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]."

REQUIRING THE POSTING AND PERIODIC UPDATE OF OPIOID PRESCRIBING GUIDANCE FOR MEDICARE BENEFICIARIES

Pub. L. 115-271, title VI, §6095, Oct. 24, 2018, 132 Stat. 4003, provided that:

"(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall post on the public website of the Centers for Medicare & Medicaid Services all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids and applicable to opioid prescriptions for individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) or enrolled under part B of such title of such Act (42 U.S.C. 1395j et seq.).

"(b) UPDATE OF GUIDANCE.—

"(1) PERIODIC UPDATE.—The Secretary shall, in consultation with the entities specified in paragraph (2), periodically (as determined appropriate by the Secretary) update guidance described in subsection (a) and revise the posting of such guidance on the website described in such subsection.

"(2) CONSULTATION.—The entities specified in this paragraph are the following:

"(A) Medical professional organizations.

"(B) Providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)).

"(C) Health care consumers or groups representing such consumers.

``(D) Other entities determined appropriate by the Secretary."

GAO STUDY ON ADVISORY OPINION AUTHORITY

Pub. L. 108-173, title IX,  $\S 904(a)$ , 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, 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 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. Beginning July 1, 2016, if the Secretary determines appropriate, the data described in this paragraph may also include standardized extracts (as determined by the Secretary) of claims data under subchapters XIX and XXI for assistance provided under such subchapters 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 or under subchapters 2 XIX or XXI.

## (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, for periods prior to July 1, 2016, into the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, and, beginning July 1, 2016, into the Centers for Medicare & Medicaid Services Program Management Account.

# (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,

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

<sup>&</sup>lt;sup>2</sup> So in original. Probably should be "subchapter".