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 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—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

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 section 111(e) of Pub. L. 89–97.

§ 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 ad-

ministrative 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 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 of this subchapter or enrolled under part B of this subchapter, 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 of this subchapter or enrolled under part B of this subchapter, 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) 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 of this subchapter 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 the activity described in section 1395ddd(b)(5) of this title (relating to prior authorization of certain items of durable medical equipment under 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 pro-

curement 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 5 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

The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

(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) of this section 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.

(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

- (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 Sec-

retary 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) of this section.

(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 administra-

tion 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) of this section (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) of title 44 (other than the requirements under

paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

(2) Independent audits

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(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) of this section (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) of this section (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) 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 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 of this subchapter or enrolled under part B of this subchapter, 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 of this subchapter or enrolled under part B of this subchapter, 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 of this subchapter or enrolled under part B of this subchapter, 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 of this subchapter or enrolled under part B of this subchapter, 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) of this section.

(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 of this subchapter or enrolled under part B of this subchapter, 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.

(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.)

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

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), 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.

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

Subsec. (h). Pub. L. 108–173, §934(a), added subsec. (h).

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title IX, $\S921(c)(2)$, 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 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 [subsec. (h) of this section], 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 [subsec. (h)(1)(B) of this section], 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 [this section], as added by subsection (a)(1).

"(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER TRANSITION CONTRACTS.—Notwithstanding the amendaments 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. 1395ddd(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 [this section], 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 [subsec. (b) of this section], 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 [section 1395h(f)(2) of this title] (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act [section 1395u(b)(2)(B) of this title] (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 [subchapter XI of this chapter and this subchapter] (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 [this section])."

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, $\S912(b)$, Dec. 8, 2003, 117 Stat. 2388, provided that:

"(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act [subsec. (e)(2) of this section] (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 [subsec. (e)(2)(A) of this section] (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 [subsec. (f) of this section], 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 [subsec. (g) of this section], 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 [subsec. (h) of this section], 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, $\S941$, 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 [this subchapter] 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 guidelines:
- "(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 program 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 paperwork burdens on physicians.
- "(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.
 - $\lq\lq(2)$ 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—
 - "(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 examine 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) 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 [this subchapter]; 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 [part C of subchapter XI of this chapter].
 - '(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 EXTENDED 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
 - (12) the term 'teaching settings' are those settings described in section 415.150 of title 42, Code of Federal Regulations."

§ 1395ll. Studies and recommendations

(a) Health care of the aged and disabled

The Secretary shall carry on studies and develop recommendations to be submitted from time to time to the Congress relating to health care of the aged and the disabled, including studies and recommendations concerning (1) the adequacy of existing personnel and facilities for health care for purposes of the programs under parts A and B of this subchapter; (2) methods for encouraging the further development of efficient and economical forms of health care which are a