

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, § 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.)

**Editorial Notes**

**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—Pub. L. 92-603 struck out reference to provisions of section 408 of this title.

**Statutory Notes and Related Subsidiaries**

**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 reimburs-

able 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<sup>2</sup> 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, 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 serv-

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

<sup>2</sup> So in original. Probably should be “subchapter”.

ices 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 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.

#### **(f) Requirement for the Secretary to establish policies and claims edits relating to incarcerated individuals, individuals not lawfully present, and deceased individuals**

The Secretary shall establish and maintain procedures, including procedures for using claims processing edits, updating eligibility information to improve provider accessibility, and conducting recoupment activities such as through recovery audit contractors, in order to ensure that payment is not made under this subchapter for items and services furnished to an individual who is one of the following:

(1) An individual who is incarcerated.

(2) An individual who is not lawfully present in the United States and who is not eligible for coverage under this subchapter.

(3) A deceased individual.

#### **(g) Requirement for enrollment data reporting**

##### **(1) In general**

Each year (beginning with 2016), the Secretary shall submit to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on Medicare enrollment data (and, in the case of part A, on data on individuals receiving benefits under such part) as of a date in such year specified by the Secretary. Such data shall be presented—

(A) by Congressional district and State; and

(B) in a manner that provides for such data based on—

(i) fee-for-service enrollment (as defined in paragraph (2));

(ii) enrollment under part C (including separate for aggregate enrollment in MA-PD plans and aggregate enrollment in MA plans that are not MA-PD plans); and

(iii) enrollment under part D.

#### **(2) Fee-for-service enrollment defined**

For purpose of paragraph (1)(B)(i), the term “fee-for-service enrollment” means aggregate enrollment (including receipt of benefits other than through enrollment) under—

(A) part A only;

(B) part B only; and

(C) both part A and part B.

(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; Pub. L. 114-10, title I, §105(c), (d), title V, §502(a), Apr. 16, 2015, 129 Stat. 137, 165; Pub. L. 114-255, div. C, title XVII, §17002, Dec. 13, 2016, 130 Stat. 1330.)

#### **Editorial Notes**

##### **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**

2016—Subsec. (g). Pub. L. 114-255 added subsec. (g).

2015—Subsec. (e). Pub. L. 114-10, §105(c)(1), struck out “Medicare” before “data” in heading.

Subsec. (e)(3). Pub. L. 114-10, §105(c)(2), inserted “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.” before “The Secretary” and “or under subchapters XIX or XXI” before period at end.

Subsec. (e)(4)(A). Pub. L. 114-10, §105(d), inserted “, for periods prior to July 1, 2016,” after “deposited” and “, and, beginning July 1, 2016, into the Centers for Medicare & Medicaid Services Program Management Account” before period at end.

Subsec. (f). Pub. L. 114-10, §502(a), added subsec. (f).

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

2008—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.

#### Statutory Notes and Related Subsidiaries

##### 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.

##### REPORT

Pub. L. 114-10, title V, §502(b), Apr. 16, 2015, 129 Stat. 165, provided that: “Not later than 18 months after the date of the enactment of this section [Apr. 16, 2015], and periodically thereafter as determined necessary by the Office of Inspector General of the Department of Health and Human Services, such Office shall submit to Congress a report on the activities described in subsection (f) of section 1874 of the Social Security Act (42 U.S.C. 1395kk), as added by subsection (a), that have been conducted since such date of enactment.”

#### § 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—

##### (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 or enrolled under part B, 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 a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

#### (4) Functions described

The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1395ff(f)(2)(B) of this title), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

##### (A) Determination of payment amounts

Determining (subject to the provisions of section 1395oo of this title and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this subchapter to be made to providers of services, suppliers and individuals.

##### (B) Making payments

Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

##### (C) Beneficiary education and assistance

Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns, or problems.

##### (D) Provider consultative services

Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this subchapter and otherwise to qualify as providers of services or suppliers.

##### (E) Communication with providers

Communicating to providers of services and suppliers any information or instruc-