



MAY 13, 2009

CIRCULAR NO. 13/09

TO MEMBERS OF THE ASSOCIATION

Dear Member:

US MEDICARE: NEW LEGISLATION ON COMPULSORY REPORTING OF PAYMENTS TO US BENEFICIARIES

Under a new US law entering into force on July 1, 2009, any business entity that pays any health insurance benefits or personal injury settlements or judgments to any US Medicare beneficiaries, which could include seamen, harbor workers, passengers and others, must promptly report each such payment to the US Government's Centers for Medicare and Medicaid Services (CMS) via the Medicare Coordinator of Benefits Contractor (COBC). The penalties for failing to make the required reports are steep, being \$1,000 per day for each day of non-compliance, per claimant.

Moreover, if Medicare pays any medical care expenses to a Medicare beneficiary that should have been paid by a "primary payer", Medicare is entitled to recover those payments from the primary payer. If prompt payment is not made to Medicare, on its demand, the US Government is authorized to sue the primary payer and recover *double* the amount Medicare paid, plus interest.

The purposes of the new requirements are (1) to protect the US Medicare system from making payments in situations in which a private insurer and/or a tortfeasor is deemed to be the "primary payer" obligated to make payment(s) to the Medicare beneficiary, and (2) to avoid possible duplicate payments to the Medicare beneficiary.

As Members may be aware, most US citizens and residents age 65 or older, and certain disabled US citizens and residents are, or may be eligible for Medicare benefits. Medicare is a form of health insurance provided to its beneficiaries under US law. Medicare pays for medical care resulting from illness or accidental injury.

Medicare beneficiaries may also be covered by other forms of group health plans and/or may be entitled to settlement payments or judgments if they are injured as a result of accidents or occurrences, including exposure to toxic substances.

If a Medicare beneficiary is reasonably expected to be entitled to payments from a tortfeasor or under an insurance policy or a health plan, with respect to expenses covered by Medicare, US law has long provided that all such payments must be exhausted before Medicare becomes liable to pay any benefits to a Medicare beneficiary. In those situations, the US Government takes the position that Medicare is the "secondary payer", and that another entity, including one with liability insurance or a health plan or a tortfeasor (each broadly defined), is the "primary payer."

The new US law is both very broad and highly complex, and the Managers have received reports on it from various US attorneys, some of whose opinions are conflicting. US courts, unfortunately, also differ on Medicare coverage and reporting issues, although all of the reported court decisions predate the new reporting law and, in some of those cases, the US Government was not a party, and thus may not be bound thereby.

In the view of your Managers, the safest, most prudent approaches for each Member should include the following steps:

1. Promptly become familiar with the terms of the new law, Social Security Act §1862(b), 42 U.S.C. § 1395 y(b)(2), "Medicare as Secondary Payer", copy attached. The more relevant portions of the new law begin on page 7 of the attachment. There are also numerous reports on line regarding this new law, which is part of Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007. [Search: "Medicare as Secondary Payer" on Google or other search engines.]

2. Assume that your company will be deemed by the US Government to be a "primary payer" if your company routinely pays claims involving seamen, harbor workers, passengers or others who are or may be Medicare beneficiaries or if it is likely that your company will soon pay any sums to such persons; and promptly commence the process of registering as a "Responsible Reporting Entity" ("RRE") with the COBC. For further information please refer to: www.cms.hhs.gov/MandatoryInsRep. The government has not as yet published all reporting details, your Managers understand.

By way of comment, it is worth noting that Club Members, in the first instance, must pay the full amounts of the costs of cure benefits for their seamen employees and pay the full amounts of any settlements with, or judgments obtained by, their employees and others arising from accidents, before seeking Club indemnity (less the agreed deductible). Thus, a US court could well deem the Member to be the "primary payer" under an "applicable [group health] plan". An "applicable plan" includes "liability insurance (including self-insurance)". Please refer to 42 U.S.C. 1395 y(b)(8)(F).

Although "cure" is not mentioned by name in the new law, cure is a health benefit which must be provided to seamen by their employers, whether or not the employers have insurance to cover that liability. Shipowners and other employers of seamen typically insure such liabilities with P&I clubs, but "self insure" to the extent of their deductibles, which, in many cases, are substantial.

3. Your Managers recommend that payments of cure by any Member to any Medicare beneficiary should be reported to Medicare along with reports of settlements or judgments in respect of personal injuries.

4. If there is any doubt as to whether an employee or another claimant is entitled to Medicare benefits, so that payments to such persons must be reported to Medicare, the claimant's status must be verified, if necessary, through an inquiry to Medicare based upon the claimant's name, social security number, and date of birth. Please note that reports are also required if the claimant will become eligible for Medicare benefits within 30 months of the payment.

5. To the extent that any part of any payment of a settlement or judgment to a Medicare beneficiary may be intended to cover future medical care, there must be a "Medicare Set Aside" ("MSA") for such future care. The amount of the MSA should be approved by Medicare and held in escrow by a responsible entity, if possible someone other than the claimant or his attorney. If

an MSA is not approved by Medicare and is later deemed insufficient by Medicare or is spent by the beneficiary, the primary payer may well be required to pay an additional sum to Medicare to cover any deficit. The above penalties may be applicable also.

By way of comment, it is also worth noting that experience to date has shown that Medicare may or may not respond to the Member's request for approval of an MSA. The fact that the Member has sought Medicare's approval of an MSA should help if a dispute with Medicare on the adequacy of the MSA later develops.

6. While each primary payer must register with Medicare as an RRE, such entity may engage an agent, a specialist in this field, to make the required inquiries and reports to Medicare. Proper reporting to Medicare, however, remains the primary payer's responsibility.

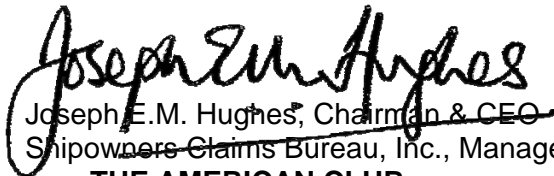
7. When seeking indemnity from the Club for payments to persons who are or may become Medicare beneficiaries, the Managers must be informed whether Medicare has confirmed that such person is or is not a Medicare beneficiary, or will or will not become a Medicare beneficiary within 30 months of the payment and, if the person is or will be a Medicare beneficiary, whether required reports have been made to Medicare and Medicare has approved any MSA and who will hold and disburse the MSA.

The foregoing is an outline only. ***If there is any possibility that your company may make payments to or on behalf of a Medicare beneficiary for medical care, you are encouraged to consult with an attorney of your choice to further clarify your obligations to Medicare.*** Please let the Managers know promptly if such attorney differs with any of the above comments and recommendations.

Your Managers are consulting with the managers of other P&I clubs in the International Group and considering jointly retaining a US attorney familiar with Medicare to advise the clubs on the new law. Your Managers will advise further, if any views different from the above are developed.

As always, your Managers are available to assist, should Members have questions. Your Managers can make recommendations as to consultants familiar with the new Medicare requirements, including attorneys and entities which can assist in reporting to Medicare, should recommendations be requested.

Yours faithfully,



Joseph E.M. Hughes, Chairman & CEO
Shipowners Claims Bureau, Inc., Managers for

THE AMERICAN CLUB

Compilation of the Social Security Laws

Social Security Online

[Social Security Act Home](#)

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER^[488]



[The Underlined section starts on page 5.]

Sec. 1862. [42 U.S.C. 1395y] (a) Notwithstanding any other provision of this title, 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, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness,

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

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

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

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

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

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d),

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

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, 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^[489] than 1 year^[490] 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 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2),

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3), and^[491]

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA);^[492]

(O)^[493] in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section;

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

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

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

(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 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), or (K) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12);

(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 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) 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 utilization and quality control peer review organization (under part B of title XI) or a carrier under section 1842 has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or^[494]

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) applies;

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

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

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

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b);

(20) in the case of outpatient occupational therapy services or outpatient physical therapy services^[495] furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A)), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) (or under such sentence through the operation of section 1861(g)^[496]) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5), 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;^[497]

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;^[498]

(23)^[499] which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B); or^[500]

(24)^[501] where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is

afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) Medicare as Secondary Payer.—

(1) Requirements of group health plans.—

(A) Working aged under group health plans.—

(i) In general.—A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), 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 multi-employer or multiple employer group health plans.—Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

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

(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^[502], 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 title under section 226(b).

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

(iii) Large group health plan defined.—In this subparagraph, the term “large group health plan” has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, 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 title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

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

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997^[503] (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting “18-month” for “12-month” each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting “30-month” for “12-month” each place it appears.

(D) Treatment of certain members of religious orders.—In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.^[504]

(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 title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer.—

(A) In general.—Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

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

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

In the subsection, the term “primary plan” means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Conditional payment.—

(i) Authority to make conditional payment.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service

promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

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

(iii) Action by United States.—In order to recover payment made under this title 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.

(iv) Subrogation rights.—The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights.—The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title.

(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.

(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^[505].

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan.—It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed \$5,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) Coordination of benefits.—Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but—

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

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis—

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

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

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 [506]) 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 and 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 title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers.—

(i) In general.—With respect to each individual (in this subparagraph referred to as an “employee”) who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986[507] by a qualified employer (as defined in section 6103(l)(12)(E)(iii), of such Code[508]), as disclosed under subparagraph (B)(i) 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 provision of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(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.

(6) Screening requirements for provider and suppliers.—

(A) In general.—Notwithstanding any other provisions of this title, 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 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7)^[509] Required submission of information by group health plans.—

(A) Requirement.—On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph, 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 a primary plan to the program under this title; and

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

(B) Enforcement.—

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

(ii) Deposit of amounts collected.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817.

(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 title 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)^[510] Required submission of information by or on behalf of liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans.—

(A) Requirement.—On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title 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.

(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 shall be subject to a civil money penalty of \$1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the

previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

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

(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.

(c) 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^[511],

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act^[512] 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^[513]) 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) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, 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)(1) No payment may be made under this title with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987^[514]), or 1866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, 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) 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) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with utilization and quality control peer review organizations pursuant to part B of title XI of this Act.

(h)(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) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) 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)(1) Any advisory committee appointed under to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code^[515], 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)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

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

(l) National and Local Coverage Determination Process.—

(1) Factors and evidence used in making national coverage determinations.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act^[516] (21 U.S.C. 371(h)).

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

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

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

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

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

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

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

(i) make a final decision on the request;

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

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

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

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

(5) Local coverage determination process.—

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

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

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

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

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

(B) Local coverage determination.—The term “local coverage determination” has the meaning given that in section 1869(f)(2)(B).

(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.

[488] See Vol. II, P.L. 108-173, §953(b), with respect to the annual publication of a list of national coverage determinations.

[489] P.L. 110-275, §101(b)(4), struck out “not later” and substituted “more”, applicable to services furnished on or after January 1, 2009.

[490] P.L. 110-275, §101(b)(3), struck out “6 months” and substituted “1 year”, applicable to services furnished on or after January 1, 2009.

[491] P.L. 110-275, §152(b)(1)(D)(i), strikes out “and”, **effective January 1, 2010.**

[492] P.L. 110-275, §152(b)(1)(D)(ii), strikes out the semicolon and substitutes “, and”, **effective January 1, 2010.**

[493] P.L. 110-275, §152(b)(1)(D)(iii), adds subparagraph (O), **effective January 1, 2010.**

[494] See Vol. II, P.L. 99-514, §1895(b)(16)(C), with respect to deeming approval.

[495] P.L. 110-275, §143(b)(7)(A), strikes out “outpatient occupational therapy services or outpatient physical therapy services” and substitutes “outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services”, **applicable to services furnished on or after July 1, 2009.**

See Vol. II, P.L. 110-275, §143(d), with respect to a rule of construction regarding existing regulations and policies.

[496] P.L. 110-275, §143(b)(7)(B), strikes out “section 1861(g)” and substitutes “subsection (g) or (II)(2) of section 1861”, **applicable to services furnished on or after July 1, 2009.**

[497] P.L. 110-275, §135(a)(2)(A)(i), strikes out “or”, **to be applicable on or after January 1, 2012.**

[498] P.L. 110-275, §135(a)(2)(A)(ii), strikes out the period and inserts “; or*”.

*P.L. 110-275, §153(b)(2)(A), strikes out “; or”.

[499] P.L. 110-275, §135(a)(2)(A)(iii), adds paragraph (23), **to be applicable to advanced diagnostic imaging services furnished on or after January 1, 2012.**

[500] P.L. 110-275, §153(b)(2)(B), struck out the period and inserted “; or”.

[501] P.L. 110-275, §153(b)(2)(C), added paragraph (24), effective July 15, 2008.

[502] See Vol. II, P.L. 83-591, §5000.

[503] August 5, 1997 [P.L. 105-33; 111 Stat. 329].

[504] See Vol. II, P.L. 103-66, §13561(f), with respect to retroactive exemption for certain situations involving religious orders.

[505] See Vol. II, P.L. 83-591, §5000.

[506] See Vol. II, P.L. 83-591, §6103(l)(12).

[507] See Vol. II, P.L. 83-591, §6051.

[508] See Vol. II, P.L. 83-591, §6103(l)(12).

[509] P.L. 110-173, §111(a), added paragraph (7), effective December 29, 2007. See Vol. II, P.L. 110-173, §111(b), with respect to a rule of construction and §111(c), with respect to implementation of paragraph (7).

[510] P.L. 110-173, §111(a), added paragraph (8), effective December 29, 2007. See Vol. II, P.L. 110-173, §111(b), with respect to a rule of construction and §111(c), with respect to implementation of paragraph (7).

[511] See Vol. II, P.L. 87-781, §103(c)(3).

[512] See Vol. II, P.L. 75-71, §505(e).

[513] See Vol. II, 21 C.F.R. 310.6.

[514] August 18, 1987 [P.L. 100-93; 101 Stat. 680].

[515] See Vol. II, 5 U.S.C. 552.

[516] P.L. 75-717.