

(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](#) [Title 26, U.S.C.A.], 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 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 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 of this subchapter 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, [\[FN1\]](#) (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, (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 or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

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

(B) Conditional payment

(i) Authority to make conditional payment

The Secretary may make payment under this subchapter 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 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.

(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.

(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](#) [Title 26, U.S.C.A.].

#### (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 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 of this subchapter or enrolls under part B of this subchapter, 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 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 of this subchapter 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 a primary plan to the program under this subchapter; 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.

(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 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.

(c) Drug products

No payment may be made under part B of this subchapter 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) of this section, 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) of this section, under part A or part B of this subchapter 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) of this section, 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) of this section 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) of this section 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) [\[FN2\]](#) of this section) 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) of this section 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.

(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 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 of this subchapter, or enrolled under part B of this subchapter, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) of this section 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 and [section 1396b\(i\)\(2\)\(C\)](#) of this title.