apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(f) Definitions

In this section, the terms "elder justice", "long-term care facility", and "law enforcement" have the meanings given those terms in section 1397j of this title.

(Aug. 14, 1935, ch. 531, title XI, §1150B, as added Pub. L. 111–148, title VI, §6703(b)(3), Mar. 23, 2010, 124 Stat. 800.)

PART B—PEER REVIEW OF UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

§ 1320c. Purpose

The purpose of this part is to establish the contracting process which the Secretary must follow pursuant to the requirements of section 1395y(g) of this title, including the definition of the quality improvement organizations with which the Secretary shall contract, the functions such quality improvement organizations are to perform, the confidentiality of medical records, and related administrative matters to facilitate the carrying out of the purposes of this part.

(Aug. 14, 1935, ch. 531, title XI, §1151, as added Pub. L. 97–248, title I, §143, Sept. 3, 1982, 96 Stat. 382; amended Pub. L. 112–40, title II, §261(a)(2)(C), Oct. 21, 2011, 125 Stat. 423.)

PRIOR PROVISIONS

A prior section 1320c, act Aug. 14, 1935, ch. 531, title XI, §1151, as added Oct. 30, 1972, Pub. L. 92–603, title II, §249F(b), 86 Stat. 1429; amended Aug. 13, 1981, Pub. L. 97–35, title XXI, §2113(a), 95 Stat. 794, set out the Congressional declaration of purpose of former part B, in the general revision of this part by Pub. L. 97–248.

AMENDMENTS

2011—Pub. L. 112-40 substituted "the quality improvement organizations" for "the utilization and quality control peer review organizations" and "such quality improvement organizations" for "such peer review organizations".

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 112–40, title II, \$261(e), Oct. 21, 2011, 125 Stat. 426, provided that: "The amendments made by this section [amending this section and sections 1320c–1 to 1320c–5, 1320c–7, 1320c–9, 1320c–10, 1395g, 1395k, 1395u, 1395x, 1395y, 1395cc, 1395dd, 1395ff, 1395mm, 1395pp, and 1395ww of this title] shall apply to contracts entered into or renewed on or after January 1, 2012."

EFFECTIVE DATE

Section 149 of Pub. L. 97–248, as amended by Pub. L. 98–369, div. B, title III, §2354(c)(3)(C), July 18, 1984, 98 Stat. 1102, provided that: "The amendments made by this subtitle [subtitle C (§141–150) of title I of Pub. L. 97–248, enacting this part, amending sections 1395b–1, 1395g, 1395k, 1395i, 1395y, 1395c, 1395pp, 1396a, and 1396b of this title, and enacting provisions set out as notes under sections 1305 and 1320c of this title] shall, subject to section 150 [section 150 of Pub. L. 97–248, set out as a note below], be effective with respect to contracts entered into or renewed on or after the date of the enactment of this Act [Sept. 3, 1982]."

IOM STUDY OF QIOS

Pub. L. 108–173, title I, §109(d), Dec. 8, 2003, 117 Stat. 2173, provided that:

"(1) IN GENERAL.—The Secretary [of Health and Human Services] shall request the Institute of Medi-

cine of the National Academy of Sciences to conduct an evaluation of the program under part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.]. The study shall include a review of the following:

- "(A) An overview of the program under such part. "(B) The duties of organizations with contracts with the Secretary under such part.
- "(C) The extent to which quality improvement organizations improve the quality of care for medicare beneficiaries.
- "(D) The extent to which other entities could perform such quality improvement functions as well as, or better than, quality improvement organizations.
- "(E) The effectiveness of reviews and other actions conducted by such organizations in carrying out those duties.
- "(F) The source and amount of funding for such organizations.
- "(G) The conduct of oversight of such organizations
- "(2) REPORT TO CONGRESS.—Not later than June 1, 2006, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.
- "(3) INCREASED COMPETITION.—If the Secretary finds based on the study conducted under paragraph (1) that other entities could improve quality in the medicare program as well as, or better than, the current quality improvement organizations, then the Secretary shall provide for such increased competition through the addition of new types of entities which may perform quality improvement functions."

COORDINATION OF PROS AND CARRIERS

Pub. L. 101–508, title IV, \$4205(c), Nov. 5, 1990, 104 Stat. 1388–113, provided that:

- "(1) DEVELOPMENT AND IMPLEMENTATION OF PLAN.— The Secretary of Health and Human Services shall develop and implement a plan to coordinate the physician review activities of peer review organizations and carriers. Such plan shall include—
 - "(A) the development of common utilization and medical review criteria;
 - "(B) criteria for the targetting of reviews by peer review organizations and carriers; and
 - "(C) improved methods for exchange of information among peer review organizations and carriers.
- "(2) REPORT.—Not later than January 1, 1992, the Secretary shall submit to Congress a report on the development of the plan described under paragraph (1) and shall include in the report such recommendations for changes in legislation as may be appropriate."

EVALUATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Pub. L. 97–448, title III, §309(d), Jan. 12, 1983, 96 Stat. 2410, provided that: "In order to avoid unfairly discriminating against professional standards review organizations whose performance was evaluated during the first and second calendar quarters of 1982, the Secretary of Health and Human Services shall disregard the results of such evaluations and shall carry out such new evaluations of such organizations as may be necessary to select utilization and quality control peer review organizations in accordance with subtitle C of title I of the Tax Equity and Fiscal Responsibility Act of 1982 [sections 141–150 of Pub. L. 97–248] and part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.] as amended by such subtitle."

MAINTENANCE OF CURRENT PROFESSIONAL STANDARDS REVIEW ORGANIZATION AGREEMENTS

Pub. L. 97-248, title I, §150, Sept. 3, 1982, 96 Stat. 395, as amended by Pub. L. 97-448, title III, §309(a)(9), Jan. 12, 1983, 96 Stat. 2408, provided that:

"(a) The Secretary of Health and Human Services shall not terminate or fail to renew any agreement in effect with a professional standards review organization under part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.] on the earlier of the date of the enactment of this Act [Sept. 3, 1982] or September 30, 1982 until such time as he enters into a contract with a utilization and quality control peer review organization under such part, as amended by this subtitle [subtitle C (§§141–150) of title I of Pub. L. 97–248], for the area served by such professional standards review organization. In complying with this subsection, the Secretary may renew any such agreement with a professional standards review organization for a period of less than 12 months.

'(b) The provisions of part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.] as in effect prior to the amendments made by this subtitle [subtitle C (§§ 141–150) of title I of Pub. L. 97–248] shall remain in effect with respect to agreements with professional standards review organizations in effect on the earlier of the date of the enactment of this Act [Sept. 3, 1982]. or September 30, 1982, until such time as such agreement is terminated or is not renewed, in accordance with subsection (a). Any matters awaiting a determination by a Statewide Professional Standards Review Council on the date of the enactment of this Act shall be transferred to the Secretary of Health and Human Services for a determination unless such determination is made by such Council within 30 days after the date of the enactment of this Act. No payments shall be made under part B of title XI of the Social Security Act to Statewide Professional Standards Review Councils for services performed under section 1162 of such Act [42 U.S.C. 1320c-11] after the end of such 30-day pe-

§ 1320c-1. Definition of quality improvement organization

The term "quality improvement organization" means an entity which—

- (1) is able, as determined by the Secretary, to perform its functions under this part in a manner consistent with the efficient and effective administration of this part and subchapter XVIII;
- (2) has at least one individual who is a representative of health care providers on its governing body; and
- (3) has at least one individual who is a representative of consumers on its governing body

(Aug. 14, 1935, ch. 531, title XI, \$1152, as added Pub. L. 97–248, title I, \$143, Sept. 3, 1982, 96 Stat. 382; amended Pub. L. 99–509, title IX, \$9353(b)(1), Oct. 21, 1986, 100 Stat. 2046; Pub. L. 112–40, title II, \$261(a)(1), (2)(A), (C), Oct. 21, 2011, 125 Stat. 423)

PRIOR PROVISIONS

A prior section 1320c–1, act Aug. 14, 1935, ch. 531, title XI, \S 1152, as added Oct. 30, 1972, Pub. L. 92–603, title II, \S 249F(b), 86 Stat. 1430; amended Dec. 31, 1975, Pub. L. 94–182, title I, \S 105, 108(a), 89 Stat. 1052, 1053; Oct. 25, 1977, Pub. L. 95–142, \S 5(a), (d)(2)(A), (B), (o)(1), 91 Stat. 1183, 1185, 1191; Dec. 5, 1980, Pub. L. 96–499, title IX, \S 921, 94 Stat. 2627; Aug. 13, 1981, Pub. L. 97–35, title XXI, \S §2112(a)(2)(A), (B), 2113(b), (c), 95 Stat. 793, 794, related to the designation of Professional Standards Review Organizations, prior to the general revision of this part by Pub. L. 97–248.

AMENDMENTS

2011—Pub. L. 112-40, §261(a)(2)(A), (C), substituted "quality improvement" for "utilization and quality control peer review" in section catchline and introductory provisions

Pars. (1), (2). Pub. L. 112-40, §261(a)(1), added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

"(1)(A) is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1320c-2 of this title, with respect to which the entity shall perform services under this part, or (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured:

"(2) is able, in the judgment of the Secretary, to perform review functions required under section 1320c–3 of this title in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and".

1986—Par. (3). Pub. L. 99–509 added par. (3).

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 1986 AMENDMENT

Pub. L. 99-509, title IX, §9353(b)(2), Oct. 21, 1986, 100 Stat. 2046, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to contracts entered into or renewed on or after January 1 1987"

§ 1320c-2. Contracts with quality improvement organizations

(a) Establishment of geographic areas

The Secretary shall establish throughout the United States such local, State, regional, national, or other geographic areas as the Secretary determines appropriate with respect to which contracts under this part will be made.

(b) Organizations entitled to contract with Secretary

(1) The Secretary shall enter into contracts with one or more quality improvement organizations for each area established under subsection (a) if a qualified organization is available in such area and such organization and the Secretary have negotiated a proposed contract which the Secretary determines will be carried out by such organization in a manner consistent with the efficient and effective administration of this part. In entering into contracts with such qualified organizations, the Secretary shall, to the extent appropriate, seek to ensure that each of the functions described in section 1320c-3(a) of this title are carried out within an area established under subsection (a). If more than one such qualified organization will be operating in an area, the Secretary shall ensure that there is no duplication of the functions carried out by such organizations within the area.

(2)(A) Prior to November 15, 1984, the Secretary shall not enter into a contract under this part with any entity which is, or is affiliated with (through management, ownership, or common control), an entity (other than a self-insured employer) which directly or indirectly makes payments to any practitioner or provider whose health care services are reviewed by such