paragraph (1) [amending this section] shall apply to substantive changes issued on or after the date of the enactment of this Act [Dec. 8, 2003]."

Pub. L. 108-173, title IX, \$903(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to compliance actions undertaken on or after the date of the enactment of this Act [Dec. 8, 2003]."

Pub. L. 108–173, title IX, \$903(c)(2), Dec. 8, 2003, 117 Stat. 2377, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003] and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003."

#### EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–203 effective Dec. 22, 1987, and applicable to budgets for fiscal years beginning with fiscal year 1989, see section 4035(a)(3) of Pub. L. 100–203, set out as a note under section 1395h of this title.

#### EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-509, title IX, §9321(e)(3)(A), Oct. 21, 1986, 100 Stat. 2018, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to notices of proposed rulemaking issued after the date of the enactment of this Act [Oct. 21, 1986]."

#### REGULATIONS

Pub. L. 101–508, title IV, §4207(j), formerly §4027(j), Nov. 5, 1990, 104 Stat. 1388–124, as renumbered and amended by Pub. L. 103–432, title I, §160(d)(4), (12), Oct. 31, 1994, 108 Stat. 4444, provided that: "The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle [subtitle A (§§4000–4361) of title IV of Pub. L. 101–508, see Tables for classification] and the amendments made by this subtitle."

Section 4039(g) of title IV of Pub. L. 100–203 provided that: "The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle and the amendments made by this subtitle [subtitle A (§§4001–4097) of title IV of Pub. L. 100–203, see Tables for classification]."

# GAO STUDY ON ADVISORY OPINION AUTHORITY

Pub. L. 108-173, title IX, §904(a), Dec. 8, 2003, 117 Stat. 2377, provided that:

"(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary [of Health and Human Services] authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

"(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003]."

## § 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this

subchapter, 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.

(Aug. 14, 1935, ch. 531, title XVIII, §1872, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 332; amended Pub. L. 92–603, title II, §242(a), Oct. 30, 1972, 86 Stat. 1419; Pub. L. 98–369, div. B, title III, §2354(b)(36), July 18, 1984, 98 Stat. 1102; Pub. L. 103–296, title I, §108(c)(4), Aug. 15, 1994, 108 Stat. 1485.)

#### AMENDMENTS

1994—Pub. L. 103–296 inserted before period at end ", except that, in applying such provisions with respect to this subchapter, 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".

1984—Pub. L. 98-369 struck out the comma after "406" and struck out reference to subsec. (f) of section 405 of this title.

 $1972\mathrm{--Pub.}$  L.  $92\mathrm{--}603$  struck out reference to provisions of section 408 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 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

Amendment by Pub. L. 92–603 not applicable to any acts, statements, or representations made or committed prior to Oct. 30, 1972, see section 242(d) of Pub. L. 92–603, set out as an Effective Date note under section 1320a–7b of this title.

# § 1395jj. Designation of organization or publication by name

Designation in this subchapter, by name, of any nongovernmental organization or publication shall not be affected by change of name of such organization or publication, and shall apply to any successor organization or publication which the Secretary finds serves the purpose for which such designation is made.

(Aug. 14, 1935, ch. 531, title XVIII, §1873, as added Pub. L. 89–97, title I, §102(a), July 30, 1965, 79 Stat. 332.)

## § 1395kk. Administration of insurance programs

# (a) Functions of Secretary; performance directly or by contract

Except as otherwise provided in this subchapter and in the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], the insurance programs established by this subchapter shall be administered by the Secretary. The Secretary may perform any of his functions under this subchapter directly, or by contract providing for payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.

# (b) Contracts to secure special data, actuarial information, etc.

The Secretary may contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions under this subchapter.

#### (c) Oaths and affirmations

In the course of any hearing, investigation, or other proceeding that he is authorized to conduct under this subchapter, the Secretary may administer oaths and affirmations.

# (d) Inclusion of Medicare provider and supplier payments in Federal Payment Levy Program

## (1) In general

The Centers for Medicare & Medicaid Services shall take all necessary steps to participate in the Federal Payment Levy Program under section 6331(h) of the Internal Revenue Code of 1986 as soon as possible and shall ensure that—

- (A) at least 50 percent of all payments under parts A and B are processed through such program beginning within 1 year after July 15, 2008;<sup>1</sup>
- (B) at least 75 percent of all payments under parts A and B are processed through such program beginning within 2 years after July 15, 2008; and
- (C) all payments under parts A and B are processed through such program beginning not later than September 30, 2011.

#### (2) Assistance

The Financial Management Service and the Internal Revenue Service shall provide assistance to the Centers for Medicare & Medicaid Services to ensure that all payments described in paragraph (1) are included in the Federal Payment Levy Program by the deadlines specified in that subsection.

# (e) Availability of Medicare data

### (1) In general

Subject to paragraph (4), the Secretary shall make available to qualified entities (as defined in paragraph (2)) data described in paragraph (3) for the evaluation of the performance of providers of services and suppliers.

# (2) Qualified entities

For purposes of this subsection, the term "qualified entity" means a public or private entity that—

- (A) is qualified (as determined by the Secretary) to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use; and
- (B) agrees to meet the requirements described in paragraph (4) and meets such other requirements as the Secretary may specify, such as ensuring security of data.

### (3) Data described

The data described in this paragraph are standardized extracts (as determined by the

Secretary) of claims data under parts A, B, and D for items and services furnished under such parts for one or more specified geographic areas and time periods requested by a qualified entity. The Secretary shall take such actions as the Secretary deems necessary to protect the identity of individuals entitled to or enrolled for benefits under such parts.

#### (4) Requirements

#### (A) Fee

Data described in paragraph (3) shall be made available to a qualified entity under this subsection at a fee equal to the cost of making such data available. Any fee collected pursuant to the preceding sentence shall be deposited into the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title.

# (B) Specification of uses and methodologies

A qualified entity requesting data under this subsection shall—

- (i) submit to the Secretary a description of the methodologies that such qualified entity will use to evaluate the performance of providers of services and suppliers using such data;
- (ii)(I) except as provided in subclause (II), if available, use standard measures, such as measures endorsed by the entity with a contract under section 1395aaa(a) of this title and measures developed pursuant to section 299b–31 of this title; or
- (II) use alternative measures if the Secretary, in consultation with appropriate stakeholders, determines that use of such alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by such standard measures;
- (iii) include data made available under this subsection with claims data from sources other than claims data under this subchapter in the evaluation of performance of providers of services and suppliers;
- (iv) only include information on the evaluation of performance of providers and suppliers in reports described in subparagraph (C);
- (v) make available to providers of services and suppliers, upon their request, data made available under this subsection; and
- (vi) prior to their release, submit to the Secretary the format of reports under subparagraph (C).

## (C) Reports

Any report by a qualified entity evaluating the performance of providers of services and suppliers using data made available under this subsection shall—

(i) include an understandable description of the measures, which shall include quality measures and the rationale for use of other measures described in subparagraph (B)(ii)(II), risk adjustment methods, physician attribution methods, other applicable methods, data specifications and limitations, and the sponsors, so that consumers, providers of services and suppliers, health

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

plans, researchers, and other stakeholders can assess such reports;

(ii) be made available confidentially, to any provider of services or supplier to be identified in such report, prior to the public release of such report, and provide an opportunity to appeal and correct errors;

(iii) only include information on a provider of services or supplier in an aggregate form as determined appropriate by the Secretary; and

(iv) except as described in clause (ii), be made available to the public.

# (D) Approval and limitation of uses

The Secretary shall not make data described in paragraph (3) available to a qualified entity unless the qualified entity agrees to release the information on the evaluation of performance of providers of services and suppliers. Such entity shall only use such data, and information derived from such evaluation, for the reports under subparagraph (C). Data released to a qualified entity under this subsection shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without consent of the applicable provider of services or supplier.

(Aug. 14, 1935, ch. 531, title XVIII, §1874, as added and amended Pub. L. 89–97, title I, §§102(a), 111(a), July 30, 1965, 79 Stat. 332, 340; Pub. L. 92–603, title II, §289, Oct. 30, 1972, 86 Stat. 1457; Pub. L. 93–445, title III, §310, Oct. 16, 1974, 88 Stat. 1359; Pub. L. 110–275, title I, §189(a), July 15, 2008, 122 Stat. 2590; Pub. L. 111–148, title X, §10332(a), Mar. 23, 2010, 124 Stat. 968.)

### REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (a), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, §101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§231 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231t of Title 45, and Tables.

The Internal Revenue Code of 1986, referred to in subsec. (d)(1), is classified generally to Title 26, Internal Revenue Code.

July 15, 2008, referred to in subsec. (d)(1)(A) and (B), was in the original "the date of the enactment of this section" and "such date", which were translated as meaning the date of enactment of Pub. L. 110–275, which enacted subsec. (d), to reflect the probable intent of Congress.

# AMENDMENTS

2010—Subsec. (e). Pub. L. 111-148 added subsec. (e).

 $2008\mbox{--}\mbox{Subsec.}$  (d). Pub. L. 110–275 added subsec. (d).

1974—Subsec. (a). Pub. L. 93-445 substituted "Railroad Retirement Act of 1974" for "Railroad Retirement Act of 1937".

1972—Subsec. (c). Pub. L. 92-603 added subsec. (c).

1965—Subsec. (a). Pub. L. 89–97 inserted reference to Railroad Retirement Act of 1937 in first sentence.

# EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-148, title X, §10332(b), Mar. 23, 2010, 124 Stat. 970, provided that: "The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2012."

## EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–275 effective July 15, 2008, see section 189(c) of Pub. L. 110–275, set out as a note under section 3716 of Title 31, Money and Finance.

#### EFFECTIVE DATE OF 1974 AMENDMENT

Amendment by Pub. L. 93–445 effective Jan. 1, 1975, see section 603 of Pub. L. 93–445, set out as a note under section 402 of this title.

### EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–97 applicable to calendar year 1966 or to any subsequent calendar year but only if by October 1 immediately preceding such calendar year the Railroad Retirement Tax Act provides for a maximum amount of monthly compensation taxable under such Act during all months of such calendar year equal to one-twelfth of maximum wages which Federal Insurance Contributions Act provides may be counted for such calendar year, see Pub. L. 89–97, title I, §111(e), July 30, 1965, 79 Stat. 343.

# § 1395kk-1. Contracts with medicare administrative contractors

#### (a) Authority

# (1) Authority to enter into contracts

The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

# (2) Eligibility of entities

An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

- (A) the entity has demonstrated capability to carry out such function;
- (B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement:
- (C) the entity has sufficient assets to financially support the performance of such function; and
- (D) the entity meets such other requirements as the Secretary may impose.

# (3) Medicare administrative contractor defined

For purposes of this subchapter and subchapter XI of this chapter—

### (A) In general

The term "medicare administrative contractor" means an agency, organization, or other person with a contract under this section

# (B) Appropriate medicare administrative contractor

With respect to the performance of a particular function in relation to an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" medicare administrative contractor is the medicare administrative contractor that has