

hospitals participating in Medicare or Medicaid can best comply with the regulations and take any additional appropriate measures to fully enforce the regulations.

3. Provide additional recommendations to me, within 180 days of the date of this memorandum, on actions the Department of Health and Human Services can take to address hospital visitation, medical decision-making, or other health care issues that affect LGBT patients and their families.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

**§ 1395y. Exclusions from coverage and medicare as secondary payer**

**(a) Items or services specifically excluded**

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B 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 1395x(ddd)(1) of this title), 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 1395x(s)(10) of this title, 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 1395ww(e)(6) of this title,<sup>1</sup>

(E) in the case of research conducted pursuant to section 1320b-12 of this title, 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 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title, and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(oo) of this title), 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 1395m(d) of this title,

(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 1395w-3a(c)(6)(C) of this title for which payment is made under part B that is furnished in a competitive area under section 1395w-3b of this title, 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,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1395x(ggg) of this title), 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 1395x(hhh)(1) of this title), 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 chapter 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 1395x(aa)(1) of this title, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, in the case of services for which payment may be made under section 1395qq(e) of this title, 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 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, 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);

<sup>1</sup> See References in Text note below.

(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;

(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 1395x(s)(8) of this title) 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 1395x(s)(10) of this title 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 1395x(s)(12) of this title;

(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 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 1395x(s)(2)(K) of this title, 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 1395x(w)(1) of this title) 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 subchapter XI) or a carrier under section 1395u of this title 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 1395w-4(i)(2)(B) of this title 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 [42 U.S.C. 14401 et seq.];

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1395w-3(a) of this title) by an entity other than an entity with which the Secretary has entered into a contract under section 1395w-3(b) of this title 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 1395yy(e)(2)(A)(i) of this title 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 1395x(s)(2)(D) of this title, 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 1395x(w)(1) of this title) 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 1395a(b) of this title;

(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 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of subsection (g) or (l)(2) of section 1395x of this title) 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 1395x(m)(5) of this title, 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 1395m(e)(1)(B) of this title for which payment is made under the fee schedule established under section 1395w-4(b) of this title and that are furnished by a supplier (as defined in section 1395x(d) of this title), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1395m(e)(2)(B) of this title;

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) 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 1395x(aa)(3)(B) of this title. In making a national coverage determination (as defined in paragraph (1)(B) of section 1395ff(f) of this title) 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 subchapter under section 426(a) of this title, 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 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

**(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, without regard to section 5000(d) of such Code.

**(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 subchapter under section 426(b) of this title.

**(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 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

**(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 Inter-

nal Revenue Code of 1986, without regard to section 5000(d) of such Code.

**(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 subchapter under section 426-1 of this title 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 426-1 of this title, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426-1 of this title 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 subchapter when an individual is entitled to or eligible for benefits under this subchapter under section 426-1 of this title 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 August 5, 1997,<sup>2</sup> (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 August 5, 1997,<sup>2</sup> (with respect to periods beginning on or after the date that is 18 months prior to August 5, 1997), 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.

**(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 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) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) 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.

In applying sections of the Internal Revenue Code of 1986 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 subchapter 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 subchapter 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<sup>3</sup> or can reasonably be expected to be made<sup>3</sup> 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 subchapter with respect to an item or service if a primary plan described in sub-

<sup>2</sup>So in original. The comma probably should not appear.

<sup>3</sup>So in original. Probably should be “made.”

paragraph (A)(ii)<sup>4</sup> 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 subchapter 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 subchapter 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 subchapter 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 subchapter.

**(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 subchapter (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

<sup>4</sup>So in original. Probably should be "subparagraph (A)".

(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 subchapter 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 pro-

vide 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 January 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 subchapter 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),<sup>5</sup> 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<sup>6</sup>

**(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.

**(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 subchapter 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 1320a-7a of this title

(other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

**(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 subchapter (without regard to deductibles and coinsurance under this subchapter) for the remainder of such charge, but—

(A) payment under this subchapter may not exceed an amount which would be payable under this subchapter for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this subchapter, 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 subchapter on the basis of reasonable cost (or other cost-related basis) or under section 1395ww of this title, the amount which would be payable under this subchapter on such basis, and

(ii) in the case of an item or service for which payment is authorized under this subchapter 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 subchapter (without regard to deductibles and coinsurance under this subchapter),

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) 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.

**(B) Disclosure to fiscal intermediaries and carriers**

In addition to any other information provided under this subchapter to fiscal intermediaries and carriers, the Administrator

<sup>5</sup> So in original. Probably should be “subparagraph (A).”.

<sup>6</sup> So in original. Probably should be followed by a period.

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 by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code), 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 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

**(D) Obtaining information from beneficiaries**

Before an individual applies for benefits under part A or enrolls under part B, 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 subchapter, no payment may be made for any item or service furnished under part B 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 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

**(7) 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 December 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 subchapter; 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 1320a-7a of this title shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. 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 subchapter 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 1395i of this title.

**(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 and enrollment under part B under this subchapter 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 December 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 subchapter 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 January 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 commit-

tees 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 1320a-7a of this title shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. 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 subchapter 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 January 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 a year 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 2014, 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 subchapter.

**(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 subchapter achieved by the Secretary implementing each such threshold.

**(e) Drug products**

No payment may be made under part B for any expenses incurred for—

(1) a drug product—

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

(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 355 of title 21 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 Regulations) 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) Items or services provided for emergency medical conditions**

For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1395dd of this title to an individual who is entitled to benefits under this subchapter, 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 subchapter 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 1320a-7, 1320a-7a, 1320c-5 or 1395u(j)(2) of this title from participation in the program under this subchapter; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1320a-7, 1320a-7a, 1320c-5 or 1395u(j)(2) of this title from participation in the program under this subchapter 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 subchapter submits a claim for payment for items or services furnished by an individual or entity excluded from participation in

the programs under this subchapter, pursuant to section 1320a-7, 1320a-7a, 1320c-5, 1320c-9 (as in effect on September 2, 1982), 1395u(j)(2), 1395y(d) (as in effect on August 18, 1987), or 1395cc of this title, 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 subchapter, 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 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 subchapter, enter into contracts with quality improvement organizations pursuant to part B of subchapter XI of this chapter.

**(h) Waiver of electronic form requirement**

(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 1395ww(e) of this title 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 1395ww(e)(6)(E) of this title 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) Nonvoting members and experts**

(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 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) Dental benefits under group health plans**

(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v))<sup>7</sup> providing supplemental or secondary coverage to individuals also entitled to services under this subchapter shall not require a medicare claims determination under this subchapter 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 subchapter in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this subchapter 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 371(h) of title 21.

**(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.

<sup>7</sup> So in original. Probably should be “(b)(1)(A)(v)”.

**(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**

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 subchapter.

**(B) Local coverage determination**

The term “local coverage determination” has the meaning given that in section 1395ff(f)(2)(B) of this title.

**(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, or enrolled under part B, 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 Regulations (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 1395m(a)(16)(B) and 1395x(o)(7)(C) of this title.

**(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 subchapter 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, section

1395w-112(b)(7) of this section (including as applied pursuant to section 1395w-27(f)(3)(D) of this title), and section 1396b(i)(2)(C) of this title.

**(4) Credible allegation of fraud**

In carrying out this subsection, section 1395w-112(b)(7) of this title (including as applied pursuant to section 1395w-27(f)(3)(D) of this title), and section 1396b(i)(2)(C) of this title, 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.

(Aug. 14, 1935, ch. 531, title XVIII, § 1862, as added Pub. L. 89-97, title I, § 102(a), July 30, 1965, 79 Stat. 325; amended Pub. L. 90-248, title I, §§ 127(b), 128, Jan. 2, 1968, 81 Stat. 846, 847; Pub. L. 92-603, title II, §§ 210, 211(c)(1), 229(a), 256(c), Oct. 30, 1972, 86 Stat. 1382, 1384, 1408, 1447; Pub. L. 93-233, § 18(k)(3), Dec. 31, 1973, 87 Stat. 970; Pub. L. 93-480, § 4(a), Oct. 26, 1974, 88 Stat. 1454; Pub. L. 94-182, title I, § 103, Dec. 31, 1975, 89 Stat. 1051; Pub. L. 95-142, §§ 7(a), 13(a), (b)(1), (2), Oct. 25, 1977, 91 Stat. 1192, 1197, 1198; Pub. L. 95-210, § 1(f), Dec. 13, 1977, 91 Stat. 1487; Pub. L. 96-272, title III, § 308(a), June 17, 1980, 94 Stat. 531; Pub. L. 96-499, title IX, §§ 913(b), 936(c), 939(a), 953, Dec. 5, 1980, 94 Stat. 2620, 2640, 2647; Pub. L. 96-611, § 1(a)(3), Dec. 28, 1980, 94 Stat. 3566; Pub. L. 97-35, title XXI, §§ 2103(a)(1), 2146(a), 2152(a), Aug. 13, 1981, 95 Stat. 787, 800, 802; Pub. L. 97-248, title I, §§ 116(b), 122(f), (g)(1), 128(a)(2)-(4), 142, 148(a), Sept. 3, 1982, 96 Stat. 353, 362, 366, 381, 394; Pub. L. 97-448, title III, § 309(b)(10), Jan. 12, 1983, 96 Stat. 2409; Pub. L. 98-21, title VI, §§ 601(f), 602(e), Apr. 20, 1983, 97 Stat. 162, 163; Pub. L. 98-369, div. B, title III, §§ 2301(a), 2304(c), 2313(c), 2344(a)-(c), 2354(b)(30), (31), July 18, 1984, 98 Stat. 1063, 1068, 1078, 1095, 1101, 1102; Pub. L. 99-272, title IX, §§ 9201(a), 9307(a), 9401(c)(1), Apr. 7, 1986, 100 Stat. 170, 193, 199; Pub. L. 99-509, title IX, §§ 9316(b), 9319(a), (b), 9320(h)(1), 9343(c)(1), Oct. 21, 1986, 100 Stat. 2007, 2010, 2011, 2016, 2040; Pub. L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 100-93, §§ 8(c)(1), (3), 10, Aug. 18, 1987, 101 Stat. 692, 693, 696; Pub. L. 100-203, title IV, §§ 4009(j)(6)(C), 4034(a), 4036(a)(1), 4039(c)(1), 4072(c), 4085(i)(15), (16), Dec. 22, 1987, 101 Stat. 1330-59, 1330-77, 1330-79, 1330-82, 1330-117, 1330-133; Pub. L. 100-360, title II, §§ 202(d), 204(d)(2), 205(e)(1), title IV, § 411(f)(4)(D)(i), (i)(4)(D), July 1, 1988, 102 Stat. 715, 729, 731, 778, 790; Pub. L. 100-485, title VI, § 608(d)(7), (24)(C), Oct. 13, 1988, 102 Stat. 2415, 2421; Pub. L. 101-234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-239, title VI, §§ 6003(g)(3)(D)(xi), 6103(b)(3)(B), 6115(b), 6202(a)(2)(A), (b)(1), (e)(1), 6411(d)(2), Dec. 19, 1989, 103 Stat. 2154, 2199, 2219, 2228, 2229, 2234, 2271; Pub. L. 101-508, title IV, §§ 4107(b), 4153(b)(2)(B), 4157(c)(1), 4161(a)(3)(C), 4163(d)(2), 4203(a)(1), (b), (c)(1), 4204(g)(1), Nov. 5, 1990, 104 Stat. 1388-62, 1388-84, 1388-89, 1388-94, 1388-100, 1388-107, 1388-112; Pub. L. 103-66, title XIII, §§ 13561(a)(1), (b)-(d)(1), (e)(1), 13581(b)(1), Aug. 10, 1993, 107 Stat. 593, 594, 611; Pub. L. 103-432, title I, §§ 145(c)(1), 147(e)(6), 151(a)(1)(A), (C), (2)(A), (b)(3)(A), (B), (c)(1), (4)-(6), (9)(B), 156(a)(2)(D), 157(b)(7), Oct. 31, 1994, 108 Stat. 4427, 4430, 4432-4436, 4441, 4442; Pub. L. 104-224, § 1, Oct. 2, 1996, 110 Stat. 3031; Pub. L. 104-226, § 1(b)(1), Oct.

2, 1996, 110 Stat. 3033; Pub. L. 105-12, § 9(a)(1), Apr. 30, 1997, 111 Stat. 26; Pub. L. 105-33, title IV, §§ 4022(b)(1)(B), 4102(c), 4103(c), 4104(c)(3), 4201(c)(1), 4319(b), 4432(b)(1), 4507(a)(2)(B), 4511(a)(2)(C), 4541(b), 4603(c)(2)(C), 4614(a), 4631(a)(1), (b), (c)(1), 4632(a), 4633(a), (b), Aug. 5, 1997, 111 Stat. 354, 361, 362, 365, 373, 394, 420, 441, 442, 456, 471, 474, 486, 487; Pub. L. 106-113, div. B, § 1000(a)(6) [title III, §§ 305(b), 321(k)(10)], Nov. 29, 1999, 113 Stat. 1536, 1501A-362, 1501A-367; Pub. L. 106-554, § 1(a)(6) [title I, § 102(c), title III, § 313(a), title IV, § 432(b)(1), title V, § 522(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-468, 2763A-499, 2763A-526, 2763A-546; Pub. L. 107-105, § 3(a), Dec. 27, 2001, 115 Stat. 1006; Pub. L. 108-173, title III, §§ 301(a)-(c), 303(i)(3)(B), title VI, §§ 611(d)(1), 612(c), 613(c), title VII, § 731(a)(1), (b)(1), title IX, §§ 900(e)(1)(J), 944(a)(1), 948(a), 950(a), Dec. 8, 2003, 117 Stat. 2221, 2222, 2254, 2304-2306, 2349, 2351, 2372, 2422, 2425, 2426; Pub. L. 109-171, title V, § 5112(d), Feb. 8, 2006, 120 Stat. 44; Pub. L. 110-173, title I, § 111(a), Dec. 29, 2007, 121 Stat. 2497; Pub. L. 110-275, title I, §§ 101(a)(3), (b)(3), (4), 135(a)(2)(A), 143(b)(7), 152(b)(1)(D), 153(b)(2), July 15, 2008, 122 Stat. 2497, 2498, 2535, 2543, 2552, 2555; Pub. L. 111-148, title I, § 1104(d), title IV, § 4103(d), title VI, § 6402(g)(3), (h)(1), Mar. 23, 2010, 124 Stat. 153, 556, 759, 760; Pub. L. 112-40, title II, § 261(a)(3)(A), Oct. 21, 2011, 125 Stat. 423; Pub. L. 112-242, title II, §§ 201, 202(a), 203-205(a), Jan. 10, 2013, 126 Stat. 2375, 2378, 2380, 2381; Pub. L. 113-188, title IX, § 902(d), Nov. 26, 2014, 128 Stat. 2022; Pub. L. 114-10, title V, § 516(a), Apr. 16, 2015, 129 Stat. 175; Pub. L. 114-255, div. A, title IV, § 4009(a), Dec. 13, 2016, 130 Stat. 1185; Pub. L. 115-271, title II, § 2008(c), (d), title IV, § 4002, Oct. 24, 2018, 132 Stat. 3931, 3959.)

REFERENCES IN TEXT

Section 1395ww(e)(6) of this title, referred to in subsec. (a)(1)(D), was repealed by Pub. L. 105-33, title IV, § 4022(b)(1)(A)(i), Aug. 5, 1997, 111 Stat. 354.

The Assisted Suicide Funding Restriction Act of 1997, referred to in subsec. (a)(16), is Pub. L. 105-12, Apr. 30, 1997, 111 Stat. 23, which is classified principally to chapter 138 (§ 14401 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 14401 of this title and Tables.

The Internal Revenue Code of 1986, referred to in subsec. (b), is classified generally to Title 26, Internal Revenue Code.

Section 107(c)(3) of the Drug Amendments of 1962, referred to in subsec. (c)(1)(A), is section 107(c)(3) of Pub. L. 87-781, title I, Oct. 10, 1962, 76 Stat. 788, which is set out as an Effective Date of 1962 Amendment note under section 321 of Title 21, Food and Drugs.

CODIFICATION

Section 1314(i) of this title, which was transferred and redesignated as subsec. (j) of this section by Pub. L. 108-173, was based on act Aug. 14, 1935, ch. 531, title XI, § 1114(i), as added Pub. L. 106-554, § 1(a)(6) [title V, § 522(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A-546.

Amendments by section 301(a) to (c) of Pub. L. 108-173 were executed to this section as it read on the date of enactment of Pub. L. 108-173 to reflect the probable intent of Congress, notwithstanding section 301(d) of Pub. L. 108-173, set out as an Effective Date of 2003 Amendment note below, which provided that the amendments by section 301(a) of Pub. L. 108-173 be effective as if included in the enactment of title III of Pub. L. 98-369 and that the amendments by section 301(b), (c) of Pub. L. 108-173 be effective as if included in the enactment of section 953 of Pub. L. 96-499. The amendments by section 301(a) are incapable of being executed to this section as it read on the effective date of title III of Pub.

L. 98-369, and the amendments by section 301(b), (c) are incapable of being executed to this section as it read on the effective date of section 953 of Pub. L. 96-499. See 2003 Amendment notes below.

#### AMENDMENTS

2018—Subsec. (b)(7)(A)(i). Pub. L. 115-271, § 4002, amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: “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 subchapter; and”.

Subsec. (o)(3). Pub. L. 115-271, § 2008(c), inserted “, section 1395w-112(b)(7) of this section (including as applied pursuant to section 1395w-27(f)(3)(D) of this title),” after “this subsection”.

Subsec. (o)(4). Pub. L. 115-271, § 2008(d), added par. (4).  
2016—Subsec. (l)(5)(D). Pub. L. 114-255 added subpar. (D).

2015—Subsec. (b)(5)(E). Pub. L. 114-10 added subpar. (E).

2014—Subsec. (b)(9)(B)(i). Pub. L. 113-188 substituted “for 2014, the Secretary shall” for “for a year, the Secretary shall”.

2013—Subsec. (b)(2)(B)(ii). Pub. L. 112-242, § 202(a)(1), substituted “Subject to paragraph (9), a primary plan” for “A primary plan”.

Subsec. (b)(2)(B)(iii). Pub. L. 112-242, § 205(a), inserted at end “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.”

Subsec. (b)(2)(B)(vii), (viii). Pub. L. 112-242, § 201, added cls. (vii) and (viii).

Subsec. (b)(8)(B). Pub. L. 112-242, § 204, inserted concluding provisions.

Subsec. (b)(8)(E)(i). Pub. L. 112-242, § 203(1), substituted “may be subject to a civil money penalty of up to \$1,000” for “shall be subject to a civil money penalty of \$1,000”.

Subsec. (b)(8)(I). Pub. L. 112-242, § 203(2), added subpar. (I).

Subsec. (b)(9). Pub. L. 112-242, § 202(a)(2), added par. (9).

2011—Subsecs. (a)(15)(A), (g). Pub. L. 112-40 substituted “quality improvement” for “utilization and quality control peer review”.

2010—Subsec. (a)(1)(P). Pub. L. 111-148, § 4103(d)(1), added subpar. (P).

Subsec. (a)(7). Pub. L. 111-148, § 4103(d)(2), substituted “(K), or (P)” for “or (K)”.

Subsec. (a)(25). Pub. L. 111-148, § 1104(d), added par. (25).

Subsec. (n). Pub. L. 111-148, § 6402(g)(3), added subsec. (n).

Subsec. (o). Pub. L. 111-148, § 6402(h)(1), added subsec. (o).

2008—Subsec. (a)(1)(A). Pub. L. 110-275, § 101(a)(3), inserted “or additional preventive services (as described in section 1395x(ddd)(1) of this title)” after “succeeding subparagraph”.

Subsec. (a)(1)(K). Pub. L. 110-275, § 101(b)(3), (4), substituted “more” for “not later” and “1 year” for “6 months”.

Subsec. (a)(1)(O). Pub. L. 110-275, § 152(b)(1)(D), added subpar. (O).

Subsec. (a)(20). Pub. L. 110-275, § 143(b)(7), 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 (l)(2) of section 1395x” for “section 1395x(g)”.

Subsec. (a)(23). Pub. L. 110-275, § 135(a)(2)(A), added par. (23).

Subsec. (a)(24). Pub. L. 110-275, § 153(b)(2), added par. (24).

2007—Subsec. (b)(7), (8). Pub. L. 110-173 added pars. (7) and (8).

2006—Subsec. (a)(1)(N). Pub. L. 109-171 added subpar. (N).

2003—Subsec. (a). Pub. L. 108-173, § 948(a)(2)(A), struck out “established under section 1314(f) of this title” after “meetings of advisory committees” in concluding provisions.

Pub. L. 108-173, § 731(a)(1)(A), inserted “consistent with subsection (l)” after “the Secretary shall ensure” in concluding provisions.

Subsec. (a)(1)(J). Pub. L. 108-173, § 303(i)(3)(B), added subpar. (J).

Subsec. (a)(1)(K). Pub. L. 108-173, § 611(d)(1)(A), added subpar. (K).

Subsec. (a)(1)(L). Pub. L. 108-173, § 612(c), added subpar. (L).

Subsec. (a)(1)(M). Pub. L. 108-173, § 613(c), added subpar. (M).

Subsec. (a)(7). Pub. L. 108-173, § 611(d)(1)(B), substituted “(H), or (K)” for “or (H)”.

Subsec. (b)(1)(A). Pub. L. 108-173, § 301(c)(1), realigned margins.

Subsec. (b)(2)(A). Pub. L. 108-173, § 301(b)(1), inserted at end of concluding provisions “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.”

Subsec. (b)(2)(A)(ii). Pub. L. 108-173, § 301(a)(1), struck out “promptly (as determined in accordance with regulations)” after “be expected to be made”.

Subsec. (b)(2)(B)(i). Pub. L. 108-173, § 301(a)(2)(B), added cl. (i). Former cl. (i) redesignated (ii).

Subsec. (b)(2)(B)(ii). Pub. L. 108-173, § 301(b)(2), substituted “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 subchapter 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.” for “Any payment under this subchapter 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 subchapter when notice or other information is received that payment for such item or service has been or could be made under such subparagraph.” and “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”.

Pub. L. 108-173, § 301(a)(2)(A), redesignated cl. (i) as (ii). Former cl. (ii) redesignated (iii).

Subsec. (b)(2)(B)(iii). Pub. L. 108-173, § 301(b)(3), substituted “In order to recover payment made under this subchapter 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.” for “In order to recover payment under this subchapter 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."

Pub. L. 108-173, §301(a)(2)(A), redesignated cl. (ii) as (iii). Former cl. (iii) redesignated (iv).

Subsec. (b)(2)(B)(iv) to (vi). Pub. L. 108-173, §301(a)(2)(A), redesignated cls. (iii) to (v) as (iv) to (vi), respectively.

Subsec. (b)(3)(A). Pub. L. 108-173, §301(c)(2), struck out "such" before "paragraphs".

Subsec. (b)(5)(A)(ii). Pub. L. 108-173, §900(e)(1)(J), substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

Subsec. (d). Pub. L. 108-173, §944(a)(1), added subsec. (d).

Subsec. (j). Pub. L. 108-173, §948(a)(1), transferred subsec. (i) of section 1314 of this title and redesignated it as subsec. (j) of this section. See Codification note above.

Subsec. (j)(1). Pub. L. 108-173, §948(a)(2)(B), in introductory provisions, struck out "under subsection (f)" after "appointed" and substituted "subsection (a)(1)" for "section 1395y(a)(1) of this title".

Subsec. (k). Pub. L. 108-173, §950(a), added subsec. (k).

Subsec. (l). Pub. L. 108-173, §731(a)(1)(B), added subsec. (l).

Subsec. (m). Pub. L. 108-173, §731(b)(1), added subsec. (m).

2001—Subsec. (a)(22). Pub. L. 107-105, §3(a)(1), added par. (22).

Subsec. (h). Pub. L. 107-105, §3(a)(2), added subsec. (h).

2000—Subsec. (a). Pub. L. 106-554, §1(a)(6) [title V, §522(b)], inserted at end "In making a national coverage determination (as defined in paragraph (1)(B) of section 1395ff(f) of this title) the Secretary shall ensure that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees established under section 1314(f) of this title 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."

Subsec. (a)(1)(F). Pub. L. 106-554, §1(a)(6) [title I, §102(c)], struck out "and," after "section 1395m(c)(1)(B) of this title," and inserted at end "and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,".

Subsec. (a)(3). Pub. L. 106-554, §1(a)(6) [title IV, §432(b)(1)], struck out second comma after "section 1395x(aa)(1) of this title" and inserted "in the case of services for which payment may be made under section 1395qq(e) of this title," after "section 1395x(aa)(3) of this title,".

Subsec. (a)(18). Pub. L. 106-554, §1(a)(6) [title III, §313(a)], substituted "during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1395x(s)(2)(D) of this title, 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)."

1999—Subsec. (a)(7). Pub. L. 106-113, §1000(a)(6) [title III, §321(k)(10)], substituted "subparagraph" for "sub-

Subsec. (a)(21). Pub. L. 106-113, §1000(a)(6) [title III, §305(b)], inserted "(including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section)" after "home health services".

1997—Subsec. (a)(1)(D). Pub. L. 105-33, §4022(b)(1)(B), substituted "Medicare Payment Advisory Commission" for "Prospective Payment Assessment Commission".

Subsec. (a)(1)(F). Pub. L. 105-33, §4102(c), inserted "and screening pelvic exam" after "screening pap smear".

Subsec. (a)(1)(G). Pub. L. 105-33, §4103(c)(1), added subpar. (G).

Subsec. (a)(1)(H). Pub. L. 105-33, §4104(c)(3)(A), added subpar. (H).

Subsec. (a)(1)(I). Pub. L. 105-33, §4614(a), added subpar. (I).

Subsec. (a)(7). Pub. L. 105-33, §4104(c)(3)(B), substituted "(G), or (H)" for "or (G)".

Pub. L. 105-33, §4103(c)(2), substituted "subparagraphs (B), (F), or (G) of paragraph (1)" for "paragraph (1)(B) or under paragraph (1)(F)".

Subsec. (a)(14). Pub. L. 105-33, §4511(a)(2)(C), substituted "section 1395x(s)(2)(K) of this title" for "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(iii) of this title".

Pub. L. 105-33, §4201(c)(1), substituted "critical access" for "rural primary care" wherever appearing.

Subsec. (a)(16). Pub. L. 105-12 added par. (16).

Subsec. (a)(17). Pub. L. 105-33, §4319(b), added par. (17).

Subsec. (a)(18). Pub. L. 105-33, §4432(b)(1), added par. (18).

Subsec. (a)(19). Pub. L. 105-33, §4507(a)(2)(B), added par. (19).

Subsec. (a)(20). Pub. L. 105-33, §4541(b), added par. (20).

Subsec. (a)(21). Pub. L. 105-33, §4603(c)(2)(C), added par. (21).

Subsec. (b)(1)(B)(i). Pub. L. 105-33, §4631(a)(1)(A), substituted "in clause (iii)" for "in clause (iv)".

Subsec. (b)(1)(B)(iii), (iv). Pub. L. 105-33, §4631(a)(1)(B), (C), redesignated cl. (iv) as (iii) and struck out heading and text of former cl. (iii). Text read as follows: "Clause (i) shall only apply to items and services furnished on or after January 1, 1987, and before October 1, 1998."

Subsec. (b)(1)(C). Pub. L. 105-33, §4631(b), in concluding provisions, substituted "August 5, 1997" for "October 1, 1998" and inserted at end "Effective for items and services furnished on or after August 5, 1997, (with respect to periods beginning on or after the date that is 18 months prior to August 5, 1997), clauses (i) and (ii) shall be applied by substituting '30-month' for '12-month' each place it appears."

Subsec. (b)(1)(F). Pub. L. 105-33, §4633(b), added subpar. (F).

Subsec. (b)(2)(B)(ii). Pub. L. 105-33, §4633(a), substituted "(directly, as a third-party administrator, or otherwise) to make payment" for "under this subsection to pay" and inserted at end "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."

Subsec. (b)(2)(B)(v). Pub. L. 105-33, §4632(a), added cl. (v).

Subsec. (b)(5)(C)(iii). Pub. L. 105-33, §4631(c)(1), struck out heading and text of cl. (iii). Text read as follows: "Clause (ii) shall not apply to inquiries made after September 30, 1998."

Subsec. (i). Pub. L. 105-33, §4022(b)(1)(B), substituted "Medicare Payment Advisory Commission" for "Prospective Payment Assessment Commission" in introductory provisions.

1996—Subsec. (b)(5)(B). Pub. L. 104-226, §1(b)(1)(A), substituted "under subparagraph (A) for purposes of carrying out this subsection" for "under—



“(i) subparagraph (A), and  
“(ii) section 1320b-14 of this title,  
for purposes of carrying out this subsection”.

Subsec. (b)(5)(C)(i). Pub. L. 104-226, §1(b)(1)(B), substituted “disclosed under subparagraph (B)” for “disclosed under subparagraph (B)(i)”.

Subsec. (h). Pub. L. 104-224 struck out subsec. (h) which required Secretary to provide registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this chapter.

1994—Subsec. (a)(1)(F). Pub. L. 103-432, §145(c)(1), substituted “or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title” for “or which does not meet the standards established under section 1395m(c)(3) of this title”.

Subsec. (a)(14). Pub. L. 103-432, §156(a)(2)(D)(i), inserted “or” at end.

Pub. L. 103-432, §147(e)(6), substituted “section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(iii) of this title” for “section 1395x(s)(2)(K)(i) of this title”.

Subsec. (a)(15). Pub. L. 103-432, §156(a)(2)(D)(ii), substituted period for “; or” at end.

Subsec. (a)(16). Pub. L. 103-432, §156(a)(2)(D)(iii), struck out par. (16) which read as follows: “furnished in connection with a surgical procedure for which a second opinion is required under section 1320c-13(c)(2) of this title and has not been obtained.”

Subsec. (b)(1)(A)(i)(II). Pub. L. 103-432, §151(c)(1)(A), 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”.

Subsec. (b)(1)(A)(ii). Pub. L. 103-432, §151(c)(1)(B), substituted “employer that has 20 or more employees” for “employer or employee organization that has 20 or more individuals in current employment status”.

Subsec. (b)(1)(A)(v). Pub. L. 103-432, §151(c)(9)(B), made technical amendment to directory language of Pub. L. 103-66, §13561(e)(1)(D). See 1993 Amendment note below.

Subsec. (b)(1)(C). Pub. L. 103-432, §151(c)(5), substituted “paying benefits secondary to this subchapter when” for “taking into account that” in closing provisions.

Pub. L. 103-432, §151(c)(4), substituted “this subparagraph” for “clauses (i) and (ii)” after “February 1, 1990,” in last sentence.

Subsec. (b)(2)(B)(i). Pub. L. 103-432, §151(b)(3)(A), (B), substituted “Repayment required” for “Primary plans” in heading and inserted at end “If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date such notice 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).”

Subsec. (b)(2)(C). Pub. L. 103-432, §151(a)(1)(C), added subpar. (C).

Subsec. (b)(3)(C). Pub. L. 103-432, §157(b)(7), substituted “group health plan or a large group health plan” for “group health plan” in heading and text, struck out “, unless such incentive is also offered to all individuals who are eligible for coverage under the plan” after “(as defined in paragraph (2)(A))”, and substituted “(other than subsections (a) and (b))” for “(other than the first sentence of subsection (a) and other than subsection (b))”.

Subsec. (b)(5)(C)(i). Pub. L. 103-432, §151(c)(6), substituted “section 6103(l)(12)(E)(iii) of such Code” for “section 6103(l)(12)(D)(iii) of such Code”.

Subsec. (b)(5)(D). Pub. L. 103-432, §151(a)(1)(A), added subpar. (D).

Subsec. (b)(6). Pub. L. 103-432, §151(a)(2)(A), added par. (6).

1993—Subsec. (b)(1)(A)(i). Pub. L. 103-66, §13561(e)(1)(A), amended subcls. (I) and (II) generally. Prior to amendment, subcls. (I) and (II) read as follows:

“(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 subchapter under section 426(a) of this title, 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.”

Subsec. (b)(1)(A)(ii). Pub. L. 103-66, §13561(e)(1)(B), 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”.

Subsec. (b)(1)(A)(iii). Pub. L. 103-66, §13561(e)(1)(C), 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”.

Subsec. (b)(1)(A)(iv). Pub. L. 103-66, §13561(c)(2), substituted “Subparagraph (C) shall apply instead of clause (i)” for “Clause (i) shall not apply” and inserted “(without regard to entitlement under section 426 of this title)” after “individual is, or”.

Subsec. (b)(1)(A)(v). Pub. L. 103-66, §13561(e)(1)(D), as amended by Pub. L. 103-432, §151(c)(9)(B), inserted before period at end “, without regard to section 5000(d) of such Code”.

Subsec. (b)(1)(B). Pub. L. 103-66, §13561(e)(1)(E), substituted “individuals” for “active individuals” in heading.

Subsec. (b)(1)(B)(i). Pub. L. 103-66, §13561(e)(1)(F), 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))”.

Subsec. (b)(1)(B)(ii). Pub. L. 103-66, §13561(c)(2), substituted “Subparagraph (C) shall apply instead of clause (i)” for “Clause (i) shall not apply” and inserted “(without regard to entitlement under section 426 of this title)” after “individual is, or”.

Subsec. (b)(1)(B)(iii). Pub. L. 103-66, §13561(b), substituted “1998” for “1995”.

Subsec. (b)(1)(B)(iv). Pub. L. 103-66, §13561(e)(1)(G), amended heading and text generally. Prior to amendment, text defined “active individual” and “large group health plan”.

Subsec. (b)(1)(C). Pub. L. 103-66, §13561(c)(1), (3), substituted “or eligible for benefits under this subchapter under” for “benefits under this subchapter solely by reason of” in cl. (i) and concluding provisions and substituted “before October 1, 1998” for “on or before January 1, 1996” in concluding provisions.

Subsec. (b)(1)(E). Pub. L. 103-66, §13561(e)(1)(H), added cls. (ii) and (iii).

Pub. L. 103-66, §13561(d)(1), added subpar. (E).

Subsec. (b)(5)(B). Pub. L. 103-66, §13581(b)(1)(A), substituted “under—” for “under subparagraph (A) for the purposes of carrying out this subsection.” and added cls. (i) and (ii) and concluding provisions.

Subsec. (b)(5)(C)(i). Pub. L. 103-66, §13581(b)(1)(B), substituted “subparagraph (B)(i)” for “subparagraph (B)”.

Subsec. (b)(5)(C)(iii). Pub. L. 103-66, §13561(a)(1), substituted “1998” for “1995”.

1990—Subsec. (a). Pub. L. 101-508, §4161(a)(3)(C)(iii), inserted at end “Paragraph (7) shall not apply to Federally qualified health center services described in section 1395x(aa)(3)(B) of this title.”

Subsec. (a)(1)(A). Pub. L. 101-508, §4163(d)(2)(A)(i), substituted “a succeeding subparagraph” for “subparagraph (B), (C), (D), or (E)”.

Subsec. (a)(1)(F). Pub. L. 101-508, § 4163(d)(2)(A)(ii)-(iv), added subpar. (F).

Subsec. (a)(2). Pub. L. 101-508, § 4161(a)(3)(C)(i), inserted before semicolon at end “, except in the case of Federally qualified health center services”.

Subsec. (a)(3). Pub. L. 101-508, § 4161(a)(3)(C)(ii), inserted “, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title,” after “section 1395x(aa)(1) of this title.”

Subsec. (a)(7). Pub. L. 101-508, § 4163(d)(2)(B), inserted “or under paragraph (1)(F)” after “paragraph (1)(B)”.

Pub. L. 101-508, § 4153(b)(2)(B), inserted “(other than eyewear described in section 1395x(s)(8) of this title)” after first reference to “eyeglasses”.

Subsec. (a)(14). Pub. L. 101-508, § 4157(c)(1), inserted “, services described by section 1395x(s)(2)(K)(i) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist,” after “this paragraph” and struck out before semicolon at end “or are services of a certified registered nurse anesthetist”.

Subsec. (a)(15). Pub. L. 101-508, § 4107(b), designated existing provisions as par. (A), substituted “, or” for “; or” at end, and added par. (B).

Subsec. (b)(1)(B)(iii). Pub. L. 101-508, § 4203(b), substituted “October 1, 1995” for “January 1, 1992”.

Subsec. (b)(1)(C). Pub. L. 101-508, § 4203(c)(1)(B), inserted at end “Effective for items and services furnished on or after February 1, 1991, and on or before January 1, 1996, (with respect to periods beginning on or after February 1, 1990), clauses (i) and (ii) shall be applied by substituting ‘18-month’ for ‘12-month’ each place it appears.”

Subsec. (b)(1)(C)(i). Pub. L. 101-508, § 4203(c)(1)(A), 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 426-1 of this title, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426-1 of this title if the individual had filed an application for such benefits; and” for “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 part A of this subchapter (if he had filed an application for such benefits) under the provisions of section 426-1(b)(1)(B) of this title; and”.

Subsec. (b)(3)(C). Pub. L. 101-508, § 4204(g)(1), added subpar. (C).

Subsec. (b)(5)(C)(iii). Pub. L. 101-508, § 4203(a)(1), substituted “September 30, 1995” for “September 30, 1991”. 1989—Pub. L. 101-239, § 6202(b)(1)(A), inserted “and medicare as secondary payer” in section catchline.

Subsec. (a)(1)(A). Pub. L. 101-234 repealed Pub. L. 100-360, § 204(d)(2)(A)(i), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (a)(1)(E). Pub. L. 101-239, § 6103(b)(3)(B), substituted “section 1320b-12” for “section 1395l(c)”.

Subsec. (a)(1)(F). Pub. L. 101-239, § 6115(b), inserted before semicolon at end “, and, in the case of screening pap smear, which is performed more frequently than is provided under 1395x(mn) of this title”.

Pub. L. 101-234 repealed Pub. L. 100-360, § 204(d)(2)(A)(ii)-(iv), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (a)(1)(G), (6), (7). Pub. L. 101-234 repealed Pub. L. 100-360, §§ 204(d)(2)(B), 205(e)(1), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below.

Subsec. (a)(14). Pub. L. 101-239, § 6003(g)(3)(D)(xi), substituted “hospital or rural primary care hospital” for “hospital” in three places.

Subsec. (b). Pub. L. 101-239, § 6202(b)(1)(B), amended heading and text generally, substituting pars. (1) to (4) relating to medicare as secondary payer for former pars. (1) to (5) relating to items or services paid under workmen’s compensation laws and end stage renal disease program.

Subsec. (b)(1)(D). Pub. L. 101-239, § 6202(e)(1), added subpar. (D).

Subsec. (b)(5). Pub. L. 101-239, § 6202(a)(2)(A), added par. (5).

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

Subsec. (e)(1). Pub. L. 101-239, § 6411(d)(2), inserted “, not including items or services furnished in an emergency room of a hospital” after “(other than an emergency item or service”.

1988—Subsec. (a)(1)(A). Pub. L. 100-360, § 204(d)(2)(A)(i), substituted “a succeeding subparagraph” for “subparagraph (B), (C), (D), or (E)”.

Subsec. (a)(1)(F). Pub. L. 100-360, § 204(d)(2)(A)(ii)-(iv), added subpar. (F) relating to screening mammography.

Subsec. (a)(1)(G). Pub. L. 100-360, § 205(e)(1)(A), as amended by Pub. L. 100-485, § 608(d)(7), added subpar. (G) relating to in-home care for chronically dependent individuals.

Subsec. (a)(6). Pub. L. 100-360, § 205(e)(1)(B), inserted “and except, in the case of in-home care, as is otherwise permitted under paragraph (1)(G)” after “paragraph (1)(C)”.

Subsec. (a)(7). Pub. L. 100-360, § 204(d)(2)(B), inserted “or under paragraph (1)(F)” after “(1)(B)”.

Subsec. (a)(15). Pub. L. 100-360, § 411(f)(4)(D)(i), inserted “(including subsequent insertion of an intraocular lens)” after “operation”.

Subsec. (c). Pub. L. 100-360, § 202(d), designated existing provisions as par. (1), redesignated former par. (1) as subpar. (A), redesignated former subpars. (A) to (D) as cls. (i) to (iv), redesignated former par. (2) as subpar. (B), redesignated former subpar. (A) as cl. (i) and substituted “subparagraph (A)” for “paragraph (1)”, redesignated former subpar. (B) as cl. (ii), and added par. (2) prohibiting payment for expenses incurred for a covered outpatient drug if the drug is dispensed in a quantity exceeding a supply of 30 days with an exception.

Subsec. (e)(1). Pub. L. 100-360, § 411(i)(4)(D)(i), as amended by Pub. L. 100-485, § 608(d)(24)(C)(i), designated existing provisions of subsec. (e) as par. (1), redesignated former par. (1) as subpar. (A), substituted “, 1320a-7a, 1320c-5 or 1395u(j)(2)” for “or section 1320a-7a”, and redesignated former par. (2) as subpar. (B).

Subsec. (e)(2). Pub. L. 100-360, § 411(i)(4)(D)(ii), as amended by Pub. L. 100-485, § 608(d)(24)(C)(ii), amended former section 1395aaa of this title by striking out the catchline “Limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities”, substituting “(2)” for the section designation, inserting “1395u(j)(2),” in text, and transferring the text to par. (2) of subsec. (e) of this section.

1987—Subsec. (a)(1)(A). Pub. L. 100-203, § 4085(i)(15), substituted “(D), or (E)” for “or (D)”.

Subsec. (a)(8). Pub. L. 100-203, § 4072(c), inserted “, other than shoes furnished pursuant to section 1395x(s)(12) of this title” before semicolon.

Subsec. (a)(14). Pub. L. 100-203, § 4085(i)(16), substituted “a patient” for “an patient”.

Pub. L. 100-203, § 4009(j)(6)(C), made technical amendment to Pub. L. 99-509, § 9320(h)(1). See 1986 Amendment note below.

Subsec. (b)(2)(A)(ii). Pub. L. 100-203, § 4036(a)(1), substituted “can reasonably be expected to be made under such a plan” for “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 subchapter”.

Subsec. (b)(4)(B)(i). Pub. L. 100-203, § 4034(a), 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”.

Subsec. (d). Pub. L. 100-93, §8(c)(1)(A), struck out subsec. (d), which provided that no payment be made under this subchapter for any item or services to an individual by a person where Secretary determines such person knowingly and willfully made any false statement or representation of a material fact, submitted excessive bills or requests, or furnished excessive services or supplies, and provided a dissatisfied person with a hearing on determination of the Secretary.

Subsec. (e) [formerly §1395aaa]. Pub. L. 100-93, §10, added par. (2). See 1988 Amendment note above.

Pub. L. 100-93, §8(c)(1)(B), amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: “No payment may be made under this subchapter with respect to any item or service furnished by a physician or other individual during the period when he is barred pursuant to section 1320a-7 of this title from participation in the program under this subchapter.”

Subsec. (h)(1)(B). Pub. L. 100-203, §4039(c)(1)(A), substituted “law (and any amount paid to a provider under any such warranty),” for “law.”

Subsec. (h)(1)(D). Pub. L. 100-203, §4039(c)(1)(B), inserted “in determining the amount subject to repayment under paragraph (2)(C),” after “(3).”

Subsec. (h)(2)(C). Pub. L. 100-203, §4039(c)(1)(C), added subpar. (C).

Subsec. (h)(4). Pub. L. 100-93, §8(c)(3), substituted “subsections (c), (f), and (g) of section 1320a-7 of this title” for “paragraphs (2) and (3) of subsection (d) of this section”.

Subsec. (h)(4)(B). Pub. L. 100-203, §4039(c)(1)(D), substituted “, has improperly” for “or has improperly” and inserted “or has failed to make repayment to the Secretary as required under paragraph (2)(C),” after “(2)(B).”

1986—Subsec. (a)(1)(E). Pub. L. 99-509, §9316(b), added subpar. (E).

Subsec. (a)(14). Pub. L. 99-509, §9343(c)(1), substituted “patient” for “inpatient”.

Pub. L. 99-509, §9320(h)(1), as amended by Pub. L. 100-203, §4009(j)(6)(C), inserted “or are services of a certified registered nurse anesthetist” after “hospital” at end.

Subsec. (a)(15). Pub. L. 99-272, §9307(a), added par. (15).

Subsec. (a)(16). Pub. L. 99-272, §9401(c)(1), added par. (16).

Subsec. (b)(2)(A). Pub. L. 99-514 substituted “Internal Revenue Code of 1986” for “Internal Revenue Code of 1954”.

Subsec. (b)(3)(A)(i). Pub. L. 99-272, §9201(a)(1), substituted “(or to the spouse of such individual)” for “who is under 70 years of age during any part of such month (or to the spouse of such individual, if the spouse is under 70 years of age during any part of such month)”.

Subsec. (b)(3)(A)(iii). Pub. L. 99-272, §9201(a)(2), struck out “and ending with the month before the month in which such individual attains the age of 70” after “section 426(a) of this title”.

Subsec. (b)(3)(A)(iv). Pub. L. 99-514 substituted “Internal Revenue Code of 1986” for “Internal Revenue Code of 1954”.

Subsec. (b)(4). Pub. L. 99-509, §9319(a), added par. (4).

Subsec. (b)(5). Pub. L. 99-509, §9319(b), added par. (5).

1984—Subsec. (a)(12). Pub. L. 98-369, §2354(b)(30), struck out second comma after “dental procedure”.

Subsec. (b)(1). Pub. L. 98-369, §2344(a), substituted “to be made promptly” for “to be made” and “has been or could be made under such a law” for “has been made under such a law”, and inserted “In order to recover payment made under this subchapter 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 subchapter 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.”

Subsec. (b)(2)(B). Pub. L. 98-369, §2344(b), substituted “has been or could be made under a plan” for “has been made under a plan”, and inserted “In order to recover payment made under this subchapter 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 subchapter 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.”

Subsec. (b)(3)(A)(i). Pub. L. 98-369, §2301(a), struck out “over 64 but” before “under 70 years” in two places.

Subsec. (b)(3)(A)(ii). Pub. L. 98-369, §2344(c), substituted “has been or could be made under a group health plan” for “has been made under a group health plan”, and inserted “In order to recover payment made under this subchapter 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 subchapter 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.”

Subsec. (b)(3)(A)(iii). Pub. L. 98-369, §2354(b)(31), inserted “before the month” after “ending with the month”.

Subsec. (h). Pub. L. 98-369, §2304(c), added subsec. (h).

Subsec. (i). Pub. L. 98-369, §2313(c), added subsec. (i).

1983—Subsec. (a)(1)(A). Pub. L. 98-21, §601(f)(1), inserted reference to subpar. (D).

Subsec. (a)(1)(D). Pub. L. 98-21, §601(f)(2)-(4), added subpar. (D).

Subsec. (a)(14). Pub. L. 98-21, §602(e), added par. (14).

Subsec. (b)(3)(A)(i). Pub. L. 97-448 inserted “in any month” after “service furnished”, and “during any part of such month” after “70 years of age” wherever appearing.

1982—Subsec. (a)(1). Pub. L. 97-248, §122(f)(1), designated existing provisions as subpars. (A) and (B), in subpar. (A) as so designated inserted exception to provisions for items and services described in subpar. (B) or (C), substituted “and” for “or” as the connector between provisions, and added subpar. (C).

Subsec. (a)(6). Pub. L. 97-248, §122(f)(2), inserted “(except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C))”.

Subsec. (a)(7). Pub. L. 97-248, §122(f)(3), substituted “paragraph (1)(B)” for “paragraph (1)”.

Subsec. (a)(9). Pub. L. 97-248, §122(f)(4), inserted “(except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C))”.

Subsec. (b)(1). Pub. L. 97-248, §128(a)(2), struck out “or plan” after “service has been made under such a law”.

Subsec. (b)(2)(A). Pub. L. 97-248, §128(a)(3), substituted “section 162(i)(2)” for “section 162(h)(2)”.

Subsec. (b)(2)(B). Pub. L. 97-248, §128(a)(4), inserted “furnished” before “to an individual”.

Subsec. (b)(3). Pub. L. 97-248, §116(b), added par. (3).

Subsec. (d)(1)(C). Pub. L. 97-248, §148(a), substituted “on the basis of information acquired by the Secretary in the administration of this subchapter” for “, on the basis of reports transmitted to him in accordance with section 1320c-6 of this title (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 subchapter).”

Subsec. (f). Pub. L. 97-248, §122(g)(1), substituted “paragraph (1)(A)” for “paragraph (1)”.

Subsec. (g). Pub. L. 97-248, §142, added subsec. (g).

1981—Subsec. (b). Pub. L. 97-35, §2146(a), designated existing provisions as par. (1) and added par. (2).

Subsec. (c). Pub. L. 97-35, §2103(a)(1), added subsec. (c).

Subsec. (f). Pub. L. 97-35, §2152(a), added subsec. (f).

1980—Subsec. (a)(1). Pub. L. 96-611, §1(a)(3)(A), inserted “, or, in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness” after “of a malformed body member”.

Subsec. (a)(7). Pub. L. 96-611, §1(a)(3)(B), inserted “(except as otherwise allowed under section 1395x(s)(10) of this title and paragraph (1))” after “immunizations”.

Subsec. (a)(12). Pub. L. 96-499, §936(c), inserted “or because of the severity of the dental procedure,” after “and clinical status”.

Subsec. (a)(13)(C). Pub. L. 96-499, §939(a), struck out “, warts,” after “corns”.

Subsec. (b). Pub. L. 96-499, §953, inserted “or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance” and “, policy, plan, or insurance” after “or a State” and “, policy, plan, or insurance” after “law or plan” and inserted provision authorizing the Secretary to waive the provisions of this subsection in the case of an individual claim if he determined that the probability of recovery or amount involved did not warrant the pursuit of the claim.

Subsec. (d)(4). Pub. L. 96-272 added par. (4).

Subsec. (e). Pub. L. 96-499, §913(b), substituted provisions barring payment under this subchapter with respect to items or services furnished by a physician or other individual during a period when such physician or other individual was barred pursuant to section 1320a-7 of this title from participation under this subchapter for provisions authorizing the Secretary to suspend a physician or individual practitioner from participation under this subchapter upon determining that such physician or practitioner had been convicted of a criminal offense related to such physician’s or practitioner’s involvement in the programs under this subchapter or the program under subchapter XIX of this chapter.

1977—Subsec. (a)(3). Pub. L. 95-210 substituted “except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, and in such other cases as the Secretary may specify” for “except in such cases as the Secretary may specify”.

Subsec. (d)(1)(B). Pub. L. 95-142, §13(b)(1), struck out requirement for concurrence of appropriate program review team for finding of Secretary under this paragraph.

Subsec. (d)(1)(C). Pub. L. 95-142, §13(b)(2), substituted provisions relating to determinations by the Secretary on the basis of reports transmitted to him in accordance with section 1320c-6 of this title or other data acquired in the administration of this subchapter, for provisions relating to determinations by the Secretary with the concurrence of appropriate review team members.

Subsec. (d)(4). Pub. L. 95-142, §13(a), struck out par. (4) which set forth provisions relating to appointment and functions of program review teams.

Subsec. (e). Pub. L. 95-142, §7(a), added subsec. (e).

1975—Subsec. (c). Pub. L. 94-182 struck out subsec. (c) prohibiting payments to Federal employees under this subchapter unless a determination and certification by the Secretary of a modification of any health benefits plan under chapter 89 of Title 5 was made which would allow a Federal employee benefits under part A or B of this subchapter.

1974—Subsec. (c). Pub. L. 93-480 substituted “January 1, 1976” for “January 1, 1975”.

1973—Subsec. (a)(12). Pub. L. 93-233 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” for “a dental procedure where the individual suffers from impairments of such severity as to require hospitalization”.

1972—Subsec. (a)(4). Pub. L. 92-603, §211(c)(1), inserted reference to physicians’ services and ambulance services furnished an individual in conjunction with emergency inpatient hospital services.

Subsec. (a)(12). Pub. L. 92-603, §256(c), authorized payment 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.

Subsec. (c). Pub. L. 92-603, §210, added subsec. (c).

Subsec. (d). Pub. L. 92-603, §229(a), added subsec. (d).

1968—Subsec. (a)(7). Pub. L. 90-248, §128, prohibited payment for procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.

Subsec. (a)(13). Pub. L. 90-248, §127(b), added par. (13).

#### EFFECTIVE DATE OF 2018 AMENDMENT

Amendment by section 2008(c), (d) of Pub. L. 115-271 applicable with respect to plan years beginning on or after Jan. 1, 2020, see section 2008(e) of Pub. L. 115-271, set out as a note under section 1395w-27 of this title.

#### EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114-255, div. A, title IV, §4009(b), Dec. 13, 2016, 130 Stat. 1185, provided that: “The amendment made by subsection (a) [amending this section] 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 [Dec. 13, 2016].”

#### EFFECTIVE DATE OF 2015 AMENDMENT

Pub. L. 114-10, title V, §516(b), Apr. 16, 2015, 129 Stat. 175, provided that: “The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Apr. 16, 2015] and shall apply to information required to be provided on or after January 1, 2016.”

#### EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 112-242, title II, §202(b), Jan. 10, 2013, 126 Stat. 2380, provided that: “The amendments made by subsection (a) [amending this section] shall apply to years beginning with 2014.”

Pub. L. 112-242, title II, §205(b), Jan. 10, 2013, 126 Stat. 2381, provided that: “The amendment made by subsection (a) [amending 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 [Jan. 10, 2013].”

#### EFFECTIVE DATE OF 2011 AMENDMENT

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

#### EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 4103(d) of Pub. L. 111-148 applicable to services furnished on or after Jan. 1, 2011, see section 4103(e) of Pub. L. 111-148, set out as a note under section 1395l of this title.

#### EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 101(a)(3), (b)(3), (4) of Pub. L. 110-275 applicable to services furnished on or after Jan. 1, 2009, see section 101(c) of Pub. L. 110-275, set out as a note under section 1395l of this title.

Pub. L. 110-275, title I, §135(a)(2)(B), July 15, 2008, 122 Stat. 2535, provided that: “The amendments made by

this paragraph [amending this section] shall apply to advanced diagnostic imaging services furnished on or after January 1, 2012.”

Amendment by section 143(b)(7) of Pub. L. 110-275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110-275, set out as a note under section 1395k of this title.

Amendment by section 152(b)(1)(D) of Pub. L. 110-275 applicable to services furnished on or after Jan. 1, 2010, see section 152(b)(2) of Pub. L. 110-275, set out as a note under section 1395w-4 of this title.

#### EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by Pub. L. 109-171 applicable to services furnished on or after Jan. 1, 2007, see section 5112(f) of Pub. L. 109-171, set out as a note under section 1395l of this title.

#### EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108-173, title III, §301(d), Dec. 8, 2003, 117 Stat. 2222, provided that: “The amendments made by this section [amending this section] shall be effective—

“(1) in the case of subsection (a), as if included in the enactment of title III [sic] of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369); and

“(2) in the case of subsections (b) and (c), as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980 (Public Law 96-499; 94 Stat. 2647).”

Amendment by section 611(d)(1) of Pub. L. 108-173 applicable to services furnished on or after Jan. 1, 2005, but only for individuals whose coverage period under this part begins on or after such date, see section 611(e) of Pub. L. 108-173, set out as a note under section 1395w-4 of this title.

Amendment by section 612(c) of Pub. L. 108-173 applicable to tests furnished on or after Jan. 1, 2005, see section 612(d) of Pub. L. 108-173, set out as a note under section 1395x of this title.

Amendment by section 613(c) of Pub. L. 108-173 applicable to tests furnished on or after Jan. 1, 2005, see section 613(d) of Pub. L. 108-173, set out as a note under section 1395x of this title.

Pub. L. 108-173, title VII, §731(a)(2), Dec. 8, 2003, 117 Stat. 2351, provided that: “The amendments made by paragraph (1) [amending this section] shall apply to national coverage determinations as of January 1, 2004, and section 1862(l)(5) of the Social Security Act [42 U.S.C. 1395y(l)(5)], as added by such paragraph, shall apply to local coverage determinations made on or after July 1, 2004.”

Pub. L. 108-173, title VII, §731(b)(2), Dec. 8, 2003, 117 Stat. 2351, provided that: “The amendment made by paragraph (1) [amending 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 [42 U.S.C. 1395y(m)], as added by such paragraph.”

Pub. L. 108-173, title IX, §944(a)(2), Dec. 8, 2003, 117 Stat. 2423, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to items and services furnished on or after January 1, 2004.”

Amendment by section 948(a) of Pub. L. 108-173 effective, except as otherwise provided, as if included in the enactment of BIPA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, H.R. 5661, as enacted by section 1(a)(6) of Public Law 106-554], see section 948(e) of Pub. L. 108-173, set out as a note under section 1314 of this title.

Pub. L. 108-173, title IX, §950(b), Dec. 8, 2003, 117 Stat. 2427, provided that: “The amendment made by subsection (a) [amending this section] shall take effect on the date that is 60 days after the date of the enactment of this Act [Dec. 8, 2003].”

#### EFFECTIVE DATE OF 2001 AMENDMENT

Pub. L. 107-105, §3(b), Dec. 27, 2001, 115 Stat. 1007, provided that: “The amendments made by subsection (a)

[amending this section] shall apply to claims submitted on or after October 16, 2003.”

#### EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title I, §102(c)] of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I, §102(d)] of Pub. L. 106-554, set out as a note under section 1395x of this title.

Amendment by section 1(a)(6) [title III, §313(a)] of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2001, see section 1(a)(6) [title III, §313(c)] of Pub. L. 106-554, set out as a note under section 1395u of this title.

Amendment by section 1(a)(6) [title IV, §432(b)(1)] of Pub. L. 106-554 applicable to services furnished on or after July 1, 2001 see section 1(a)(6) [title IV, §432(c)] of Pub. L. 106-554, set out as a note under section 1395u of this title.

Amendment by section 1(a)(6) [title V, §522(b)] of Pub. L. 106-554 applicable with respect to a review of any national or local coverage determination filed, a request to make such a determination made, and a national coverage determination made, on or after Oct. 1, 2001, see section 1(a)(6) [title V, §522(d)] of Pub. L. 106-554, set out as a note under section 1314 of this title.

#### EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(6) [title III, §305(b)] of Pub. L. 106-113 applicable to payments for services provided on or after Nov. 29, 1999, see §1000(a)(6) [title III, §305(c)] of Pub. L. 106-113, set out as a note under section 1395u of this title.

Amendment by section 1000(a)(6) [title III, §321(k)(10)] of Pub. L. 106-113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105-33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106-113, set out as a note under section 1395d of this title.

#### EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-12 effective Apr. 30, 1997, and applicable to Federal payments made pursuant to obligations incurred after Apr. 30, 1997, for items and services provided on or after such date, subject to also being applicable with respect to contracts entered into, renewed, or extended after Apr. 30, 1997, as well as contracts entered into before Apr. 30, 1997, to the extent permitted under such contracts, see section 11 of Pub. L. 105-12, set out as an Effective Date note under section 14401 of this title.

Amendment by section 4022(b)(1)(B) of Pub. L. 105-33 effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105-33, set out as an Effective Date; Transition; Transfer of Functions note under section 1395b-6 of this title.

Amendment by section 4102(c) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Amendment by section 4103(c) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 2000, see section 4103(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Amendment by section 4104(c)(3) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

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

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

Amendment by section 4507(a)(2)(B) of Pub. L. 105-33 applicable with respect to contracts entered into on

and after Jan. 1, 1998, see section 4507(c) of Pub. L. 105-33, set out as a note under section 1395a of this title.

Amendment by section 4511(a)(2)(C) of Pub. L. 105-33 applicable with respect to services furnished and supplies provided on and after Jan. 1, 1998, see section 4511(e) of Pub. L. 105-33, set out as a note under section 1395k of this title.

Amendment by section 4541(b) of Pub. L. 105-33 applicable to services furnished on or after Jan. 1, 1998, including portions of cost reporting periods occurring on or after such date, see section 4541(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

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

Pub. L. 105-33, title IV, §4614(c), Aug. 5, 1997, 111 Stat. 475, provided that: "The amendments made by this section [amending this section] apply to services furnished on or after October 1, 1997."

Pub. L. 105-33, title IV, §4632(b), Aug. 5, 1997, 111 Stat. 486, provided that: "The amendments made by this section [amending this section] apply to items and services furnished on or after the date of the enactment of this Act [Aug. 5, 1997]."

Pub. L. 105-33, title IV, §4633(c), Aug. 5, 1997, 111 Stat. 487, provided that: "The amendments made by this section [amending this section] apply to items and services furnished on or after the date of the enactment of this Act [Aug. 5, 1997]."

#### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 145(c)(1) of Pub. L. 103-432 applicable to mammography furnished by a facility on and after the first date that the certificate requirements of section 263b(b) of this title apply to such mammography conducted by such facility, see section 145(d) of Pub. L. 103-432, set out as a note under section 1395m of this title.

Amendment by section 147(e)(6) of Pub. L. 103-432 effective as if included in the enactment of Pub. L. 101-508, see section 147(g) of Pub. L. 103-432, set out as a note under section 1320a-3a of this title.

Pub. L. 103-432, title I, §151(a)(2)(B), Oct. 31, 1994, 108 Stat. 4433, provided that: "The amendment made by subparagraph (A) [amending 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 [Oct. 31, 1994]."

Pub. L. 103-432, title I, §151(b)(3)(C), Oct. 31, 1994, 108 Stat. 4434, provided that: "The amendments made by this paragraph [amending this section] shall apply to payments for items and services furnished on or after the date of the enactment of this Act [Oct. 31, 1994]."

Pub. L. 103-432, title I, §151(c)(1), (9), Oct. 31, 1994, 108 Stat. 4435, 4436, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103-66.

Pub. L. 103-432, title I, §151(c)(4), Oct. 31, 1994, 108 Stat. 4435, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 101-508.

Pub. L. 103-432, title I, §151(c)(5), (6), Oct. 31, 1994, 108 Stat. 4436, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 101-239.

Amendment by section 156(a)(2)(D) of Pub. L. 103-432 applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103-432, set out as a note under section 1320c-3 of this title.

Pub. L. 103-432, title I, §157(b)(8), Oct. 31, 1994, 108 Stat. 4442, provided that: "The amendments made by this subsection [amending this section, section 1395mm of this title, and provisions set out as notes under section 1395mm of this title] shall take effect as if included in the enactment of OBRA-1990 [Pub. L. 101-508]."

#### EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103-432, title I, §151(c)(10), Oct. 31, 1994, 108 Stat. 4436, provided that: "The amendment made by

section 13561(e)(1)(G) of OBRA-1993 [Pub. L. 103-66, amending 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 [Pub. L. 101-239]."

Amendment by section 13561(d)(1) of Pub. L. 103-66 effective 90 days after Aug. 10, 1993, see section 13561(d)(3) of Pub. L. 103-66, set out as a note under section 5000 of Title 26, Internal Revenue Code.

Pub. L. 103-66, title XIII, §13561(e)(1)(D), Aug. 10, 1993, 107 Stat. 595, as amended by Pub. L. 103-432, title I, §151(c)(9)(A), Oct. 31, 1994, 108 Stat. 4436, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 101-239.

Pub. L. 103-66, title XIII, §13581(d), Aug. 10, 1993, 107 Stat. 611, provided that: "The amendments made by this section [enacting section 1320b-14 of this title and amending this section, section 1396a of this title, and section 552a of Title 5, Government Organization and Employees] shall take effect on January 1, 1994."

#### EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4153(b)(2)(B) of Pub. L. 101-508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(b)(2)(C) of Pub. L. 101-508, set out as a note under section 1395x of this title.

Amendment by section 4157(c)(1) of Pub. L. 101-508 applicable to services furnished on or after Jan. 1, 1991, see section 4157(d) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Amendment by section 4161(a)(3)(C) of Pub. L. 101-508 applicable to services furnished on or after Oct. 1, 1991, see section 4161(a)(8) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Amendment by section 4163(d)(2)(A)(i)-(iii), (B) of Pub. L. 101-508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101-508, as amended, set out as a note under section 1395l of this title.

Pub. L. 101-508, title IV, §4163(d)(3), as added by Pub. L. 103-432, title I, §147(f)(5)(A), Oct. 31, 1994, 108 Stat. 4431, provided that: "The amendment made by paragraph (2)(A)(iv) [amending this section] shall apply to screening pap smears performed on or after July 1, 1990."

Pub. L. 101-508, title IV, §4204(g)(2), Nov. 5, 1990, 104 Stat. 1388-112, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to incentives offered on or after the date of the enactment of this Act [Nov. 5, 1990]."

#### EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6115(b) of Pub. L. 101-239 applicable to screening pap smears performed on or after July 1, 1990, see section 6115(d) of Pub. L. 101-239, set out as a note under section 1395x of this title.

Amendment by section 6202(b)(1) of Pub. L. 101-239 applicable to items and services furnished after Dec. 19, 1989, see section 6202(b)(5) of Pub. L. 101-239, set out as a note under section 162 of Title 26, Internal Revenue Code.

Pub. L. 101-239, title VI, §6202(e)(2), Dec. 19, 1989, 103 Stat. 2235, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to items and services furnished on or after October 1, 1989."

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

#### EFFECTIVE DATE OF 1988 AMENDMENT

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

Amendment by section 202(d) of Pub. L. 100-360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100-360, set out as a note under section 1395u of this title.

Amendment by section 204(d)(2) of Pub. L. 100-360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100-360, set out as a note under section 1395m of this title.

Amendment by section 205(e)(1) of Pub. L. 100-360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100-360, set out as a note under section 1395k of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(i)(4)(D) of Pub. L. 100-360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, effective as if included in the enactment of that provision in Pub. L. 100-203, see section 411(a) of Pub. L. 100-360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Pub. L. 100-360, title IV, § 411(f)(4)(D)(ii), July 1, 1988, 102 Stat. 778, provided that: "The amendment made by clause (i) [amending this section] shall apply to operations performed on or after 60 days after the date of the enactment of this Act [July 1, 1988]."

#### EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100-203, title IV, § 4009(j)(6), Dec. 22, 1987, 101 Stat. 1330-59, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 99-509.

Pub. L. 100-203, title IV, § 4034(b), Dec. 22, 1987, 101 Stat. 1330-77, provided that: "The amendment made by subsection (a) [amending this section] shall be effective as if included in the enactment of section 9319(a) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99-509]."

Pub. L. 100-203, title IV, § 4036(a)(2), Dec. 22, 1987, 101 Stat. 1330-79, provided that: "The amendment made by paragraph (1) [amending 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 [Dec. 22, 1987]."

Pub. L. 100-203, title IV, § 4039(c)(2), Dec. 22, 1987, 101 Stat. 1330-82, provided that: "The amendments made by paragraph (1) [amending this section] shall become effective on January 1, 1988."

For effective date of amendment by section 4072(c) of Pub. L. 100-203, see section 4072(e) of Pub. L. 100-203, set out as a note under section 1395x of this title.

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

#### EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-509, title IX, § 9319(f), Oct. 21, 1986, 100 Stat. 2013, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [enacting section 5000 of Title 26, Internal Revenue Code, and amending this section and sections 1395p and 1395r of this title] shall apply to items and services furnished on or after January 1, 1987.

"(2) The amendments made by subsection (c) [amending sections 1395p and 1395r of this title] shall apply to enrollments occurring on or after January 1, 1987."

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

Amendment by section 9343(c)(1) of Pub. L. 99-509 applicable to services furnished after June 30, 1987, see section 9343(h)(2) of Pub. L. 99-509, as amended, set out as a note under section 1395l of this title.

Pub. L. 99-272, title IX, § 9201(d)(1), Apr. 7, 1986, 100 Stat. 171, provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to items and services furnished on or after May 1, 1986."

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

#### EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98-369, div. B, title III, § 2301(c)(1), July 18, 1984, 98 Stat. 1063, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to items and services furnished on or after January 1, 1985."

Amendment by section 2304(c) of Pub. L. 98-369 applicable to pacemaker devices and leads implanted or removed on or after the effective date of final regulations promulgated to carry out such amendment, see section 2304(d) of Pub. L. 98-369, set out as a note below.

Pub. L. 98-369, div. B, title III, § 2313(e), July 18, 1984, 98 Stat. 1079, provided that: "The amendments made by this section [amending this section and section 1395ww of this title] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Pub. L. 98-369, div. B, title III, § 2344(d), July 18, 1984, 98 Stat. 1096, provided that: "The amendments made by this section [amending this section] shall apply to items and services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2354(b)(30), (31) of Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

#### EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by section 601(f) of Pub. L. 98-21 applicable to items and services furnished by or under arrangement with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, and amendment by section 602(e)(3) of Pub. L. 98-21 effective Oct. 1, 1983, see section 604(a)(1), (2) of Pub. L. 98-21, set out as a note under section 1395ww of this title.

Amendment by Pub. L. 97-448 effective as if originally included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248, see section 309(c)(2) of Pub. L. 97-448, set out as a note under section 426-1 of this title.

#### EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by section 116(b) of Pub. L. 97-248 applicable with respect to items and services furnished on or after Jan. 1, 1983, see section 116(c) of Pub. L. 97-248, set out as a note under section 623 of Title 29, Labor.

Amendment by section 122(f), (g)(1) of Pub. L. 97-248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97-248, as amended, set out as a note under section 1395c of this title.

Amendment by section 128(a)(2)-(4) of Pub. L. 97-248 effective as if originally included as part of this section as this section was amended by the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, see section 128(e)(2) of Pub. L. 97-248, set out as a note under section 1395x of this title.

Amendment by sections 142 and 148(a) of Pub. L. 97-248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97-248, set out as an Effective Date note under section 1320c of this title.

#### EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97-35, title XXI, § 2103(a)(2), Aug. 13, 1981, 95 Stat. 787, provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to expenses incurred on or after October 1, 1981."

Pub. L. 97-35, title XXI, §2146(c)(1), Aug. 13, 1981, 95 Stat. 801, provided that: “The amendments made by subsection (a) [amending this section] shall become effective on October 1, 1981.”

#### EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-611 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96-611, set out as a note under section 1395l of this title.

Amendment by section 936(c) of Pub. L. 96-499 applicable with respect to services provided on or after July 1, 1981, see section 936(d) of Pub. L. 96-499, set out as a note under section 1395f of this title.

Pub. L. 96-499, title IX, §939(b), Dec. 5, 1980, 94 Stat. 2640, provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to services furnished on or after July 1, 1981.”

#### EFFECTIVE DATE OF 1977 AMENDMENT

Amendment by Pub. L. 95-210 applicable to services rendered on or after first day of third calendar month which begins after Dec. 31, 1977, see section 1(j) of Pub. L. 95-210, set out as a note under section 1395k of this title.

Pub. L. 95-142, §13(c), Oct. 25, 1977, 91 Stat. 1198, provided that: “The amendments made by this section [amending this section and sections 1320c-6 and 1395cc of this title] shall take effect on the date of the enactment of this Act [Oct. 25, 1977].”

#### EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93-233 effective with respect to admissions subject to the provisions of section 1395(a)(2) of this title which occur after Dec. 31, 1973, see section 18(z-3)(2) of Pub. L. 93-233, set out as a note under section 1395f of this title.

#### EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 211(c)(1) of Pub. L. 92-603 applicable to services furnished with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 92-603, set out as a note under section 1395f of this title.

Amendment by section 256(c) of Pub. L. 92-603 applicable with respect to admissions occurring after the second month following the month of enactment of Pub. L. 92-603 which was approved on Oct. 30, 1972, see section 256(d) of Pub. L. 92-603, set out as a note under section 1395f of this title.

#### EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 127(b) of Pub. L. 90-248 applicable with respect to services furnished after Dec. 31, 1967, see section 127(c) of Pub. L. 90-248, set out as a note under section 1395x of this title.

#### CONSTRUCTION OF 2008 AMENDMENT

For construction of amendment by section 153(b)(2) of Pub. L. 110-275, see section 153(b)(4) of Pub. L. 110-275, set out as a note under section 1395rr of this title.

#### CONSTRUCTION OF 2007 AMENDMENT

Pub. L. 110-173, title I, §111(b), Dec. 29, 2007, 121 Stat. 2499, provided that: “Nothing in the amendments made by this section [amending 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 U.S.C. 1395 et seq.], including under parts C and D of such title.”

#### CONSTRUCTION OF 2003 AMENDMENT

Pub. L. 108-173, title VII, §731(b)(3), Dec. 8, 2003, 117 Stat. 2351, provided that: “Nothing in the amendment made by paragraph (1) [amending this section] shall be construed as applying to, or affecting, coverage or payment for a nonexperimental/investigational (category B) device.”

#### APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108-173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108-173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108-173 (see note above), amendment by section 303 of Pub. L. 108-173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108-173, set out as a note under section 1395u of this title.

#### TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS

Pub. L. 108-173, title IX, §943, Dec. 8, 2003, 117 Stat. 2422, provided that:

“(a) IN GENERAL.—The Secretary [of Health and Human Services] 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 [42 U.S.C. 1395y(b)] (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 [probably means part A of title XVIII of the Social Security Act which is classified to part A of this subchapter] or enrolled under part B [probably means part B of title XVIII of the Social Security Act which is classified to 42 U.S.C. 1395j et seq.], or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.”

#### ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS

Pub. L. 108-173, title IX, §953(b), Dec. 8, 2003, 117 Stat. 2428, provided that: “The Secretary [of Health and Human Services] 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 U.S.C. 1395 et seq.] in the previous year and information on how to get more information with respect to such determinations.”

#### NOTIFICATION TO PHYSICIANS OF EXCESSIVE HOME HEALTH VISITS

Pub. L. 105-33, title IV, §4614(b), Aug. 5, 1997, 111 Stat. 474, provided that: “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 U.S.C. 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.”

#### DISTRIBUTION OF QUESTIONNAIRE BY CONTRACTOR

Pub. L. 103-432, title I, §151(a)(1)(B), Oct. 31, 1994, 108 Stat. 4433, provided that: “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 en-



actment of the Social Security Act Amendments of 1994 [Oct. 31, 1994], to distribute the questionnaire described in section 1862(b)(5)(D) of the Social Security Act [42 U.S.C. 1395y(b)(5)(D)] (as added by subparagraph (A)).”

RETROACTIVE EXEMPTION FOR CERTAIN SITUATIONS INVOLVING RELIGIOUS ORDERS

Pub. L. 103-66, title XIII, §13561(f), Aug. 10, 1993, 107 Stat. 595, provided that: “Section 1862(b)(1)(D) of the Social Security Act [42 U.S.C. 1395y(b)(1)(D)] 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.”

GAO STUDY OF EXTENSION OF SECONDARY PAYER PERIOD

Pub. L. 101-508, title IV, §4203(c)(2), Nov. 5, 1990, 104 Stat. 1388-108, as amended by Pub. L. 103-432, title I, §151(c)(7), Oct. 31, 1994, 108 Stat. 4436, directed Comptroller General to conduct study of impact of second sentence of subsec. (b)(1)(C) of this section and to submit preliminary report to Congress not later than Jan. 1, 1993, and final report not later than Jan. 1, 1995.

DEADLINE FOR FIRST TRANSMITTAL AND REQUEST OF MATCHING INFORMATION

Pub. L. 101-239, title VI, §6202(a)(2)(B), Dec. 19, 1989, 103 Stat. 2229, provided that: “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 [42 U.S.C. 1395y(b)(5)(A)(i)] (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 U.S.C. 6013(l)(12)(A)], by not later than 14 days after the date of the enactment of this Act [Dec. 19, 1989].”

DESIGNATION OF PEDIATRIC HOSPITALS AS MEETING CERTIFICATION AS HEART TRANSPLANT FACILITY

Pub. L. 100-203, title IV, §4009(b), Dec. 22, 1987, 101 Stat. 1330-57, provided that: “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 [42 U.S.C. 1395y(a)(1)(A)], 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.”

APPROVAL OF SURGICAL ASSISTANTS FOR PROCEDURES PERFORMED APRIL 1, 1986, TO DECEMBER 15, 1986

Pub. L. 99-514, title XVIII, §1895(b)(16)(C), Oct. 22, 1986, 100 Stat. 2934, provided that: “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.”

EXTENDING WAIVER OF LIABILITY PROVISIONS TO HOSPICE PROGRAMS

Pub. L. 99-509, title IX, §9305(f), Oct. 21, 1986, 100 Stat. 1991, as amended by Pub. L. 100-360, title IV, §426(a), July 1, 1988, 102 Stat. 814; Pub. L. 101-508, title IV, §4008(a)(2), Nov. 5, 1990, 104 Stat. 1388-44, provided that:

“(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 [42 U.S.C. 1395y(a)(1)(C)], apply (under section 1879(a) of such Act [42 U.S.C. 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 [Oct. 21, 1986] and before December 31, 1995.”

[Pub. L. 101-508, title IV, §4008(a)(3), Nov. 5, 1990, 104 Stat. 1388-44, provided that: “The amendments made by paragraphs (1) and (2) [amending section 9305(f) of Pub. L. 99-509, set out above, and section 9126(c) of Pub. L. 99-272, set out below] shall take effect on the date of the enactment of this Act [Nov. 5, 1990].”]

STUDY OF IMPACT ON DISABLED BENEFICIARIES AND FAMILY OF AMENDMENTS RELATING TO LARGE GROUP HEALTH PLANS AND MEDICARE AS SECONDARY PAYER

Pub. L. 99-509, title IX, §9319(e), Oct. 21, 1986, 100 Stat. 2012, directed Comptroller General to study and report to Congress, not later than Mar. 1, 1990, the impact of the amendments made by this section (enacting section 5000 of Title 26, Internal Revenue Code, and amending this section and sections 1395p and 1395r of this title) on access of disabled individuals and members of their family to employment and health insurance, such report to include information relating to number of disabled medicare beneficiaries for whom medicare has become secondary, either through their employment or the employment of a family member, amount of savings to the medicare program achieved annually through this provision, and effect on employment, and employment-based health coverage, of disabled individuals and family members.

REINSTATEMENT OF WAIVER OF LIABILITY PRESUMPTION

Pub. L. 99-272, title IX, §9126(c), Apr. 7, 1986, 100 Stat. 170, as amended by Pub. L. 100-360, title IV, §426(b), July 1, 1988, 102 Stat. 814; Pub. L. 101-508, title IV, §4008(a)(1), Nov. 5, 1990, 104 Stat. 1388-44, provided that: “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 [42 U.S.C. 1395y(a)(1)(A)], 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 [Apr. 7, 1986] and ending on December 31, 1995.”

HOME HEALTH WAIVER OF LIABILITY

Pub. L. 99-272, title IX, §9205, Apr. 7, 1986, 100 Stat. 178, as amended by Pub. L. 100-360, title IV, §426(d), July 1, 1988, 102 Stat. 814; Pub. L. 103-432, title I, §158(b)(1), Oct. 31, 1994, 108 Stat. 4442, provided that: “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 [42 U.S.C. 1395y(a)(1)(A)], 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.”

[Pub. L. 103-432, title I, §158(b)(2), Oct. 31, 1994, 108 Stat. 4443, provided that: "The amendment made by paragraph (1) [amending section 9205 of Pub. L. 99-272, set out above] shall take effect as if included in the enactment of OBRA-1990 [Pub. L. 101-508]."]

RECOMMENDATIONS AND GUIDELINES FOR ELIMINATION OF ASSISTANTS AT SURGERY; REPORT TO CONGRESS

Pub. L. 99-272, title IX, §9307(d), Apr. 7, 1986, 100 Stat. 194, provided that the Secretary of Health and Human Services, after consultation with the Physician Payment Review Commission, develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery was generally not medically necessary and circumstances under which use of an assistant at surgery was generally appropriate but should be subject to prior approval of an appropriate entity and that the Secretary report to Congress, not later than January 1, 1987, on these recommendations and guidelines.

PACEMAKER REIMBURSEMENT REVIEW AND REFORM; PROMULGATION OF REGULATIONS; EFFECTIVE DATE OF PACEMAKER REGISTRATION

Pub. L. 98-369, div. B, title III, §2304(d), July 18, 1984, 98 Stat. 1069, provided that: "The Secretary of Health and Human Services shall promulgate final regulations to carry out this section and the amendment made by this section [amending this section and enacting provisions set out as a note under section 1395f of this title] prior to January 1, 1985, and the amendment made by subsection (c) [amending this section] shall apply to pacemaker devices and leads implanted or removed on or after the effective date of such regulations."

PAYMENT FOR DEBRIDEMENT OF MYCOTIC TOENAILS

Pub. L. 98-369, div. B, title III, §2325, July 18, 1984, 98 Stat. 1087, provided that: "The Secretary shall provide, pursuant to section 1862(a) of the Social Security Act [42 U.S.C. 1395y(a)], that payment will not be made under part B of title XVIII of such Act [42 U.S.C. 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."

INTERIM WAIVER IN CERTAIN CASES OF BILLING RULE FOR ITEMS AND SERVICES OTHER THAN PHYSICIANS' SERVICES

Pub. L. 98-21, title VI, §602(k), Apr. 20, 1983, 97 Stat. 165, as amended by Pub. L. 99-272, title IX, §9112(a), Apr. 7, 1986, 100 Stat. 163, provided that:

"(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 [42 U.S.C. 1395y(a)(14), 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 U.S.C. 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 but that the payments to such hospital under part A of such title [42 U.S.C. 1395c et seq.] shall be reduced by the amount of the billings for such services under part B of such title. 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 as is appropriate, given the organizational structure of the institution.

"(2) 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 all the payments which are made under part B of such title solely by reason of such waiver.

"(3) 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 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."

[Pub. L. 99-272, title IX, §9112(b), Apr. 7, 1986, 100 Stat. 163, provided that:

"(1) Section 602(k)(2) of the Social Security Amendments of 1983 (as added by subsection (a)) [set out above] shall apply to cost reporting periods beginning on or after January 1, 1986.

"(2) Section 602(k)(3) of the Social Security Amendments of 1983 (as added by subsection (a)) [set out above] shall apply to items and services furnished after the end of the 10-day period beginning on the date of the enactment of this Act [Apr. 7, 1986]."]

PROHIBITION OF PAYMENT FOR INEFFECTIVE DRUGS

Pub. L. 97-248, title I, §115(b), Sept. 3, 1982, 96 Stat. 353, provided that: "No provision of law limiting the use of funds for purposes of enforcing or implementing section 1862(c) [42 U.S.C. 1395y(c)] or section 1903(i)(5) [42 U.S.C. 1396b(i)(5)] of the Social Security Act, section 2103 of the Omnibus Budget Reconciliation Act of 1981 [section 2103 of Pub. L. 97-35, amending sections 1395y and 1396b of this title and enacting provisions set out as notes under sections 1395y and 1396b of this title], 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 [Sept. 3, 1982] and specifically states that such provision is to supersede this section."

ESTABLISHMENT AND IMPLEMENTATION OF GUIDELINES

Pub. L. 97-35, title XXI, §2152(b), Aug. 13, 1981, 95 Stat. 802, directed the Secretary of Health and Human Services to establish, and provide for the implementation of, the guidelines described in subsec. (f) of this section not later than Oct. 1, 1981.

REPORT TO CONGRESSIONAL COMMITTEES ON IMPLEMENTATION OF CERTIFICATION REQUIREMENTS RELATING TO MODIFICATION OF HEALTH BENEFITS PLAN OR PROGRAM; FAILURE TO SUBMIT REPORT

Pub. L. 93-480, §4(b), Oct. 26, 1974, 88 Stat. 1454, provided that the Civil Service Commission and the Secretary of Health, Education, and Welfare submit a report on or before Mar. 1, 1975, on the steps which have been taken, and the steps which are planned, to enable the Secretary to make the determination and certification referred to in former subsec. (c) of this section and that if such report is not submitted by Mar. 1, 1975, the date specified in former subsec. (c) shall be deemed to be July 1, 1975, rather than Jan. 1, 1976.

**§ 1395z. Consultation with State agencies and other organizations to develop conditions of participation for providers of services**

In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15),<sup>1</sup> (o)(6), (cc)(2)(I), and<sup>2</sup> (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title, the Secretary shall

<sup>1</sup> See References in Text note below.

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