

§ 1395ee. Practicing Physicians Advisory Council; Council for Technology and Innovation

(a) Repealed. Pub. L. 111-148, title III, § 3134(b)(2), Mar. 23, 2010, 124 Stat. 435

(b) Council for Technology and Innovation

(1) Establishment

The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as “CMS”).

(2) Composition

The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) Duties

The Council shall coordinate the activities of coverage, coding, and payment processes under this subchapter with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) Executive Coordinator for Technology and Innovation

The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this subchapter.

(Aug. 14, 1935, ch. 531, title XVIII, § 1868, as added Pub. L. 101-508, title IV, § 4112, Nov. 5, 1990, 104 Stat. 1388-64; amended Pub. L. 108-173, title IX, § 942(a), Dec. 8, 2003, 117 Stat. 2420; Pub. L. 111-148, title III, § 3134(b)(2), Mar. 23, 2010, 124 Stat. 435.)

PRIOR PROVISIONS

A prior section 1395ee, act Aug. 14, 1935, ch. 531, title XVIII, § 1868, as added July 30, 1965, Pub. L. 89-97, title I, § 102(a), 79 Stat. 329, provided for creation of a National Medical Review Committee, functions of such Committee, including submission of annual reports to the Secretary and Congress, employment of technical assistance, and for availability of assistance and data, prior to repeal by Pub. L. 90-248, title I, § 164(c), Jan. 2, 1968, 81 Stat. 874.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111-148 struck out subsec. (a) which related to the Practicing Physicians Advisory Council.

2003—Pub. L. 108-173, § 942(a)(1), inserted “; Council for Technology and Innovation” in section catchline.

Subsec. (a). Pub. L. 108-173, § 942(a)(2)-(4), inserted subsec. heading, redesignated existing provisions as par. (1), substituted “in this subsection” for “in this section”, and redesignated former subsecs. (b) and (c) as pars. (2) and (3), respectively.

Subsec. (b). Pub. L. 108-173, § 942(a)(5), added subsec. (b). Former subsec. (b) redesignated par. (2) of subsec. (a).

Subsec. (c). Pub. L. 108-173, § 942(a)(4), redesignated subsec. (c) as par. (3) of subsec. (a).

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

§ 1395ff. Determinations; appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1320c-3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w-22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI of this chapter.

(2) Deadlines for making initial determinations

(A) In general

Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims

Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general

In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations**(i) Appeal rights**

No initial determination may be reconsidered or appealed under subsection (b) of this section unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker

No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines**(i) Filing for redetermination**

A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations

Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction

For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations

With respect to an initial determination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the determination shall include—

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations

With respect to a redetermination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the redetermination shall include—

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights**(1) In general****(A) Reconsideration of initial determination**

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 405 of this title shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) Representation by provider or supplier**(i) In general**

Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary

Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation

If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary

The provisions of section 405(j) of this title and of section 406 of this title (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment

The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals**(i) Reconsiderations**

Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3) of this section, or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary

The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 405 and 406 of this title.

(E) Amounts in controversy**(i) In general**

A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than \$100, and judicial review shall not be available to the individual if the amount in controversy is less than \$1,000.

(ii) Aggregation of claims

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve—

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts

For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

(F) Expedited proceedings**(i) Expedited determination**

In the case of an individual who has received notice from a provider of services that such provider plans—

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1) of this section, as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review

For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review**(A) In general**

The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations

If, after or coincident with appropriately filing a request for an administrative hear-

ing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review

(i) In general

If the appropriate review entity—

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B),

then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing

Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue

Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy

Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimburse-

ment due providers of services or suppliers under this subchapter.

(D) Review entity defined

For purposes of this subsection, the term “review entity” means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers

A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c) of this section, unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors

(1) In general

The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1) of this section. Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor

For purposes of this subsection, the term “qualified independent contractor” means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1) of this section, and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements

Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general

The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations

(i) In general

The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial de-

termination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations

(I) National coverage determinations

If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1395y(a) of this title, such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations

If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination

In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions

(i) Reconsiderations

Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline

In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) Expedited reconsiderations

The qualified independent contractor shall perform an expedited reconsideration

under subsection (b)(1)(F) of this section as follows:

(I) Deadline for decision

Notwithstanding section 416(j) of this title and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary

In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges

A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1320c-3(e) of this title as in effect on the date that precedes December 21, 2000.

(iv) Extension

An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers

The requirements of subsection (g) of this section shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision

Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate) and shall include¹ a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and² a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section³ and³ in the case of a determination of whether an item or service is reasonable and

¹ So in original.

² So in original. The word "and" probably should not appear.

³ So in original. A comma probably should appear.

necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title)³ an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements

Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A of this subchapter or part B of this subchapter of such decision.

(G) Dissemination of decisions on reconsiderations

Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1395h of this title), carriers (under section 1395u of this title), quality improvement organizations (under part B of subchapter XI of this chapter), Medicare+Choice organizations offering Medicare+Choice plans under part C of this subchapter, other entities under contract with the Secretary to make initial determinations under part A of this subchapter or part B of this subchapter or subchapter XI of this chapter, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) Ensuring consistency in decisions

Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection

(i) In general

Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected

Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting

Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary

The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements

(i) In general

Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

(I) is not a related party (as defined in subsection (g)(5) of this section);

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation

Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation

Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors

The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability

No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof)

provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice

(1) Hearing by administrative law judge

(A) In general

Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) of this section and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) Waiver of deadline by party seeking hearing

The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review

(A) In general

The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure

In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines

(A) Hearing by administrative law judge

In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) Departmental Appeals Board review

In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) Notice

Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(e) Administrative provisions

(1) Limitation on review of certain regulations

A regulation or instruction that relates to a method for determining the amount of payment under part B of this subchapter and that was initially issued before January 1, 1981, shall not be subject to judicial review.

(2) Outreach

The Secretary shall perform such outreach activities as are necessary to inform individuals entitled to benefits under this subchapter and providers of services and suppliers with respect to their rights of, and the process for, appeals made under this section. The Secretary shall use the toll-free telephone number maintained by the Secretary under section 1395b-2(b) of this title to provide information regarding appeal rights and respond to inquiries regarding the status of appeals.

(3) Continuing education requirement for qualified independent contractors and administrative law judges

The Secretary shall provide to each qualified independent contractor, and, in consultation with the Commissioner of Social Security, to administrative law judges that decide appeals of reconsiderations of initial determinations or other decisions or determinations under this section, such continuing education with respect to coverage of items and services under this subchapter or policies of the Secretary with respect to part B of subchapter XI of this chapter as is necessary for such qualified independent contractors and administrative law judges to make informed decisions with respect to appeals.

(4) Reports

(A) Annual report to Congress

The Secretary shall submit to Congress an annual report describing the number of appeals for the previous year, identifying issues that require administrative or legislative actions, and including any recommendations of the Secretary with respect to such actions. The Secretary shall include in such report an analysis of determinations by qualified independent contractors with respect to inconsistent decisions and an analysis of the causes of any such inconsistencies.

(B) Survey

Not less frequently than every 5 years, the Secretary shall conduct a survey of a valid sample of individuals entitled to benefits under this subchapter who have filed appeals of determinations under this section, providers of services, and suppliers to determine the satisfaction of such individuals or entities with the process for appeals of determinations provided for under this section and education and training provided by the Secretary with respect to that process. The Secretary shall submit to Congress a report

describing the results of the survey, and shall include any recommendations for administrative or legislative actions that the Secretary determines appropriate.

(f) Review of coverage determinations

(1) National coverage determinations

(A) In general

Review of any national coverage determination shall be subject to the following limitations:

(i) Such a determination shall not be reviewed by any administrative law judge.

(ii) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(iii) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services. In conducting such a review, the Departmental Appeals Board—

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the Board determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(iv) The Secretary shall implement a decision of the Departmental Appeals Board within 30 days of receipt of such decision.

(v) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of national coverage determination

For purposes of this section, 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, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered.

(2) Local coverage determination

(A) In general

Review of any local coverage determination shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge. The administrative law judge—

(I) shall review the record and shall permit discovery and the taking of evi-

dence to evaluate the reasonableness of the determination, if the administrative law judge determines that the record is incomplete or lacks adequate information to support the validity of the determination;

(II) may, as appropriate, consult with appropriate scientific and clinical experts; and

(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(ii) Upon the filing of a complaint by an aggrieved party, a decision of an administrative law judge under clause (i) shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services.

(iii) The Secretary shall implement a decision of the administrative law judge or the Departmental Appeals Board within 30 days of receipt of such decision.

(iv) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of local coverage determination

For purposes of this section, the term “local coverage determination” means a determination by a fiscal intermediary or a carrier under part A of this subchapter or part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title.

(3) No material issues of fact in dispute

In the case of a determination that may otherwise be subject to review under paragraph (1)(A)(iii) or paragraph (2)(A)(i), where the moving party alleges that—

(A) there are no material issues of fact in dispute, and

(B) the only issue of law is the constitutionality of a provision of this subchapter, or that a regulation, determination, or ruling by the Secretary is invalid,

the moving party may seek review by a court of competent jurisdiction without filing a complaint under such paragraph and without otherwise exhausting other administrative remedies.

(4) Pending national coverage determinations

(A) In general

In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if any) during such 90-day pe-

riod), the Secretary shall take one of the following actions:

(i) Issue a national coverage determination, with or without limitations.

(ii) Issue a national noncoverage determination.

(iii) Issue a determination that no national coverage or noncoverage determination is appropriate as of the end of such 90-day period with respect to national coverage of such items or services.

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in clause (i), (ii), or (iii).

(B) Deemed action by the Secretary

In the case of an action described in subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in subparagraph (A)(iii) as of the deadline.

(C) Explanation of determination

When issuing a determination under subparagraph (A), the Secretary shall include an explanation of the basis for the determination. An action taken under subparagraph (A) (other than clause (iv)) is deemed to be a national coverage determination for purposes of review under paragraph (1)(A).

(5) Standing

An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under part A of this subchapter, or enrolled under part B of this subchapter, or both, who are in need of the items or services that are the subject of the coverage determination.

(6) Publication on the Internet of decisions of hearings of the Secretary

Each decision of a hearing by the Secretary with respect to a national coverage determination shall be made public, and the Secretary shall publish each decision on the Medicare⁴ Internet site of the Department of Health and Human Services. The Secretary shall remove from such decision any information that would identify any individual, provider of services, or supplier.

(7) Annual report on national coverage determinations

(A) In general

Not later than December 1 of each year, beginning in 2001, the Secretary shall submit to Congress a report that sets forth a detailed compilation of the actual time periods that were necessary to complete and fully implement national coverage determina-

tions that were made in the previous fiscal year for items, services, or medical devices not previously covered as a benefit under this subchapter, including, with respect to each new item, service, or medical device, a statement of the time taken by the Secretary to make and implement the necessary coverage, coding, and payment determinations, including the time taken to complete each significant step in the process of making and implementing such determinations.

(B) Publication of reports on the Internet

The Secretary shall publish each report submitted under clause (i) on the Medicare Internet site of the Department of Health and Human Services.

(8) Construction

Nothing in this subsection shall be construed as permitting administrative or judicial review pursuant to this section insofar as such review is explicitly prohibited or restricted under another provision of law.

(g) Qualifications of reviewers

(1) In general

In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) of this section composed of physicians or other health care professionals (each in this subsection referred to as a "reviewing professional"), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

(2) Independence

(A) In general

Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.

(B) Exception

Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

⁴So in original. Probably should not be capitalized.

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, or such individual's authorized representative, and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) Limitations on reviewer compensation

Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) Licensure and expertise

Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) Related party defined

For purposes of this section, the term "related party" means, with respect to a case under this subchapter involving a specific individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) Prior determination process for certain items and services

(1) Establishment of process

(A) In general

With respect to a medicare administrative contractor that has a contract under section 1395kk-1 of this title that provides for making payments under this subchapter with respect to physicians' services (as defined in section 1395w-4(j)(3) of this title), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) Eligible requester

For purposes of this subsection, each of the following shall be an eligible requester:

(i) A participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under this subchapter and who has consented to the physician making the request under this subsection for those physicians' services.

(ii) An individual entitled to benefits under this subchapter, but only with respect to a physicians' service for which the individual receives, from a physician, an advance beneficiary notice under section 1395pp(a) of this title.

(2) Secretarial flexibility

The Secretary shall establish by regulation reasonable limits on the physicians' services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the physicians' service, administrative costs and burdens, and other relevant factors.

(3) Request for prior determination

(A) In general

Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians' service, as to whether the physicians' service is covered under this subchapter consistent with the applicable requirements of section 1395y(a)(1)(A) of this title (relating to medical necessity).

(B) Accompanying documentation

The Secretary may require that the request be accompanied by a description of the physicians' service, supporting documentation relating to the medical necessity for

the physicians' service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) Response to request

(A) In general

Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

- (i) the physicians' service is so covered;
- (ii) the physicians' service is not so covered; or
- (iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

(B) Contents of notice for certain determinations

(i) Noncoverage

If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under subsection (a) of this section.

(ii) Insufficient information

If the contractor makes the determination described in subparagraph (A)(iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(C) Deadline to respond

Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A) of this section.

(D) Informing beneficiary in case of physician request

In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians' service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians' service and have a claim submitted for the physicians' service.

(5) Binding nature of positive determination

If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(6) Limitation on further review

(A) In general

Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (relating to

pre-service claims) are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) Decision not to seek prior determination or negative determination does not impact right to obtain services, seek reimbursement, or appeal rights

Nothing in this subsection shall be construed as affecting the right of an individual who—

- (i) decides not to seek a prior determination under this subsection with respect to physicians' services; or
- (ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such physicians' services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to physicians' service shall not be taken into account in such administrative or judicial review.

(C) No prior determination after receipt of services

Once an individual is provided physicians' services, there shall be no prior determination under this subsection with respect to such physicians' services.

(i) Mediation process for local coverage determinations

(1) Establishment of process

The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

(2) Responsibility of mediator

Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1395x(d) of this title), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.

(Aug. 14, 1935, ch. 531, title XVIII, §1869, as added Pub. L. 89-97, title I, §102(a), July 30, 1965, 79 Stat. 330; amended Pub. L. 92-603, title II, §2990(a), Oct. 30, 1972, 86 Stat. 1464; Pub. L. 98-369, div. B, title III, §2354(b)(35), July 18, 1984, 98 Stat. 1102; Pub. L. 99-509, title IX, §§9313(a)(1), (b)(1), 9341(a)(1), Oct. 21, 1986, 100 Stat. 2002, 2037; Pub. L. 100-93, §8(e), Aug. 18, 1987, 101 Stat. 694; Pub. L. 100-203, title IV, §§4082(a), (b), 4085(i)(18), (19), Dec. 22, 1987, 101 Stat. 1330-128, 1330-133; Pub. L. 103-296, title I, §108(c)(5), Aug. 15, 1994, 108 Stat. 1485; Pub. L. 105-33, title IV, §4611(c), Aug. 5, 1997, 111 Stat. 473; Pub. L. 106-554, §1(a)(6)

[title V, §§ 521(a), 522(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-534, 2763A-543; Pub. L. 108-173, title IX, §§ 931(d), 932(a), 933(a)(1), (b)-(d)(3), 938(a), 940(a), (b)(1), 940A(a), 948(b)(1), (c), Dec. 8, 2003, 117 Stat. 2399, 2402-2406, 2413, 2416, 2417, 2426; Pub. L. 112-40, title II, § 261(a)(3)(A), (F), Oct. 21, 2011, 125 Stat. 423.)

AMENDMENTS

2011—Subsec. (a)(1)(C). Pub. L. 112-40, § 261(a)(3)(A), substituted “quality improvement” for “utilization and quality control peer review”.

Subsec. (c)(3)(G). Pub. L. 112-40, § 261(a)(3)(F), substituted “quality improvement organizations” for “peer review organizations”.

2003—Subsec. (a)(3)(C)(ii). Pub. L. 108-173, § 940(a)(1), substituted “60-day period” for “30-day period” in two places.

Subsec. (a)(4), (5). Pub. L. 108-173, § 933(c)(1), added pars. (4) and (5).

Subsec. (b)(1)(A). Pub. L. 108-173, § 932(a)(1)(A), inserted “, subject to paragraph (2),” before “to judicial review of the Secretary’s final decision”.

Subsec. (b)(1)(E)(iii). Pub. L. 108-173, § 940(b)(1), added cl. (iii).

Subsec. (b)(1)(F)(ii). Pub. L. 108-173, § 932(a)(2), amended heading and text of cl. (ii) generally. Prior to amendment, text read as follows: “In a hearing by the Secretary under this section, in which the moving party alleges that no material issues of fact are in dispute, the Secretary shall make an expedited determination as to whether any such facts are in dispute and, if not, shall render a decision expeditiously.”

Subsec. (b)(2). Pub. L. 108-173, § 932(a)(1)(B), added par. (2).

Subsec. (b)(3). Pub. L. 108-173, § 933(a)(1), added par. (3).

Subsec. (c)(3)(A). Pub. L. 108-173, § 933(d)(1)(A), substituted “sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing” for “sufficient training and expertise in medical science and legal matters”.

Subsec. (c)(3)(B)(i). Pub. L. 108-173, § 933(b), inserted “(including the medical records of the individual involved)” after “clinical experience”.

Subsec. (c)(3)(C)(i). Pub. L. 108-173, § 940(a)(2), substituted “60-day period” for “30-day period”.

Subsec. (c)(3)(D). Pub. L. 108-173, § 933(d)(2)(A), amended heading and text of subpar. (D) generally, substituting provisions directing that subsec. (g) requirements be met for provisions prohibiting a physician or health care professional from reviewing a determination where such physician or health care professional had been directly responsible for furnishing services or had had a significant financial interest in the institution, organization, or agency which provided the services.

Subsec. (c)(3)(E). Pub. L. 108-173, § 933(c)(2), inserted “be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate)” after “in writing,” and “and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section” after “such decision.”

Subsec. (c)(3)(I)(ii)(III). Pub. L. 108-173, § 948(b)(1)(A), substituted “determination” for “policy”.

Subsec. (c)(3)(I)(ii)(IV). Pub. L. 108-173, § 948(b)(1)(B), substituted “coverage determinations” for “medical review policies”.

Subsec. (c)(3)(J)(i). Pub. L. 108-173, § 933(c)(4), substituted “submit” for “prepare” and struck out “with respect to a reconsideration to the Secretary for a hearing, including as necessary, explanations of issues involved in the decision and relevant policies” after “decision of the contractor”.

Subsec. (c)(3)(K). Pub. L. 108-173, § 933(d)(1)(B), added subpar. (K).

Subsec. (c)(4). Pub. L. 108-173, § 933(d)(3), substituted “a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection” for “not fewer than 12 qualified independent contractors under this subsection”.

Subsec. (d). Pub. L. 108-173, § 933(c)(3)(A), inserted “; notice” after “Secretary” in heading.

Subsec. (d)(4). Pub. L. 108-173, § 933(c)(3)(B), added par. (4).

Subsec. (f)(2)(A)(i). Pub. L. 108-173, § 931(d), struck out “of the Social Security Administration” after “an administrative law judge” in introductory provisions.

Subsec. (f)(4)(A)(iv). Pub. L. 108-173, § 948(c)(1), substituted “clause (i), (ii), or (iii)” for “subclause (I), (II), or (III)”.

Subsec. (f)(4)(B). Pub. L. 108-173, § 948(c)(2), substituted “subparagraph (A)(iv)” for “clause (i)(IV)” and “subparagraph (A)(iii)” for “clause (i)(III)”.

Subsec. (f)(4)(C). Pub. L. 108-173, § 948(c)(3), substituted “subparagraph (A)” for “clause (i)” in two places, “clause (iv)” for “subclause (IV)”, and “paragraph (1)(A)” for “subparagraph (A)”.

Subsec. (g). Pub. L. 108-173, § 933(d)(2)(B), added subsec. (g).

Subsec. (h). Pub. L. 108-173, § 938(a), added subsec. (h).

Subsec. (i). Pub. L. 108-173, § 940A(a), added subsec. (i).

2000—Pub. L. 106-554, § 1(a)(6) [title V, § 521(a)], amended section generally, completely revising and expanding provisions relating to determinations with respect to benefits under part A or part B of this subchapter, changing the structure of the section from two subsections, lettered (a) and (b) to five subsections, lettered (a) to (e).

Subsec. (f). Pub. L. 106-554, § 1(a)(6) [title V, § 522(a)], added subsec. (f).

1997—Subsec. (b)(2)(B). Pub. L. 105-33 inserted “(or \$100 in the case of home health services)” after “\$500”.

1994—Subsec. (b)(1). Pub. L. 103-296 inserted “, except that, in so applying such sections and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively” after “section 405(g) of this title” in closing provisions.

1987—Subsec. (a). Pub. L. 100-203, § 4085(i)(18), inserted “or a claim for benefits with respect to home health services under part B of this subchapter” before “shall”.

Subsec. (b)(2). Pub. L. 100-203, § 4085(i)(19), inserted “and (1)(D)” after “paragraph (1)(C)” in two places.

Subsec. (b)(3)(B). Pub. L. 100-203, § 4082(a), substituted “section 553” for “chapter 5”.

Subsec. (b)(5). Pub. L. 100-203, § 4082(b), added par. (5).

Subsec. (c). Pub. L. 100-93 struck out subsec. (c) which read as follows: “Any institution or agency dissatisfied with any determination by the Secretary that it is not a provider of services, or with any determination described in section 1395cc(b)(2) of this title, shall be entitled to a hearing thereon by the Secretary (after reasonable notice and opportunity for hearing) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary’s final decision after such hearing as is provided in section 405(g) of this title.”

1986—Subsec. (a). Pub. L. 99-509, § 9341(a)(1)(A), inserted “or part B” after “amount of benefits under part A”.

Pub. L. 99-509, § 9313(b)(1)(A), inserted “and any other determination with respect to a claim for benefits under part A of this subchapter” before “shall”.

Subsec. (b)(1). Pub. L. 99-509, § 9313(a)(1), in concluding provisions, inserted at end “Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this subsection by a person that furnishes or supplies the individual, directly or indirectly, with services or items solely on the basis that the person furnishes or supplies the individual with

such a service or item. Any person that furnishes services or items to an individual may not represent an individual under this subsection with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal. If a person furnishes services or items to an individual and represents the individual under this subsection, the person may not impose any financial liability on such individual in connection with such representation.”

Subsec. (b)(1)(C). Pub. L. 99-509, §9341(a)(1)(B), inserted “or part B”.

Subsec. (b)(1)(D). Pub. L. 99-509, §9313(b)(1)(B), added subpar. (D).

Subsec. (b)(2). Pub. L. 99-509, §9341(a)(1)(C), amended par. (2) generally. Prior to amendment, par. (2) read as follows: “Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than \$100; nor shall judicial review be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than \$1,000.”

Subsec. (b)(3), (4). Pub. L. 99-509, §9341(a)(1)(D), added pars. (3) and (4).

1984—Subsec. (b)(1)(B). Pub. L. 98-369 struck out the comma before “or section 1395i-2” and struck out “, or section 1819” after “section 1395i-2 of this title”.

1972—Subsec. (b). Pub. L. 92-603 redesignated existing provisions as par. (1), generally amended conditions under which a dissatisfied individual shall be entitled to a hearing by Secretary and to judicial review of final decision of Secretary after such hearing, and added par. (2).

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108-173, set out as a note under section 1395w-21 of this title.

EFFECTIVE DATE OF 2011 AMENDMENT

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

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 932(a) of Pub. L. 108-173 applicable to appeals filed on or after Oct. 1, 2004, see section 932(d) of Pub. L. 108-173, set out as a note under section 1395i-3 of this title.

Pub. L. 108-173, title IX, §933(a)(2), Dec. 8, 2003, 117 Stat. 2402, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on October 1, 2004.”

Pub. L. 108-173, title IX, §933(d)(4), Dec. 8, 2003, 117 Stat. 2406, provided that: “The amendments made by paragraphs (1) and (2) [amending this section] shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, H.R. 5661, as enacted by section 1(a)(6) of Public Law 106-554] (114 Stat. 2763A-534).”

Pub. L. 108-173, title IX, §938(b), Dec. 8, 2003, 117 Stat. 2415, provided that:

“(1) EFFECTIVE DATE.—The Secretary [of Health and Human Services] shall establish the prior determination process under the amendment made by subsection (a) [amending this section] in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003].

“(2) SUNSET.—Such prior determination process shall not apply to requests filed after the end of the 5-year period beginning on the first date on which requests for determinations under such process are accepted.

“(3) TRANSITION.—During the period in which the amendment made by subsection (a) [amending this section] has become effective but contracts are not provided under section 1874A of the Social Security Act [section 1395kk-1 of this title] with medicare administrative contractors, any reference in section 1869(g) [probably should be 1869(h)] of such Act [subsec. (h) of this section] (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act [sections 1395h and 1395u of this title].

“(4) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment made by subsection (a) [amending this section] shall not be considered to be a change in law or regulation.”

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

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section §1(a)(6) [title V, §521(a)] of Pub. L. 106-554 applicable with respect to initial determinations made on or after Oct. 1, 2002, see section 1(a)(6) [title V, §521(d)] of Pub. L. 106-554, set out as a note under section 1320c-3 of this title.

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

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-33 applicable to services furnished on or after Jan. 1, 1998, and for purposes of applying such amendment, any home health spell of illness that began, but did not end, before such date, to be considered to have begun as of such date, see section 4611(f) of Pub. L. 105-33, set out as a note under section 1395d of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103-296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100-203, title IV, §4082(e)(1), (2), Dec. 22, 1987, 101 Stat. 1330-128, provided that:

“(1) The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 22, 1987].

“(2) The amendment made by subsection (b) [amending this section] shall apply to requests for hearings filed after the end of the 60-day period beginning on the date of the enactment of this Act.”

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

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-509, title IX, §9313(b)(2), Oct. 21, 1986, 100 Stat. 2003, provided that: “The amendments made by this subsection [amending this section] take effect on the date of the enactment of this Act [Oct. 21, 1986].”

Pub. L. 99-509, title IX, §9341(b), Oct. 21, 1986, 100 Stat. 2038, provided that: “The amendments made by subsection (a) [amending this section and sections 1395u and 1395pp of this title] shall apply to items and services furnished on or after January 1, 1987.”

EFFECTIVE DATE OF 1984 AMENDMENT

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

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92-603, title II, §2990(b), Oct. 30, 1972, 86 Stat. 1465, provided that:

“(1) The provisions of subparagraphs (A) and (B) of section 1869(b)(1) of the Social Security Act [subsec. (b)(1)(A), (B) of this section], as amended by subsection (a) of this section, shall be effective on the date of enactment of this Act [Oct. 30, 1972].

“(2) The provisions of paragraph (2) and subparagraph (C) of paragraph (1) of section 1869(b) of the Social Security Act [subsec. (b)(1)(C) and (b)(2) of this section], as amended by subsection (a) of this section, shall be effective with respect to any claims under part A of title XVIII of such Act [part A of this subchapter], filed—

“(A) in or after the month in which this Act is enacted [Oct. 1972], or

“(B) before the month in which this Act is enacted [Oct. 1972], but only if a civil action with respect to a final decision of the Secretary of Health, Education, and Welfare on such claim has not been commenced under such section 1869(b) [subsec. (b) of this section] before such month.”

TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS

Pub. L. 108-173, title IX, §931(a)-(c), Dec. 8, 2003, 117 Stat. 2396-2398, provided that:

“(a) TRANSITION PLAN.—

“(1) IN GENERAL.—Not later than April 1, 2004, the Commissioner of Social Security and the Secretary [of Health and Human Services] shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act [this subchapter] (and related provisions in title XI of such Act [subchapter XI of this chapter]) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

“(2) CONTENTS.—The plan shall include information on the following:

“(A) WORKLOAD.—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

“(B) COST PROJECTIONS AND FINANCING.—Funding levels required for fiscal year 2005 and subsequent fiscal years to carry out the functions transferred under the plan.

“(C) TRANSITION TIMETABLE.—A timetable for the transition.

“(D) REGULATIONS.—The establishment of specific regulations to govern the appeals process.

“(E) CASE TRACKING.—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the medicare program.

“(F) FEASIBILITY OF PRECEDENTIAL AUTHORITY.—The feasibility of developing a process to give decisions of the Departmental Appeals Board in the Department of Health and Human Services addressing broad legal issues binding, precedential authority.

“(G) ACCESS TO ADMINISTRATIVE LAW JUDGES.—The feasibility of—

“(i) filing appeals with administrative law judges electronically; and

“(ii) conducting hearings using tele- or video-conference technologies.

“(H) INDEPENDENCE OF ADMINISTRATIVE LAW JUDGES.—The steps that should be taken to ensure the independence of administrative law judges consistent with the requirements of subsection (b)(2).

“(I) GEOGRAPHIC DISTRIBUTION.—The steps that should be taken to provide for an appropriate geographic distribution of administrative law judges throughout the United States to carry out subsection (b)(3).

“(J) HIRING.—The steps that should be taken to hire administrative law judges (and support staff) to carry out subsection (b)(4).

“(K) PERFORMANCE STANDARDS.—The appropriateness of establishing performance standards for administrative law judges with respect to timelines for decisions in cases under title XVIII of the Social Security Act [this subchapter] taking into account requirements under subsection (b)(2) for the independence of such judges and consistent with the applicable provisions of title 5, United States Code[,] relating to impartiality.

“(L) SHARED RESOURCES.—The steps that should be taken to carry out subsection (b)(6) (relating to the arrangements with the Commissioner of Social Security to share office space, support staff, and other resources, with appropriate reimbursement).

“(M) TRAINING.—The training that should be provided to administrative law judges with respect to laws and regulations under title XVIII of the Social Security Act [this subchapter].

“(3) ADDITIONAL INFORMATION.—The plan may also include recommendations for further congressional action, including modifications to the requirements and deadlines established under section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act).

“(4) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

“(b) TRANSFER OF ADJUDICATION AUTHORITY.—

“(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

“(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another officer of the Department of Health and Human Services.

“(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

“(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Acts, the Secretary shall have authority to hire administrative law judges to hear such cases, taking into consideration those judges with expertise in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

“(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges perform-

ing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

“(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

“(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

“(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

“(2) improve education and training opportunities for administrative law judges (and their staffs); and

“(3) increase the staff of the Departmental Appeals Board.”

TRANSITION

Pub. L. 108-173, title IX, §933(d)(5), Dec. 8, 2003, 117 Stat. 2406, provided that: “In applying section 1869(g) of the Social Security Act [subsec. (g) of this section] (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).”

PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS

Pub. L. 108-173, title IX, §937, Dec. 8, 2003, 117 Stat. 2412, provided that:

“(a) CLAIMS.—The Secretary [of Health and Human Services] shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act [section 1395zz(g) of this title], as inserted by section 301(a)(1) [probably should be 921(f)(1)]) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act [this subchapter], a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

“(b) DEADLINE.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall first develop the process under subsection (a).”

STUDY OF AGGREGATION RULE FOR CLAIMS FOR SIMILAR PHYSICIANS' SERVICES

Pub. L. 101-508, title IV, §4113, Nov. 5, 1990, 104 Stat. 1388-64, directed Secretary of Health and Human Services to carry out a study of the effects of permitting the aggregation of claims that involve common issues of law and fact furnished in the same carrier area to two or more individuals by two or more physicians within the same 12-month period for purposes of appeals provided for under subsec. (b)(2) of this section, and to report on the results of such study and any recommendations to Congress by Dec. 31, 1992.

MEDICARE HEARINGS AND APPEALS

Pub. L. 100-203, title IV, §4037, Dec. 22, 1987, 101 Stat. 1330-80, provided that:

“(a) MAINTAINING CURRENT SYSTEM FOR HEARINGS AND APPEALS.—Any hearing conducted under section 1869(b)(1) of the Social Security Act [subsec. (b)(1) of this section] prior to the earliest of the date on which the Secretary of Health and Human Services submits the report required to be submitted by the Secretary under subsection (b)(1) or September 1 shall be conducted by Administrative Law Judges of the Office of Hearings and Appeals of the Social Security Administration in the same manner as are hearings conducted under section 205(b)(1) of such Act [section 405(b)(1) of this title].

“(b) STUDY AND REPORT ON USE OF TELEPHONE HEARINGS.—

“(1) The Secretary of Health and Human Services and the Comptroller General of the United States shall each conduct a study on holding hearings under section 1869(b)(1) of the Social Security Act [subsec. (b)(1) of this section] by telephone and shall each report the results of the study not later than 6 months after the date of enactment of this Act [Dec. 22, 1987].

“(2) The studies under paragraph (1) shall focus on whether telephone hearings allow for a full and fair evidentiary hearing, in general, or with respect to any particular category of claims and shall examine the possible improvements to the hearing process (such as cost-effectiveness, convenience to the claimant, and reduction in time under the process) resulting from the use of such hearings as compared to the adoption of other changes to the process (such as expansions in staff and resources).”

§ 1395gg. Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals

(a) Payments to providers of services or other person regarded as payment to individuals

Any payment under this subchapter to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Incorrect payments on behalf of individuals; payment adjustment

Where—

(1) more than the correct amount is paid under this subchapter to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1395f(e) of this title to a provider of services or other person for items or services furnished an individual,

proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments—

(3) to which such individual is entitled under subchapter II of this chapter or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other