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 [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 REQUIREMENTS.—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 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

''(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. 1395kk(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)), notwith-

standing 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),[1] 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.

(4) Data use agreement

A qualified entity and an authorized user described in clauses (i), (ii), and (v) of paragraph (9)(A) shall enter into an agreement regarding the use of any data that the qualified entity is providing or selling to the authorized user under paragraph (2). Such agreement shall describe the requirements for privacy and security of the data and, as determined appropriate by the Secretary, any prohibitions on using such data to link to other individually identifiable sources of information. If the authorized user is not a covered entity under the rules promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, the agreement shall identify the relevant regulations, as determined by the Secretary, that the user shall comply with as if it were acting in the capacity of such a covered entity.

(5) No redisclosure of analyses or data

(A) In general

Except as provided in subparagraph (B), an authorized user that is provided or sold an analysis or data under paragraph (1) or (2) shall not redisclose or make public such analysis or data or any analysis using such data.

(B) Permitted redisclosure

A provider of services or supplier that is provided or sold an analysis or data under paragraph (1) or (2) may, as determined by the Secretary, redisclose such analysis or data for the purposes of performance improvement and care coordination activities but shall not make public such analysis or data or any analysis using such data.

(6) Opportunity for providers of services and suppliers to review

Prior to a qualified entity providing or selling an analysis to an authorized user under paragraph (1), to the extent that such analysis would individually identify a provider of services or supplier who is not being provided or sold such analysis, such qualified entity shall provide such provider or supplier with the opportunity to appeal and correct errors in the manner described in section 1874(e)(4)(C)(ii) of the Social Security Act (42 U.S.C. 1395kk(e)(4)(C)(ii)).

(7) Assessment for a breach

(A) In general

In the case of a breach of a data use agreement under this section or section 1874(e) of the Social Security Act (42 U.S.C. 1395kk(e)), the Secretary shall impose an assessment on the qualified entity both in the case of—

(i) an agreement between the Secretary and a qualified entity; and

(ii) an agreement between a qualified entity and an authorized user.

(B) Assessment

The assessment under subparagraph (A) shall be an amount up to $100 for each individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.] or enrolled for benefits under part B of such title [42 U.S.C. 1395j et seq.]—

(i) in the case of an agreement described in subparagraph (A)(i), for whom the Secretary provided data on to the qualified entity under paragraph (2); and

(ii) in the case of an agreement described in subparagraph (A)(ii), for whom the qualified entity provided data on to the authorized user under paragraph (2).

[1] So in original. The comma probably should not appear.

(C) Deposit of amounts collected

Any amounts collected pursuant to this paragraph shall be deposited in Federal[2] Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(8) Annual reports

Any qualified entity that provides or sells an analysis or data under paragraph (1) or (2) shall annually submit to the Secretary a report that includes—

(A) a summary of the analyses provided or sold, including the number of such analyses, the number of purchasers of such analyses, and the total amount of fees received for such analyses;

(B) a description of the topics and purposes of such analyses;

(C) information on the entities who received the data under paragraph (2), the uses of the data, and the total amount of fees received for providing, selling, or sharing the data; and

(D) other information determined appropriate by the Secretary.

(9) Definitions

In this subsection and subsection (b):

(A) Authorized user

The term ''authorized user'' means the following:

(i) A provider of services.

(ii) A supplier.

(iii) An employer (as defined in section 1002(5) of title 29).

(iv) A health insurance issuer (as defined in section 300gg–91 of this title).

(v) A medical society or hospital association.

(vi) Any entity not described in clauses (i) through (v) that is approved by the Secretary (other than an employer or health insurance issuer not described in clauses (iii) and (iv), respectively, as determined by the Secretary).

(B) Provider of services

The term ''provider of services'' has the meaning given such term in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)).

(C) Qualified entity

The term ''qualified entity'' has the meaning given such term in section 1874(e)(2) of the Social Security Act (42 U.S.C. 1395kk(e)).[3]

(D) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(E) Supplier

The term ''supplier'' has the meaning given such term in section 1861(d) of the Social Security Act (42 U.S.C. 1395x(d)).

(b) Access to Medicare data by qualified clinical data registries to facilitate quality improvement

(1) Access

(A) In general

To the extent consistent with applicable information, privacy, security, and disclosure laws, beginning July 1, 2016, the Secretary shall, at the request of a qualified clinical data registry under section 1848(m)(3)(E) of the Social Security Act (42 U.S.C. 1395w–4(m)(3)(E)), provide the data described in subparagraph (B) (in a form and manner determined to be appropriate) to such qualified clinical data registry for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety, provided that any public reporting of such analyses or research that identifies a provider of services or supplier shall only be conducted with the opportunity of such provider or supplier to appeal and correct errors in the manner described in subsection (a)(6).

(B) Data described

The data described in this subparagraph is—

(i) claims data under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

(ii) if the Secretary determines appropriate, claims data under the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.] and the State Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.].

(2) Fee

Data described in paragraph (1)(B) shall be provided to a qualified clinical data registry under paragraph (1) at a fee equal to the cost of providing such data. Any fee collected pursuant to the preceding sentence shall be deposited in the Centers for Medicare & Medicaid Services Program Management Account.

(Pub. L. 114–10, title I, §105, Apr. 16, 2015, 129 Stat. 133.)

Editorial Notes

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (a)(4), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

The Social Security Act, referred to in subsecs. (a)(7)(B) and (b)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to this subchapter and subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.) of this chapter, respectively. Parts A and B of title XVIII of the Act are classified generally to parts A (§1395c et seq.) and B (§1395j et seq.) of this subchapter, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section is comprised of section 105 of Pub. L. 114–10. Subsecs. (c) and (d) of section 105 of Pub. L. 114–10 amended section 1395kk of this title.

[2] So in original. Probably should be preceded by ''the''.

[3] So in original. Probably should be ''1395kk(e)(2)).''

Section was enacted as part of the Medicare Access and CHIP Reauthorization Act of 2015, and not as part of the Social Security Act which comprises this chapter.

§ 1395*ll*. 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 constructive alternative to inpatient hospital care; and (3) the effects of the deductibles and coinsurance provisions upon beneficiaries, persons who provide health services, and the financing of the program.

(b) Operation and administration of insurance programs

The Secretary shall make a continuing study of the operation and administration of this subchapter (including a validation of the accreditation process of national accreditation bodies under section 1395bb(a) of this title[1] the operation and administration of health maintenance organizations authorized by section 226 of the Social Security Amendments of 1972 [42 U.S.C. 1395mm], the experiments and demonstration projects authorized by section 402 of the Social Security Amendments of 1967 [42 U.S.C. 1395b–1] and the experiments and demonstration projects authorized by section 222(a) of the Social Security Amendments of 1972 [42 U.S.C. 1395b–1 note]), and shall transmit to the Congress annually a report concerning the operation of such programs.

(Aug. 14, 1935, ch. 531, title XVIII, § 1875, as added Pub. L. 89–97, title I, § 102(a), July 30, 1965, 79 Stat. 332; amended Pub. L. 90–248, title IV, § 402(c), Jan. 2, 1968, 81 Stat. 931; Pub. L. 92–603, title II, §§ 201(c)(7), 222(c), 226(d), 244(d), Oct. 30, 1972, 86 Stat. 1373, 1393, 1404, 1423; Pub. L. 98–369, div. B, title III, § 2354(b)(17), July 18, 1984, 98 Stat. 1101; Pub. L. 99–509, title IX, § 9316(a), Oct. 21, 1986, 100 Stat. 2006; Pub. L. 100–203, title IV, § 4085(i)(20), Dec. 22, 1987, 101 Stat. 1330–133; Pub. L. 100–647, title VIII, § 8413, Nov. 10, 1988, 102 Stat. 3801; Pub. L. 101–234, title III, § 301(b)(5), (d)(2), Dec. 13, 1989, 103 Stat. 1985, 1986; Pub. L. 101–239, title VI, § 6103(b)(3)(A), Dec. 19, 1989, 103 Stat. 2199; Pub. L. 108–173, title I, § 101(e)(7), Dec. 8, 2003, 117 Stat. 2152; Pub. L. 110–275, title I, § 125(b)(4), July 15, 2008, 122 Stat. 2519.)

Editorial Notes

References in Text

Section 226 of the Social Security Amendments of 1972, referred to in subsec. (b), is section 226 of Pub. L. 92–603, which enacted section 1395mm of this title and provisions set out as notes under that section and amended this section and sections 1395f, 1395*l*, and 1396b of this title.

Section 402 of the Social Security Amendments of 1967, referred to in subsec. (b), is section 402 of Pub. L. 90–248, which enacted section 1395b–1 of this title and amended this section.

Section 222(a) of the Social Security Amendments of 1972, referred to in subsec. (b), is section 222(a) of Pub. L. 92–603, which enacted provisions set out as note under section 1395b–1 of this title.

Amendments

2008—Subsec. (b). Pub. L. 110–275 substituted ''national accreditation bodies under section 1395bb(a) of this title'' for ''the Joint Commission on Accreditation of Hospitals,''.

2003—Subsec. (b). Pub. L. 108–173 substituted ''this subchapter'' for ''the insurance programs under parts A and B of this subchapter''.

1989—Subsec. (c). Pub. L. 101–239 struck out subsec. (c) which related to patient outcome assessment research program.

Subsec. (c)(7). Pub. L. 101–234, § 301(b)(5), (d)(2), amended par. (7) identically, substituting ''date of the enactment of this section'' for ''date of the enactment of this Act''.

1988—Subsec. (c)(3). Pub. L. 100–647 amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''For purposes of carrying out the research program, there are authorized to be appropriated—

''(A) from the Federal Hospital Insurance Trust Fund $4,000,000 for fiscal year 1987 and $5,000,000 for each of fiscal years 1988 and 1989, and

''(B) from the Federal Supplementary Medical Insurance Trust Fund $2,000,000 for fiscal year 1987 and $2,500,000 for each of fiscal years 1988 and 1989.''

1987—Subsec. (c)(3)(B). Pub. L. 100–203 substituted ''fiscal year 1987'' for ''fiscal years 1987''.

1986—Subsec. (c). Pub. L. 99–509 added subsec. (c).

1984—Subsec. (b). Pub. L. 98–369 struck out ''the'' after ''Joint Commission on''.

1972—Subsec. (a). Pub. L. 92–603, § 201(c)(7), inserted ''and the disabled'' after ''aged''.

Subsec. (b). Pub. L. 92–603, §§ 222(c), 226(d)(1), 244(d), substituted ''(including a validation of the accreditation process of the Joint Commission on the Accreditation of Hospitals, the operation and administration of health maintenance organizations authorized by section 226 of the Social Security Amendments of 1972, the experiments and demonstration projects authorized by section 402 of the Social Security Amendments of 1967 and the experiments and demonstration projects authorized by section 222(a) of the Social Security Amendments of 1972)'' for ''(including the experimentation authorized by section 402 of the Social Security Amendments of 1967)''. Pub. L. 92–603, § 226(d)(2), which directed the substitution of ''1972'' for ''1971'', could not be executed because ''1971'' did not appear.

1968—Subsec. (b). Pub. L. 90–248 inserted ''(including the experimentation authorized by section 402 of the Social Security Amendments of 1967'' after ''under parts A and B of this subchapter''.

Statutory Notes and Related Subsidiaries

Effective Date of 2008 Amendment; Transition Rule

Amendment by Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110–275, set out as a note under section 1395bb of this title.

Effective Date of 1989 Amendment

Pub. L. 101–239, title VI, § 6103(b)(3)(A), Dec. 19, 1989, 103 Stat. 2199, provided that the amendment made by that section is effective for fiscal years beginning after fiscal year 1990.

Effective Date of 1984 Amendment

Amendment by Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any

[1] So in original. Probably should be followed by a comma.