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.)

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''.

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.

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

(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 area served by such review organization, in assuring that each practitioner or person (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

(Aug. 14, 1935, ch. 531, title XI, § 1156, as added Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 388; amended Pub. L. 100–93, § 6, Aug. 18, 1987, 101 Stat. 691; Pub. L. 100–203, title IV, § 4095(a), Dec. 22, 1987, 101 Stat. 1330–138; Pub. L. 100–203, title IV, § 4039(h)(5), Dec. 22, 1987, as added Pub. L. 100–360, title IV, § 411(e)(3), July 1, 1988, 102 Stat. 775; Pub. L. 101–508, title IV, § 4205(a)(1), (d)(2)(A), Nov. 5, 1990, 104 Stat. 1388–112, 1388–114; Pub. L. 101–597, title IV, § 401(c)(1), Nov. 16, 1990, 104 Stat. 3035; Pub. L. 103–432, title I, § 156(b)(1), Oct. 31, 1994, 108 Stat. 4441; Pub. L. 104–191, title II, §§ 214, 231(f), Aug. 21, 1996, 110 Stat. 2005, 2014; Pub. L. 112–40, title II, § 261(a)(2)(C), Oct. 21, 2011, 125 Stat. 423.)

PRIOR PROVISIONS

A prior section 1320c–5, act Aug. 14, 1935, ch. 531, title XI, § 1156, as added Oct. 30, 1972, Pub. L. 92–603, title II, § 249F(b), 86 Stat. 1435, provided for development of norms of health care services by Professional Standards Review Organizations, prior to the general revision of this part by Pub. L. 97–248.

AMENDMENTS

2011—Subsec. (a)(3). Pub. L. 112–40 substituted ''quality improvement'' for ''peer review''.

Subsec. (c). Pub. L. 112–40 substituted ''quality improvement'' for ''utilization and quality control peer review''.

1996—Subsec. (b)(1). Pub. L. 104–191, § 214(b)(2), struck out in concluding provisions ''In determining whether a practitioner or person has demonstrated an unwillingness or lack of ability substantially to comply with such obligations, the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the organization submits its report and recommendations, to enter into and successfully complete a corrective action plan.'' after ''chapter on a reimbursable basis.''

Pub. L. 104–191, § 214(b)(1), struck out in concluding provisions ''and determines that such practitioner or person, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this chapter, has demonstrated an unwillingness or a lack of ability substantially to comply with such obligations,'' after ''agrees with such determination,''.

Pub. L. 104–191, § 214(a)(1), substituted ''may prescribe, except that such period may not be less than 1 year)'' for ''may prescribe)'' in concluding provisions.

Subsec. (b)(2). Pub. L. 104–191, § 214(a)(2), substituted ''shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain'' for ''shall remain''.

Subsec. (b)(3). Pub. L. 104–191, § 231(f), substituted ''up to $10,000 for each instance'' for ''the actual or estimated cost''.

1994—Subsec. (b)(1). Pub. L. 103–432 substituted ''whether'' for ''whehter'' in third sentence.

1990—Subsec. (b)(1). Pub. L. 101–508, §4205(a)(1), inserted ''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,'' after ''concerned,'' in introductory provisions and inserted after second sentence ''In determining whehter [sic] a practitioner or person has demonstrated an unwillingness or lack of ability substantially to comply with such obligations, the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the organization submits its report and recommendations, to enter into and successfully complete a corrective action plan.''

Subsec. (b)(5). Pub. L. 101–597 substituted ''health professional shortage area'' for ''health manpower shortage area (HMSA)''.

Subsec. (b)(6). Pub. L. 101–508, §4205(d)(2)(A), added par. (6).

1988—Subsec. (b). Pub. L. 100–360 added Pub. L. 100–203, §4039(h)(5), see 1987 Amendment notes below.

1987—Subsec. (a). Pub. L. 100–93, §6(1), substituted ''this chapter'' for ''subchapter XVIII of this chapter'' and ''this subchapter''.

Subsec. (b)(1). Pub. L. 100–203, §4039(h)(5)(A), as added by Pub. L. 100–360, substituted ''services under this chapter'' for ''such services''.

Pub. L. 100–93, §6(2), substituted ''this chapter'' for ''subchapter XVIII of this chapter''.

Subsec. (b)(2). Pub. L. 100–203, §4039(h)(5)(B), as added by Pub. L. 100–360, substituted ''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'' for ''at such time and upon such reasonable notice to the public and to the practitioner or person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in this chapter with respect to terminations of provider agreements)''.

Pub. L. 100–93, §6(2), substituted ''this chapter'' for ''subchapter XVIII of this chapter''.

Subsec. (b)(5). Pub. L. 100–203 added par. (5).

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 1996 AMENDMENT

Amendment by section 214 of Pub. L. 104–191 effective Jan. 1, 1997, except as otherwise provided, see section 218 of Pub. L. 104–191, set out as a note under section 1320a–7 of this title.

Amendment by section 231(f) of Pub. L. 104–191 applicable to acts or omissions occurring on or after Jan. 1, 1997, see section 231(i) of Pub. L. 104–191, set out as a note under section 1320a–7a of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–432 effective as if included in the enactment of Pub. L. 101–508, see section 156(b)(6)(A) of Pub. L. 103–432, set out as a note under section 1320c–9 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, §4205(a)(2), Nov. 5, 1990, 104 Stat. 1388–113, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to initial determinations made by organizations on or after the date of the enactment of this Act [Nov. 5, 1990].''

Pub. L. 101–508, title IV, §4205(d)(2)(B), Nov. 5, 1990, 104 Stat. 1388–114, as amended by Pub. L. 103–432, title I, §156(b)(3), Oct. 31, 1994, 108 Stat. 4441, provided that: ''The amendment made by this paragraph [amending this section] shall apply to sanctions effected more than 60 days after the date of the enactment of this Act [Nov. 5, 1990].''

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–203, title IV, §4095(b), Dec. 22, 1987, 101 Stat. 1330–138, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to determinations made by the Secretary of Health and Human Services under section 1156(b) of the Social Security Act [42 U.S.C. 1320c–5(b)] on or after the date of the enactment of this Act [Dec. 22, 1987].''

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

TELECOMMUNICATIONS DEMONSTRATION PROJECTS

Pub. L. 100–203, title IV, §4094(e), Dec. 22, 1987, 101 Stat. 1330–138, as amended by Pub. L. 100–360, title IV, §411(j)(3)(C), as added by Pub. L. 100–485, title VI, §608(d)(25)(A), Oct. 13, 1988, 102 Stat. 2421, provided that: ''The Secretary of Health and Human Services shall enter into agreements with entities submitting applications under this subsection (in such form as the Secretary may provide) to establish demonstration projects to examine the feasibility of requiring instruction and oversight of rural physicians, in lieu of imposing sanctions, through use of video communication between rural hospitals and teaching hospitals under this title [probably means title XI of the Social Security Act, 42 U.S.C. 1301 et seq.]. Under such demonstration projects, the Secretary may provide for payments to physicians consulted via video communication systems. No funds may be expended under the demonstration projects for the acquisition of capital items including computer hardware.''

PREEXCLUSION HEARINGS; TRANSITION FOR CURRENT CASES AND REDETERMINATION IN CERTAIN CASES

Pub. L. 100–203, title IV, §4095(c), (d), Dec. 22, 1987, 101 Stat. 1330–138, provided that:

''(c) TRANSITION FOR CURRENT CASES.—In the case of a practitioner or person—

''(1) for whom a notice of determination under section 1156(b) of the Social Security Act [42 U.S.C. 1320c–5(b)] has been provided within 365 days before the date of the enactment of this Act [Dec. 22, 1987],

''(2) who has not exhausted the administrative remedies available under section 1156(b)(4) of such Act for review of the determination, and

''(3) who requests, within 90 days after the date of the enactment of this Act, a hearing established under this subsection,

the Secretary of Health and Human Services shall provide for a hearing described in section 1156(b)(5) of the Social Security Act (as amended by subsection (a) of this section).

''(d) REDETERMINATIONS IN CERTAIN CASES.—If, in hearing under subsection (c), the judge does not determine, by a preponderance of the evidence, that the provider or practitioner will pose a serious risk to individuals entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] if permitted to con-

tinue or resume furnishing such services, the Secretary shall not effect the exclusion (or shall suspend the exclusion, if previously effected) under paragraph (2) of section 1156(b) of such Act [42 U.S.C. 1320c–5(b)] until the provider or practitioner has been provided an administrative hearing thereon under paragraph (4) of such section, notwithstanding any failure by the provider or practitioner to request the hearing on a timely basis.''

§ 1320c–6. Limitation on liability

(a) Providers of information to organizations having a contract with Secretary

Notwithstanding any other provision of law, no person providing information to any organization having a contract with the Secretary under this part shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) unless—

(1) such information is unrelated to the performance of the contract of such organization; or

(2) such information is false and the person providing it knew, or had reason to believe, that such information was false.

(b) Employees and fiduciaries of organizations having contracts with Secretary

No organization having a contract with the Secretary under this part and no person who is employed by, or who has a fiduciary relationship with, any such organization or who furnishes professional services to such organization, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this part or to a valid contract entered into under this part, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(c) Physicians and providers

No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by an organization under contract pursuant to section 1320c–2 of this title operating in the area where such doctor of medicine or osteopathy or provider took such action; but only if—

(1) he takes such action in the exercise of his profession as a doctor of medicine or osteopathy or in the exercise of his functions as a provider of health care services; and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

(d) Reimbursement by Secretary for expenses incurred in defense of legal proceedings

The Secretary shall make payment to an organization under contract with him pursuant to this part, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such organization, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any suit, action, or proceeding brought against such organization, member, or employee related to the performance of any duty or function under such contract by such organization, member, or employee.

(Aug. 14, 1935, ch. 531, title XI, § 1157, as added Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 389; amended Pub. L. 101–508, title IV, § 4205(f), Nov. 5, 1990, 104 Stat. 1388–114.)

PRIOR PROVISIONS

A prior section 1320c–6, act Aug. 14, 1935, ch. 531, title XI, § 1157, as added Oct. 30, 1972, Pub. L. 92–603, title II, § 249F(b), 86 Stat. 1437; amended Oct. 25, 1977, Pub. L. 95–142, § 13(b)(4), 91 Stat. 1198, related to submission of reports by Professional Standards Review Organizations, prior to the general revision of this part by Pub. L. 97–248.

AMENDMENTS

1990—Subsec. (b). Pub. L. 101–508 inserted ''organization having a contract with the Secretary under this part and no'' after ''No'', struck out ''by him'' after ''the performance'', and substituted ''due care was exercised in the performance of such duty, function, or activity'' for ''he has exercised due care''.

§ 1320c–7. Application of this part to certain State programs receiving Federal financial assistance

(a) State plan provision that functions of quality improvement organizations may be performed by contract with such organization

A State plan approved under subchapter XIX of this chapter may provide that the functions specified in section 1320c–3 of this title may be performed in an area by contract with a quality improvement organization that has entered into a contract with the Secretary in accordance with the provisions of section 1395y(g) of this title.

(b) Federal share of expenditures

In the event a State enters into a contract in accordance with subsection (a), the Federal share of the expenditures made to the contracting organization for its costs in the performance of its functions under the State plan shall be 75 percent (as provided in section 1396b(a)(3)(C) of this title).

(Aug. 14, 1935, ch. 531, title XI, § 1158, as added Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 390; amended Pub. L. 112–40, title II, § 261(a)(2)(C), Oct. 21, 2011, 125 Stat. 423.)

PRIOR PROVISIONS

A prior section 1320c–7, act Aug. 14, 1935, ch. 531, title XI, § 1158, as added Oct. 30, 1972, Pub. L. 92–603, title II, § 249F(b), 86 Stat. 1437; amended Oct. 25, 1977, Pub. L. 95–142, §§ 5(d)(1), 22(a), 91 Stat. 1185, 1208; Dec. 5, 1980, Pub. L. 96–499, title IX, §§ 902(a)(3), 931(h), 94 Stat. 2613, 2634; Aug. 13, 1981, Pub. L. 97–35, title XXI, §§ 2113(e), 2121(g), 95 Stat. 794, 796, related to review approval as a condition of payment of claims, prior to the general revision of this part by Pub. L. 97–248.