Pub. L. 99–272, title IX, § 9307(e), Apr. 7, 1986, 100 Stat. 194, provided that: ''The amendments made by this section [amending this section and sections 1395u and 1395y of this title] shall apply to services performed on or after April 1, 1986.''

Pub. L. 99–272, title IX, § 9401(d), Apr. 7, 1986, 100 Stat. 200, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to items and services furnished on or after January 1, 1987. The Secretary of Health and Human Services shall provide for such modification of contracts under part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.] that are in effect on that date as may be necessary to effect these amendments on a timely basis.''

Pub. L. 99–272, title IX, § 9403(c), Apr. 7, 1986, 100 Stat. 200, provided that: ''The amendments made by this section [amending this section and section 1395cc of this title] shall become effective on the date of the enactment of this Act [Apr. 7, 1986].''

Pub. L. 99–272, title IX, § 9405(b), Apr. 7, 1986, 100 Stat. 201, as amended by Pub. L. 99–509, title IX, § 9353(a)(5), Oct. 21, 1986, 100 Stat. 2046, provided that: ''The amendment made by this section [amending this section] shall apply to items and services furnished on or after April 1, 1987.''

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by Pub. L. 97–448 effective as if originally included as a part of this section as this section was added by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 309(c)(2) of Pub. L. 97–448, set out as a note under section 426–1 of this title.

STATE REGULATORY PROGRAMS

For provisions relating to changes required to conform State regulatory programs to amendments by section 171 of Pub. L. 103–432, see section 171(m) of Pub. L. 103–432, set out as a note under section 1395ss of this title.

REVIEW AND ANALYSIS OF VARIATIONS IN UTILIZATION OF HOSPITAL AND OTHER HEALTH CARE SERVICES

Pub. L. 99–509, title IX, § 9353(a)(4), Oct. 21, 1986, 100 Stat. 2046, provided that: ''The Secretary of Health and Human Services shall provide, to at least 12 utilization and quality control peer review organizations with contracts under part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.], data and data processing assistance to allow each of these organizations to review and analyze small-area variations, in the service area of the organization, in the utilization of hospital and other health care services for which payment is made under title XVIII of such Act [42 U.S.C. 1395 et seq.].''

§ 1320c–4. Right to hearing and judicial review

Any beneficiary who is entitled to benefits under subchapter XVIII, and, subject to section 1320c–3(a)(3)(D) of this title, any practitioner or provider, who is dissatisfied with a determination made by a contracting quality improvement organization in conducting its review responsibilities under this part, shall be entitled to a reconsideration of such determination by the reviewing organization. Where the reconsideration is adverse to the beneficiary and where the matter in controversy is $200 or more, such beneficiary shall be entitled to a hearing by the Secretary (to the same extent as beneficiaries under subchapter II are entitled to a hearing by the Commissioner of Social Security under section 405(b) of this title). For purposes of the preceding sentence, subsection (*l*) of section 405 of this title shall apply, except that any reference in such subsection to the Commissioner of Social Security or the Social Security Administration shall be deemed a reference to the Secretary or the Department of Health and Human Services, respectively. Where the amount in controversy is $2,000 or more, such beneficiary shall be entitled to judicial review of any final decision relating to a reconsideration described in this subsection.

(Aug. 14, 1935, ch. 531, title XI, § 1155, as added Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 388; amended Pub. L. 101–239, title VI, § 6224(b)(2), Dec. 19, 1989, 103 Stat. 2257; Pub. L. 103–296, title I, § 108(b)(14), Aug. 15, 1994, 108 Stat. 1485; Pub. L. 112–40, title II, § 261(a)(2)(C), Oct. 21, 2011, 125 Stat. 423.)

Editorial Notes

PRIOR PROVISIONS

A prior section 1320c–4, act Aug. 14, 1935, ch. 531, title XI, § 1155, as added Oct. 30, 1972, Pub. L. 92–603, title II, § 249F(b), 86 Stat. 1433; amended Oct. 25, 1977, Pub. L. 95–142, § 5(c)(1), (d)(3), (*o*)(2), (p), 91 Stat. 1184, 1188, 1191, 1192; Dec. 5, 1980, Pub. L. 96–499, title IX, §§ 924(b)–(d), 925–927(a), 931(g), 94 Stat. 2629, 2630, 2634; Aug. 13, 1981, Pub. L. 97–35, title XXI, §§ 2111, 2113(d), 2121(f), 95 Stat. 793, 794, 796, related to functions and duties of Professional Standards Review Organizations, prior to the general revision of this part by Pub. L. 97–248.

AMENDMENTS

2011—Pub. L. 112–40 substituted ''quality improvement'' for ''peer review''.

1994—Pub. L. 103–296 substituted ''(to the same extent as beneficiaries under subchapter II are entitled to a hearing by the Commissioner of Social Security under section 405(b) of this title). For purposes of the preceding sentence, subsection (*l*) of section 405 of this title shall apply, except that any reference in such subsection to the Commissioner of Social Security or the Social Security Administration shall be deemed a reference to the Secretary or the Department of Health and Human Services, respectively. Where the amount in controversy is $2,000 or more, such beneficiary shall be entitled to judicial review of any final decision relating to a reconsideration described in this subsection.'' for ''(to the same extent as is provided in section 405(b) of this title), and, where the amount in controversy is $2,000 or more, to judicial review of the Secretary's final decision.''

1989—Pub. L. 101–239 inserted '', subject to section 1320c–3(a)(3)(D) of this title,'' before ''any practitioner or provider''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–40 applicable to contracts entered into or renewed on or after Jan. 1, 2012, see section 261(e) of Pub. L. 112–40, set out as a note under section 1320c of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103–296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 applicable to determinations by utilization and quality control peer review organizations with respect to which preliminary notifications were made under section 1320c–3(a)(3)(B) of this title more than 30 days after Dec. 19, 1989, see section 6224(b)(3) of Pub. L. 101–239, set out as a note under section 1320c–3 of this title.

§ 1320c–5. Obligations of health care practitioners and providers of health care services; sanctions and penalties; hearings and review

(a) Assurances regarding services and items ordered or provided by practitioner or provider

It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this chapter, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter—

(1) will be provided economically and only when, and to the extent, medically necessary;

(2) will be of a quality which meets professionally recognized standards of health care; and

(3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities.

(b) Sanctions and penalties; hearings and review

(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part determines that such practitioner or person has—

(A) failed in a substantial number of cases substantially to comply with any obligation imposed on him under subsection (a), or

(B) grossly and flagrantly violated any such obligation in one or more instances,

such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination, the Secretary (in addition to any other sanction provided under law) may exclude (permanently or for such period as the Secretary may prescribe, except that such period may not be less than 1 year) such practitioner or person from eligibility to provide services under this chapter on a reimbursable basis. If the Secretary fails to act upon the recommendations submitted to him by such organization within 120 days after such submission, such practitioner or person shall be excluded from eligibility to provide services on a reimbursable basis until such time as the Secretary determines otherwise.

(2) A determination made by the Secretary under this subsection to exclude a practitioner or person shall be effective on the same date and in the same manner as an exclusion from participation under the programs under this chapter becomes effective under section 1320a–7(c) of this title, and shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or person to provide such health care services on a reimbursable basis) such practitioner or person pays[1] to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or person of health care services which were medically improper or unnecessary, an amount not in excess of up to $10,000 for each instance of the medically improper or unnecessary services so provided. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the practitioner or person from whom such amount is claimed.

(4) Any practitioner or person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

(5) Before the Secretary may effect an exclusion under paragraph (2) in the case of a provider or practitioner located in a rural health professional shortage area or in a county with a population of less than 70,000, the provider or practitioner adversely affected by the determination is entitled to a hearing before an administrative law judge (described in section 405(b) of this title) respecting whether the provider or practitioner should be able to continue furnishing services to individuals entitled to benefits under this chapter, pending completion of the administrative review procedure under paragraph (4). If the judge does not determine, by a preponderance of the evidence, that the provider or practitioner will pose a serious risk to such individuals if permitted to continue furnishing such services, the Secretary shall not effect the exclusion under paragraph (2) until the provider or practitioner has been provided reasonable notice and opportunity for an administrative hearing thereon under paragraph (4).

(6) When the Secretary effects an exclusion of a physician under paragraph (2), the Secretary shall notify the State board responsible for the licensing of the physician of the exclusion.

(c) Enlistment of support of other organizations to assure practitioner's or provider's compliance with obligations

It shall be the duty of each quality improvement organization to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the

[1] So in original. Probably should be ''pay''.