned basis for declining to do so because certifications were relevant part of factual record, treating physician's certifications that nurse was required to oversee and monitor patient's care plan was supported by treating nurses' notes, patient's certified plan of care was specifically tailored to patient, and there was no evidence contradicting certifications. *Exec. Dir. ex rel. Carey v Sebelius (2009, DC Vt) 698 F Supp 2d 436,* adopted, motion gr, motion den, remanded (2010, DC Vt) *698 F Supp 2d 436.*

In plaintiff's action for review of reimbursement amount collected by Centers for Medicare and Medicaid Services (CMS) following settlement of wrongful death and survival action, defendant was entitled to summary judgment, because amount collected by CMS was in accordance with applicable laws regulating reimbursements given to Medicare from wrongful death settlement and because plaintiff was not denied due process. *Benson v Sebelius (2011, DC Dist Col) 771 F Supp 2d 68.*

Insurer's suit against federal government seeking reimbursement under *42 USCS § 1395y* of medical expenses it paid to eight motorists because this law was not money-mandating statute that conferred jurisdiction on Federal Court of Claims under *28 USCS § 1491*. *Citizens Ins. Co. of Am. v United States (2011) 102 Fed Cl 733.*

Unpublished Opinions

Unpublished: Plaintiff lacked Article III standing to bring Medicare Secondary Payer Act claim because complaint did not allege that plaintiff suffered injury-in-fact because complaint alleged that Medicare alone suffered injury as result of defendants' purported failure to pay Medicare for plaintiff's medical bills resulting from slip and fall, and plaintiff's injuries from trip and fall could not have been traced back to defendants' alleged nonpayment to *Medicare. Plante v Dake (2015, CA2 NY) 621 Fed Appx 67.*

Unpublished: Under this section and *42 CFR § 411.24*, Government's action under Medicare Secondary Payer Act, accrued when $ 275 million was transferred by polychlorinated biphenyl (PCB) producers to PCB plaintiffs' lawyers and thus, even if six-year limitations period applied, Government's action was untimely. *United States v Stricker (2013, CA11 Ala) 2013 US App LEXIS 15204.*

Unpublished: Dialysis provider's complaint was properly dismissed because complaint's allegations that city violated statute by impermissibly taking into account that patient who was participant in city's group health plan was eligible for end-stage renal disease (ESRD)-based Medicare benefits and that city violated statute by impermissibly differentiating in benefits provided to individuals without ESRD and those with ESRD on basis of ESRD or need for dialysis treatment were mere legal conclusions, and provider failed to make factual allegations that rose to level of plausible claim. *Hapeville Dialysis Ctr., LLC v City of Atlanta (2013, CA11 Ga) 2013 US App LEXIS 22908.*

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Related Statutes & Rules:

This section is referred to in *10 USCS § 1095*; *26 USCS §§ 5000*, *6103*; *42 USCS §§ 1314*, *1320a-7a*, *1320c*, *1320c-3*, *1320c-7*, *1320c-8*, *1395h*, *1395l*, *1395m*, *1395p*, *1395r*, *1395u*, *1395w-22*, *1395x*, *1395cc*, *1395ff*, *1395gg*, *1395oo*, *1395pp*, *1395ss*, *1395ww*, *1395ddd*, *1395eee*, *1395ggg*, *1396b*; *45 USCS § 231f*.

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Annotations:

Validity, construction, and application of medicare secondary payer provisions of Social Security Act (42 USCS § 1385y(b)) and regulations promulgated thereunder. 126 ALR Fed 553.

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