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.

#### (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 139500 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 instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

## (F) Provider education and technical assistance

Performing the functions relating to provider education, training, and technical assistance.

## (G) Improper payment outreach and education program

Having in place an improper payment outreach and education program described in subsection (h).

## (H) Additional functions

Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1395ddd of this title, as are necessary to carry out the purposes of this subchapter.

## (5) Relationship to MIP contracts

## (A) Nonduplication of duties

In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under a contract entered into under the Medicare Integrity Program under section 1395ddd of this title. The previous sentence shall not apply with respect to the activity described in section 1395 dd(b)(5) of this title (relating to prior authorization of certain items of durable medical equipment under section 1395m(a)(15) of this title).

## (B) Construction

An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1395ddd of this title.

## (6) Application of Federal Acquisition Regulation

Except to the extent inconsistent with a specific requirement of this section, the Federal Acquisition Regulation applies to contracts under this section.

## (b) Contracting requirements

## (1) Use of competitive procedures

## (A) In general

Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

## **(B) Renewal of contracts**

The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 6101 of title 41 or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 10 years.

## (C) Transfer of functions

The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

#### (D) Incentives for quality

#### (i) In general

Subject to clauses (ii) and (iii), the Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

## (ii) Improper payment rate reduction incentives

The Secretary shall provide incentives for medicare administrative contractors to reduce the improper payment error rates in their jurisdictions.

## (iii) Incentives

The incentives provided for under clause (ii)—

(I) may include a sliding scale of award fee payments and additional incentives to medicare administrative contractors that either reduce the improper payment rates in their jurisdictions to certain thresholds, as determined by the Secretary, or accomplish tasks, as determined by the Secretary, that further improve payment accuracy; and

(II) may include substantial reductions in award fee payments under cost-plusaward-fee contracts, for medicare administrative contractors that reach an upper end improper payment rate threshold or other threshold as determined by the Secretary, or fail to accomplish tasks, as determined by the Secretary, that further improve payment accuracy.

## (2) Compliance with requirements

No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

## (3) Performance requirements

## (A) Development of specific performance requirements

## (i) In general

The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this subchapter to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements. Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.

## (ii) Consultation

In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this subchapter, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

## (iii) Publication of standards

The Secretary shall make such performance requirements and measurement standards available to the public.

## (iv) Contractor performance transparency

To the extent possible without compromising the process for entering into and renewing contracts with medicare administrative contractors under this section, the Secretary shall make available to the public the performance of each medicare administrative contractor with respect to such performance requirements and measurement standards.

#### **(B)** Considerations

The Secretary shall include, as one of the standards developed under subparagraph (A), provider and beneficiary satisfaction levels.

## (C) Inclusion in contracts

All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

## (4) Information requirements

The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this subchapter; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this subchapter.

#### (5) Surety bond

A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

#### (c) Terms and conditions

## (1) In general

A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

## (2) Prohibition on mandates for certain data collection

The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this subchapter with data used in the administration of this subchapter for purposes of identifying situations in which the provisions of section 1395y(b) of this title may apply.

## (d) Limitation on liability of medicare administrative contractors and certain officers

## (1) Certifying officer

No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

## (2) Disbursing officer

No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General of the United States) of a certifying officer designated as provided in paragraph (1) of this subsection.

## (3) Liability of medicare administrative contractor

## (A) In general

No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

#### (B) Relationship to False Claims Act

Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31.

## (4) Indemnification by Secretary

#### (A) In general

Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this subchapter, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

## (B) Conditions

The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

#### (C) Scope of indemnification

Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

# (D) Written approval for settlements or compromises

A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

#### (E) Construction

Nothing in this paragraph shall be construed—

(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulation.

#### (e) Requirements for information security

#### (1) Development of information security program

A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this subchapter. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section  $3544(b)^1$  of title 44 (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

#### (2) Independent audits

#### (A) Performance of annual evaluations

Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this subchapter. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44) relating to such functions under this subchapter and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40.

## **(B) Deadline for initial evaluation**

## (i) New contractors

In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1395h or 1395u of this title, the first independent evaluation conducted pursuant to subparagraph (A) shall be completed prior to commencing such functions.

#### (ii) Other contractors

In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant to subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

#### (C) Reports on evaluations

# (i) To the Department of Health and Human Services

The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

## (ii) To Congress

The Inspector General of the Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

#### (iii) Agency reporting

The Secretary shall address the results of such evaluations in reports required under section  $3544(c)^{1}$  of title 44.

#### (f) Incentives to improve contractor performance in provider education and outreach

The Secretary shall use specific claims payment error rates or similar methodology of

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

medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.

## (g) Communications with beneficiaries, providers of services and suppliers

## (1) Communication strategy

The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this subchapter.

#### (2) Response to written inquiries

Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this subchapter within 45 business days of the date of receipt of such inquiries.

## (3) Response to toll-free lines

The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this subchapter.

#### (4) Monitoring of contractor responses

#### (A) In general

Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency,

and timeliness of the information so provided.

## (B) Development of standards

## (i) In general

The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

#### (ii) Evaluation

In conducting evaluations of individual medicare administrative contractors, the

Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

## (C) Direct monitoring

Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

## (5) Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this subsection.

# (h) Improper payment outreach and education program

## (1) In general

In order to reduce improper payments under this subchapter, each medicare administrative contractor shall establish and have in place an improper payment outreach and education program under which the contractor, through outreach, education, training, and technical assistance or other activities, shall provide providers of services and suppliers located in the region covered by the contract under this section with the information described in paragraph (2). The activities described in the preceding sentence shall be conducted on a regular basis.

#### (2) Information to be provided through activities

The information to be provided under such payment outreach and education program shall include information the Secretary determines to be appropriate, which may include the following information:

(A) A list of the providers' or suppliers' most frequent and expensive payment errors over the last quarter.

(B) Specific instructions regarding how to correct or avoid such errors in the future.

(C) A notice of new topics that have been approved by the Secretary for audits conducted by recovery audit contractors under section 1395ddd(h) of this title.

(D) Specific instructions to prevent future issues related to such new audits.

(E) Other information determined appropriate by the Secretary.

#### (3) Priority

A medicare administrative contractor shall give priority to activities under such program that will reduce improper payments that are one or more of the following:

(A) Are for items and services that have the highest rate of improper payment.

(B) Are for items and service<sup>2</sup> that have the greatest total dollar amount of improper payments.

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

(C) Are due to clear misapplication or misinterpretation of Medicare policies.

(D) Are clearly due to common and inadvertent clerical or administrative errors.

(E) Are due to other types of errors that the Secretary determines could be prevented through activities under the program.

## (4) Information on improper payments from recovery audit contractors

## (A) In general

In order to assist medicare administrative contractors in carrying out improper payment outreach and education programs, the Secretary shall provide each contractor with a complete list of the types of improper payments identified by recovery audit contractors under section 1395ddd(h) of this title with respect to providers of services and suppliers located in the region covered by the contract under this section. Such information shall be provided on a time frame the Secretary determines appropriate which may be on a quarterly basis.

## **(B) Information**

The information described in subparagraph (A) shall include information such as the following:

(i) Providers of services and suppliers that have the highest rate of improper payments.

(ii) Providers of services and suppliers that have the greatest total dollar amounts of improper payments.

(iii) Items and services furnished in the region that have the highest rates of improper payments.

(iv) Items and services furnished in the region that are responsible for the greatest total dollar amount of improper payments.

(v) Other information the Secretary determines would assist the contractor in carrying out the program.

#### (5) Communications

Communications with providers of services and suppliers under an improper payment outreach and education program are subject to the standards and requirements of subsection (g).

(Aug. 14, 1935, ch. 531, title XVIII, §1874A, as added and amended Pub. L. 108–173, title IX, §§911(a)(1), 912(a), 921(b)(1), (c)(1), 934(a), 940A(b), Dec. 8, 2003, 117 Stat. 2378, 2387–2389, 2406, 2417; Pub. L. 111–152, title I, §1302, Mar. 30, 2010, 124 Stat. 1057; Pub. L. 114–10, title V, §§505(a), 509(a), (c), Apr. 16, 2015, 129 Stat. 166, 170; Pub. L. 114–115, §7(a), Dec. 28, 2015, 129 Stat. 3134.)

#### References in Text

Section 3544 of title 44, referred to in subsec. (e)(1), (2)(C)(ii), was repealed by Pub. L. 113-283, §2(a), Dec. 18, 2014, 128 Stat. 3073. Provisions similar to section 3544 of title 44 are now contained in section 3554 of title 44, as enacted by Pub. L. 113-283.

#### CODIFICATION

In subsec. (b)(1)(B), "section 6101 of title 41" substituted for "section 5 of title 41, United States Code," on authority of Pub. L. 111-350, 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

2015—Subsec. (a)(4)(G), (H). Pub. L. 114–10, 505(a)(1), added subpar. (G) and redesignated former subpar. (G) as (H).

Subsec. (b)(1)(B). Pub. L. 114-10, §509(a), substituted "10 years" for "5 years". Subsec. (b)(1)(D). Pub. L. 114-115 designated existing

Subsec. (b)(1)(D). Pub. L. 114-115 designated existing provisions as cl. (i) and inserted heading, substituted "Subject to clauses (ii) and (iii), the Secretary" for

"The Secretary", and added cls. (ii) and (iii). Subsec. (b)(3)(A)(iv). Pub. L. 114-10, §509(c), added cl. (iv).

Subsec. (h). Pub. L. 114-10, §505(a)(2), added subsec. (h). 2010—Subsec. (h). Pub. L. 111-152 struck out subsec.

2010—Subsec. (h). Pub. L. 111-152 struck out subsec. (h) which related to conduct of prepayment review. 2003—Subsec. (b)(3)(A)(i). Pub. L. 108-173, §940A(b), in-

2003—Subsec. (b)(3)(A)(1). Pub. L. 108–173, §940A(b), inserted at end "Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor."

Subsec. (e). Pub. L. 108–173, §912(a), added subsec. (e). Subsec. (f). Pub. L. 108–173, §921(b)(1), added subsec. (f).

Subsec. (g). Pub. L. 108–173, §921(c)(1), added subsec. (g).

(g). Subsec. (h). Pub. L. 108–173, §934(a), added subsec. (h). EFFECTIVE DATE OF 2015 AMENDMENT

EFFECTIVE DATE OF 2015 AMENDMENT

Pub. L. 114-115, §7(b), Dec. 28, 2015, 129 Stat. 3134, provided that:

"(1) IN GENERAL.—The amendments made by subsection (a) [amending this section] shall apply to contracts entered into or renewed on or after the date that is 3 years after the date of enactment of this Act [Dec. 28, 2015].

"(2) APPLICATION TO EXISTING CONTRACTS.—In the case of contracts in existence on or after the date of the enactment of this Act and that are not subject to the effective date under paragraph (1), the Secretary of Health and Human Services shall, when appropriate and practicable, seek to apply the incentives provided for in the amendments made by subsection (a) through contract modifications."

contract modifications." Pub. L. 114-10, title V, §509(b), Apr. 16, 2015, 129 Stat. 170, provided that: "The amendments made by subsection (a) [amending this section] shall apply to contracts entered into on or after, and to contracts in effect as of, the date of the enactment of this Act [Apr. 16, 2015]."

#### EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108-173, title IX, §921(c)(2), Dec. 8, 2003, 117 Stat. 2390, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect October 1, 2004."

Pub. L. 108-173, title IX, §934(b), Dec. 8, 2003, 117 Stat. 2407, provided that: "(1) IN GENERAL.—Except as provided in this sub-

"(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) [amending this section] shall take effect 1 year after the date of the enactment of this Act [Dec. 8, 2003].

"(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULA-TIONS.—The Secretary [of Health and Human Services] shall first issue regulations under section 1874A(h) of the Social Security Act [42 U.S.C. 1395kk-1(h)], as added by subsection (a), by not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003].

"(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act [42 U.S.C. 1395kk-1(h)(1)(B)], as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003]) as the Secretary shall specify."

#### EFFECTIVE DATE; TRANSITION RULE

Pub. L. 108-173, title IX, §911(d), Dec. 8, 2003, 117 Stat. 2385, provided that:

#### "(1) EFFECTIVE DATE.—

"(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title] shall take effect on October 1, 2005, and the Secretary [of Health and Human Services] is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

"(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act [see Tables for classification], other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

"(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2011.

"(2) GENERAL TRANSITION RULES.—

(A) AUTHORITY TO CONTINUE TO ENTER INTO NEW AGREEMENTS AND CONTRACTS AND WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—Prior to October 1, 2005, the Secretary may, consistent with subparagraph (B), continue to enter into agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u). The Secretary may enter into new agreements under section 1816 prior to October 1, 2005, without regard to any of the provider nomination provisions of such section.

"(B) APPROPRIATE TRANSITION.—The Secretary shall take such steps as are necessary to provide for an appropriate transition from agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A [42 U.S.C. 1395kk-1], as added by subsection (a)(1).

"(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER TRANSITION CONTRACTS.—Notwithstanding the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title], the provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395dd(d)(2)) shall continue to apply during the period that begins on the date of the enactment of this Act [Dec. 8, 2003] and ends on October 1, 2011, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act [42 U.S.C. 1395kk-1], as inserted by subsection (a)(1), that continues the activities referred to in such provisions."

#### CONSTRUCTION

Pub. L. 108–173, title IX, §901(a), Dec. 8, 2003, 117 Stat. 2374, provided that: "Nothing in this title [see Tables for classification] shall be construed—

"(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (commonly known as the 'False Claims Act'); or

"(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this division [Pub. L. 108-173 does not contain any divisions] does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue."

## CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS

Pub. L. 108–173, title IX, §911(a)(2), Dec. 8, 2003, 117 Stat. 2383, provided that: "In developing contract performance requirements under section 1874A(b) of the Social Security Act [42 U.S.C. 1395kk–1(b)], as inserted by paragraph (1), the Secretary [of Health and Human Services] shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act [42 U.S.C. 1395h(f)(2)] (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act [42 U.S.C. 1395u(b)(2)(B)] (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act [Dec. 8, 2003]."

#### References

Pub. L. 108–173, title IX, §911(e), Dec. 8, 2003, 117 Stat. 2386, provided that: "On and after the effective date provided under subsection (d)(1) [set out above], any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act [42 U.S.C. 1301 et seq., 1395 et seq.] (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the Social Security Act [42 U.S.C. 1395kk-1])."

SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL

Pub. L. 108–173, title IX, §911(f), Dec. 8, 2003, 117 Stat. 2386, provided that: "Not later than 6 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section [enacting this section, amending sections 1395h and 1395u of this title, and enacting provisions set out as notes under this section]."

#### REPORTS ON IMPLEMENTATION

Pub. L. 108-173, title IX, §911(g), Dec. 8, 2003, 117 Stat. 2386, provided that:

"(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary [of Health and Human Services] shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title]. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

"(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

"(A) The number of contracts that have been competitively bid as of such date

"(B) The distribution of functions among contracts and contractors.

 $``(C)\ A$  timeline for complete transition to full competition.

"(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition."

Application to Fiscal Intermediaries and Carriers

Pub. L. 108–173, title IX,  $912(b),\, {\rm Dec.}\ 8,\, 2003,\, 117$  Stat. 2388, provided that:

"(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act [42 U.S.C.

1395kk-1(e)(2)] (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act [Dec. 8, 2003], the first evaluation under section 1874A(e)(2)(A) of the Social Security Act [42 U.S.C. 1395kk-1(e)(2)(A)] (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary [of Health and Human Services]) by not later than 1 year after such date.

Pub. L. 108-173, title IX, §921(b)(2), Dec. 8, 2003, 117 Stat. 2389, provided that: "The provisions of section 1874A(f) of the Social Security Act [42 U.S.C. 1395kk-1(f)], as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative

Contractors under such provisions." Pub. L. 108-173, title IX, §921(c)(3), Dec. 8, 2003, 117 Stat. 2390, provided that: "The provisions of section 1874A(g) of the Social Security Act [42 U.S.C. 1395kk-1(g)], as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative

contractors under such provisions." Pub. L. 108–173, title IX, §934(c), Dec. 8, 2003, 117 Stat. 2407, provided that: "The provisions of section 1874A(h) of the Social Security Act [42 U.S.C. 1395kk–1(h)], as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions."

POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES

Pub. L. 108-173, title IX, §941, Dec. 8, 2003, 117 Stat. 2418, provided that:

"(a) IN GENERAL.-The Secretary [of Health and Human Services] may not implement any new or modified documentation guidelines (which for purposes of this section includes clinical examples) for evaluation and management physician services under the [sic] title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] on or after the date of the enactment of this Act [Dec. 8, 2003] unless the Secretary

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of

the proposed guidelines by the physician community; "(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

"(3) has conducted appropriate and representative pilot projects under subsection (b) to test such guide-

lines; "(4) finds, based on reports submitted under subsection (b)(5) with respect to pilot projects conducted for such or related guidelines, that the objectives described in subsection (c) will be met in the implementation of such guidelines; and "(5) has established, and is implementing, a pro-

gram to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paper-

"(b) PILOT PROJECTS TO TEST MODIFIED OR NEW EVAL-UATION AND MANAGEMENT DOCUMENTATION GUIDE-LINES -

"(1) IN GENERAL.—With respect to proposed new or modified documentation guidelines referred to in subsection (a), the Secretary shall conduct under this subsection appropriate and representative pilot projects to test the proposed guidelines.

"(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall-

(A) be voluntary

"(B) be of sufficient length as determined by the Secretary (but in no case to exceed 1 year) to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

'(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists)

'(3) RANGE OF PILOT PROJECTS .- Of the pilot projects conducted under this subsection with respect to proposed new or modified documentation guidelines

 $\tilde{(A)}$  at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to codes used for billing purposes for such services:

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting. "(4) STUDY OF IMPACT.—Each pilot project shall ex-

amine the effect of the proposed guidelines on-

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

"(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

"(5) REPORT ON PILOT PROJECTS.—Not later than 6 months after the date of completion of pilot projects carried out under this subsection with respect to a proposed guideline described in paragraph (1), the Secretary shall submit to Congress a report on the pilot projects. Each such report shall include a finding by the Secretary of whether the objectives described in subsection (c) will be met in the implementation of such proposed guideline. "(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT

GUIDELINES .- The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to— "(1) identify clinically relevant documentation

needed to code accurately and assess coding levels accurately:

"(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

"(4) educate both physicians and reviewers. "(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.-

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are

 ${}^{\!\!\!\!\!\!}(A\bar{)}$  the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

"(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

"(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

"(4) APPLICATION OF HIPAA UNIFORM CODING REQUIRE-MENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.].

"(5) REPORT TO CONGRESS.—

"(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

"(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

"(e) STUDY ON APPROPRIATE CODING OF CERTAIN EX-TENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

"(1) the term 'rural area' has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)); and

"(2) the term 'teaching settings' are those settings described in section 415.150 of title 42, Code of Federal Regulations."

## §1395kk-2. Expanding availability of Medicare data

# (a) Expanding uses of Medicare data by qualified entities

#### (1) Additional analyses

#### (A) In general

Subject to subparagraph (B), to the extent consistent with applicable information, privacy, security, and disclosure laws (including paragraph (3)), notwithstanding paragraph (4)(B) of section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)) and the second sentence of paragraph (4)(D) of such section, beginning July 1, 2016, a qualified entity may use the combined data described in paragraph (4)(B)(iii) of such section received by such entity under such section, and information derived from the evaluation described in such paragraph (4)(D), to conduct additional non-public analyses (as determined appropriate by the Secretary) and provide or sell such analyses to authorized users for non-public use (including for the purposes of assisting providers of services and suppliers to develop and participate in quality and patient care improvement activities, including developing new models of care).

# (B) Limitations with respect to analyses(i) Employers

Any analyses provided or sold under subparagraph (A) to an employer described in paragraph (9)(A)(iii) may only be used by such employer for purposes of providing health insurance to employees and retirees of the employer.

#### (ii) Health insurance issuers

A qualified entity may not provide or sell an analysis to a health insurance issuer described in paragraph (9)(A)(iv) unless the issuer is providing the qualified entity with data under section 1874(e)(4)(B)(iii) of the Social Security Act (42 U.S.C. 1395 kk(e)(4)(B)(iii)).

## (2) Access to certain data

## (A) Access

To the extent consistent with applicable information, privacy, security, and disclosure laws (including paragraph (3)), notwithstanding paragraph (4)(B) of section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)) and the second sentence of paragraph (4)(D) of such section, beginning July 1, 2016, a qualified entity may—

(i) provide or sell the combined data described in paragraph (4)(B)(iii) of such section to authorized users described in clauses (i), (ii), and (v) of paragraph (9)(A) for non-public use, including for the purposes described in subparagraph (B); or

(ii) subject to subparagraph (C), provide Medicare claims data to authorized users described in clauses (i), (ii), and (v),<sup>1</sup> of paragraph (9)(A) for non-public use, including for the purposes described in subparagraph (B).

## (B) Purposes described

The purposes described in this subparagraph are assisting providers of services and suppliers in developing and participating in quality and patient care improvement activities, including developing new models of care.

# (C) Medicare claims data must be provided at no cost

A qualified entity may not charge a fee for providing the data under subparagraph (A)(ii).

## (3) Protection of information

## (A) In general

Except as provided in subparagraph (B), an analysis or data that is provided or sold under paragraph (1) or (2) shall not contain information that individually identifies a patient.

# (B) Information on patients of the provider of services or supplier

To the extent consistent with applicable information, privacy, security, and disclosure laws, an analysis or data that is provided or sold to a provider of services or supplier under paragraph (1) or (2) may contain information that individually identifies a patient of such provider or supplier, including with respect to items and services furnished to the patient by other providers of services or suppliers.

# (C) Prohibition on using analyses or data for marketing purposes

An authorized user shall not use an analysis or data provided or sold under paragraph (1) or (2) for marketing purposes.

<sup>&</sup>lt;sup>1</sup>So in original. The comma probably should not appear.