

(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, §1152, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1430; amended Dec. 31, 1975, Pub. L. 94-182, title I, §§105, 108(a), 89 Stat. 1052, 1053; Oct. 25, 1977, Pub. L. 95-142, §5(a), (d)(2)(A), (B), (o)(1), 91 Stat. 1183, 1185, 1191; Dec. 5, 1980, Pub. L. 96-499, title IX, §921, 94 Stat. 2627; Aug. 13, 1981, Pub. L. 97-35, title XXI, §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) of this section 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 entity or would be reviewed by such entity if it entered into a contract with the Secretary under this part. For purposes of this paragraph, an entity shall not be considered to be affiliated with another entity which makes payments (directly or indirectly) to any practitioner or provider, by reason of management, ownership, or common control, if the management, ownership, or common control consists only of members of the governing board being affiliated (through management, ownership, or common control) with a health maintenance organization or competitive medical plan which is an “eligible organization” as defined in section 1395mm(b) of this title.

(B) If, after November 14, 1984, the Secretary determines that there is no other entity available for an area with which the Secretary can enter into a contract under this part or the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1320c-3(a) of this title, the Secretary may then enter into a contract under this part with an entity described in subparagraph (A) for such area if such entity otherwise meets the requirements of this part.

(3)(A) 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), a health care facility within the area served by such entity or

which would be served by such entity if it entered into a contract with the Secretary under this part.

(B) For purposes of subparagraph (A), an entity shall not be considered to be affiliated with a health care facility by reason of management, ownership, or common control if the management, ownership, or common control consists only of not more than 20 percent of the members of the governing board of the entity being affiliated (through management, ownership, or common control) with one or more of such facilities.

(4) The Secretary may consider a variety of factors in selecting the contractors that the Secretary determines would provide for the most efficient and effective administration of this part, such as geographic location, size, and prior experience in health care quality improvement. Quality improvement organizations operating as of January 1, 2012, shall be allowed to compete for new contracts (as determined appropriate by the Secretary) along with other qualified organizations and are eligible for renewal of contracts for terms five years thereafter (as determined appropriate by the Secretary).

(c) Terms of contract

Each contract with an organization under this section shall provide that—

(1) the organization shall perform a function or functions under section 1320c-3 of this title directly or may subcontract for the performance of all or some of such function or functions (and for purposes of paragraphs (2) and (3) of subsection (b) of this section, a subcontract under this paragraph shall not constitute an affiliation with the subcontractor);

(2) the Secretary shall have the right to evaluate the quality and effectiveness of the organization in carrying out the functions specified in the contract;

(3) the contract shall be for an initial term of five years and shall be renewable for terms of five years thereafter;

(4) the Secretary shall include in the contract negotiated objectives against which the organization's performance will be judged, and negotiated specifications for use of regional norms, or modifications thereof based on national norms, for performing review functions under the contract; and

(5) reimbursement shall be made to the organization on a monthly basis, with payments for any month being made consistent with the Federal Acquisition Regulation.

In evaluating the performance of quality improvement organizations under contracts under this part, the Secretary shall place emphasis on the performance of such organizations in educating providers and practitioners (particularly those in rural areas) concerning the review process and criteria being applied by the organization.

(d) Repealed. Pub. L. 112-40, title II, § 261(b)(3)(C), Oct. 21, 2011, 125 Stat. 424

(e) Authority of Secretary

(1) Except as provided in paragraph (2), contracting authority of the Secretary under this section may be carried out without regard to

any provision of law relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the purposes of this part. The Secretary may use different contracting methods with respect to different geographical areas.

(2) If a quality improvement organization with a contract under this section is required to carry out a review function in addition to any function required to be carried out at the time the Secretary entered into or renewed the contract with the organization, the Secretary shall, before requiring such organization to carry out such additional function, negotiate the necessary contractual modifications, including modifications that provide for an appropriate adjustment (in light of the cost of such additional function) to the amount of reimbursement made to the organization.

(f) Termination not subject to judicial review

Any determination by the Secretary to terminate or not to renew a contract under this section shall not be subject to judicial review.

(g) Timely provision of hospital data to quality improvement organizations

The Secretary shall provide that fiscal intermediaries furnish to quality improvement organizations, each month on a timely basis, data necessary to initiate the review process under section 1320c-3(a) of this title on a timely basis. If the Secretary determines that a fiscal intermediary is unable to furnish such data on a timely basis, the Secretary shall require the hospital to do so.

(h) Publication of new policy or procedure and general criteria and standards for evaluation; performance comparison report

(1) The Secretary shall publish in the Federal Register any new policy or procedure adopted by the Secretary that affects substantially the performance of contract obligations under this section not less than 30 days before the date on which such policy or procedure is to take effect. This paragraph shall not apply to the extent it is inconsistent with a statutory deadline.

(2) The Secretary shall publish in the Federal Register the general criteria and standards used for evaluating the efficient and effective performance of contract obligations under this section and shall provide opportunity for public comment with respect to such criteria and standards.

(3) The Secretary shall regularly furnish each quality improvement organization with a contract under this section with a report that documents the performance of the organization in relation to the performance of other such organizations.

(Aug. 14, 1935, ch. 531, title XI, §1153, as added Pub. L. 97-248, title I, §143, Sept. 3, 1982, 96 Stat. 382; amended Pub. L. 97-448, title III, §309(b)(2), Jan. 12, 1983, 96 Stat. 2408; Pub. L. 98-21, title VI, §602(a), Apr. 20, 1983, 97 Stat. 163; Pub. L. 98-369, div. B, title III, §§2334(a), (b), 2347(c), July 18, 1984, 98 Stat. 1090, 1097; Pub. L. 99-272, title IX, §§9402(b), 9404(a), 9406(a), Apr. 7, 1986, 100 Stat. 200, 201; Pub. L. 99-509, title IX, §9352(a)(1), Oct. 21, 1986, 100 Stat. 2044; Pub. L. 100-203, title IV,

§§ 4091(a)(2)(A), (b)(1), (2), 4092(a), 4094(d)(1), Dec. 22, 1987, 101 Stat. 1330-134, 1330-135, 1330-137; Pub. L. 112-40, title II, § 261(a)(2)(A), (C), (b), (c)(1), Oct. 21, 2011, 125 Stat. 423, 425.)

PRIOR PROVISIONS

A prior section 1320c-2, act Aug. 14, 1935, ch. 531, title XI, § 1153, as added Oct. 30, 1972, Pub. L. 92-603, title II, § 249F(b), 86 Stat. 1432, related to review pending designation of a Professional Standards Review Organization in a given area, prior to the general revision of this part by Pub. L. 97-248.

AMENDMENTS

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

Subsec. (a). Pub. L. 112-40, § 261(b)(1)(A), added subsec. (a) and struck out former subsec. (a) which related to establishment and consolidation of geographic areas.

Subsec. (b)(1). Pub. L. 112-40, § 261(c)(1)(A), after first sentence, inserted “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).”

Pub. L. 112-40, § 261(b)(1)(B), substituted “contracts with one or more quality improvement organizations” for “a contract with a quality improvement organization” and “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” for “meets the requirements of the preceding sentence, priority shall be given to any such organization which is described in section 1320c-1(1)(A) of this title”.

Pub. L. 112-40, § 261(a)(2)(C), substituted “quality improvement organization” for “utilization and quality control peer review organization”.

Subsec. (b)(2)(B). Pub. L. 112-40, § 261(b)(1)(C), which directed insertion of “or the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1320c-3(a) of this title” after “under this part”, was executed by making the insertion after “under this part” the first place appearing, to reflect the probable intent of Congress.

Subsec. (b)(3)(A). Pub. L. 112-40, § 261(b)(1)(D)(i), struck out “, or association of such facilities,” after “facility”.

Subsec. (b)(3)(B). Pub. L. 112-40, § 261(b)(1)(D)(ii)(II), struck out “or associations” after “one or more of such facilities”.

Pub. L. 112-40, § 261(b)(1)(D)(ii)(I), which directed striking out “or association of such facilities”, was executed by striking out “or association of facilities” after “facility”, to reflect the probable intent of Congress.

Subsec. (b)(4). Pub. L. 112-40, § 261(b)(3)(A), added par. (4).

Subsec. (c). Pub. L. 112-40, § 261(a)(2)(C), substituted “quality improvement” for “utilization and quality control peer review” in concluding provisions.

Subsec. (c)(1). Pub. L. 112-40, § 261(c)(1)(B), substituted “a function or functions under section 1320c-3 of this title directly or may subcontract for the performance of all or some of such function or functions” for “the functions set forth in section 1320c-3(a) of this title, or may subcontract for the performance of all or some of such functions”.

Subsec. (c)(3). Pub. L. 112-40, § 261(b)(2), substituted “five years and shall be renewable for terms of five years” for “three years and shall be renewable on a triennial basis”.

Subsec. (c)(4). Pub. L. 112-40, § 261(b)(3)(B), redesignated par. (7) as (4) and struck out former par. (4) which read as follows: “if the Secretary intends not to renew a contract, he shall notify the organization of his decision at least 90 days prior to the expiration of the con-

tract term, and shall provide the organization an opportunity to present data, interpretations of data, and other information pertinent to its performance under the contract, which shall be reviewed in a timely manner by the Secretary.”

Subsec. (c)(5). Pub. L. 112-40, § 261(b)(4), amended par. (5) generally. Prior to amendment, par. (5) read as follows: “reimbursement shall be made to the organization on a monthly basis, with payments for any month being made not later than 15 days after the close of such month.”

Pub. L. 112-40, § 261(b)(3)(B), redesignated par. (8) as (5) and struck out former par. (5) which read as follows: “the organization may terminate the contract upon 90 days notice to the Secretary.”

Subsec. (c)(6) to (8). Pub. L. 112-40, § 261(b)(3)(B), redesignated pars. (7) and (8) as (4) and (5), respectively, and struck out former par. (6) which read as follows: “the Secretary may terminate the contract prior to the expiration of the contract term upon 90 days notice to the organization if the Secretary determines that—

“(A) the organization does not substantially meet the requirements of section 1320c-1 of this title; or

“(B) the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part, but only after such organization has had an opportunity to submit data and have such data reviewed by the panel established under subsection (d) of this section.”

Subsec. (d). Pub. L. 112-40, § 261(b)(3)(C), struck out subsec. (d) which related to panel review prior to termination of contract.

Subsecs. (e)(2), (g), (h)(3). Pub. L. 112-40, § 261(a)(2)(C), substituted “quality improvement” for “peer review”.

Subsec. (i). Pub. L. 112-40, § 261(b)(1)(E), struck out subsec. (i) which related to preference in contracting with in-State organizations.

1987—Subsec. (c). Pub. L. 100-203, § 4094(d)(1), inserted after and below par. (8) the following: “In evaluating the performance of utilization and quality control peer review organizations under contracts under this part, the Secretary shall place emphasis on the performance of such organizations in educating providers and practitioners (particularly those in rural areas) concerning the review process and criteria being applied by the organization.”

Subsec. (c)(3). Pub. L. 100-203, § 4091(a)(2)(A), substituted “three” for “two” and “triennial” for “biennial”.

Subsec. (e). Pub. L. 100-203, § 4091(b)(2), designated existing provisions as par. (1), substituted “Except as provided in paragraph (2), contracting” for “Contracting”, and added par. (2).

Subsec. (h). Pub. L. 100-203, § 4091(b)(1), added subsec. (h).

Subsec. (i). Pub. L. 100-203, § 4092(a), added subsec. (i). 1986—Subsec. (b)(2)(A). Pub. L. 99-272, § 9404(a), substituted “consists only of members of the governing board” for “consists only of one individual member of the governing board”.

Subsec. (c)(8). Pub. L. 99-272, § 9402(b), amended par. (8) generally. Prior to amendment, par. (8) read as follows: “reimbursement shall be made to the organization in accordance with the terms of the contract.”

Subsec. (d)(4). Pub. L. 99-272, § 9406(a), added par. (4).

Subsec. (g). Pub. L. 99-509 added subsec. (g).

1984—Subsec. (b)(2)(A). Pub. L. 98-369, § 2347(c)(1), substituted “Prior to November 15, 1984” for “During the first twelve months in which the Secretary is entering into contracts under this section”.

Pub. L. 98-369, § 2334(b), inserted “(other than a self-insured employer)” and provision that for purposes of this paragraph an entity shall not be considered to be affiliated with another entity which makes payments (directly or indirectly) to any practitioner or provider, by reason of management, ownership, or common control, if the management, ownership, or common control consists only of one individual member of the governing board being affiliated (through management, own-

ership, or common control) with a health maintenance organization or competitive medical plan which is an "eligible organization" as defined in section 1395mm(b) of this title.

Subsec. (b)(2)(B). Pub. L. 98-369, § 2347(c)(2), substituted "after November 14, 1984" for "after the expiration of the twelve-month period referred to in subparagraph (A)".

Subsec. (b)(2)(C). Pub. L. 98-369, § 2347(c)(3), struck out subpar. (C) which provided that the twelve-month period formerly referred to in subpar. (A) would be deemed to have begun not later than October 1983.

Subsec. (b)(3). Pub. L. 98-369, § 2334(a), designated existing provisions as subpar. (A) and added subpar. (B). 1983—Subsec. (b)(2)(C). Pub. L. 98-21 added subpar. (C).

Subsec. (d). Pub. L. 97-448 substituted reference to "subsection (c)(6)(B)" for "subsection (c)(5)(B)" and "subsection (c)(5)(C)" in pars. (1) and (2), respectively.

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 1987 AMENDMENT

Pub. L. 100-203, title IV, § 4091(a)(2)(B), Dec. 22, 1987, 101 Stat. 1330-134, provided that: "The amendment made by subparagraph (A) [amending this section] shall apply with respect to contracts entered into or renewed on or after the date of the enactment of this Act [Dec. 22, 1987]."

Pub. L. 100-203, title IV, § 4091(b)(3), Dec. 22, 1987, 101 Stat. 1330-135, provided that: "The amendment made by paragraphs (1) and (2) [amending this section] shall become effective on the date of enactment of this Act [Dec. 22, 1987]."

Pub. L. 100-203, title IV, § 4092(b), Dec. 22, 1987, 101 Stat. 1330-135, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to contracts scheduled to be renewed on or after the first day of the eighth month to begin after the date of enactment of this Act [Dec. 22, 1987]."

Pub. L. 100-203, title IV, § 4094(d)(2), Dec. 22, 1987, 101 Stat. 1330-137, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to contracts under part B of title XI of the Social Security Act [this part] as of January 1, 1988."

EFFECTIVE DATE OF 1986 AMENDMENTS

Pub. L. 99-509, title IX, § 9352(c)(1), Oct. 21, 1986, 100 Stat. 2044, provided that: "The Secretary of Health and Human Services shall implement the amendment made by subsection (a) [amending this section and section 1395h of this title] not later than 6 months after the date of the enactment of this Act [Oct. 21, 1986]."

Pub. L. 99-272, title IX, § 9402(c)(2), Apr. 7, 1986, 100 Stat. 200, provided that: "The amendment made by subsection (b) [amending this section] shall apply to contracts entered into or renewed on or after the date of the enactment of this Act [Apr. 7, 1986]."

Pub. L. 99-272, title IX, § 9404(b), Apr. 7, 1986, 100 Stat. 201, provided that: "The amendment made by this section [amending this section] shall become effective on the date of the enactment of this Act [Apr. 7, 1986]."

Pub. L. 99-272, title IX, § 9406(b), Apr. 7, 1986, 100 Stat. 201, provided that: "The amendment made by this section [amending this section] shall become effective on the date of the enactment of this Act [Apr. 7, 1986]."

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98-369, div. B, title III, § 2334(c), July 18, 1984, 98 Stat. 1090, provided that: "The amendments made by this section [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Pub. L. 98-369, div. B, title III, § 2347(d), July 18, 1984, 98 Stat. 1097, provided that: "The provisions of, and amendments made by, this section [amending this sec-

tion and section 1395cc of this title and enacting provisions set out as a note under section 1395cc of this title] shall become effective on the date of the enactment of this Act [July 18, 1984]."

EFFECTIVE DATE OF 1983 AMENDMENTS

Amendment by Pub. L. 98-21 applicable to items and services furnished by or under arrangement with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, see section 604(a)(1) of Pub. L. 98-21, set out as a note under section 1395ww of this title.

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.

EXTENSIONS OF PEER REVIEW CONTRACT PERIOD; ONE-TIME EXTENSIONS TO PERMIT STAGGERING OF EXPIRATION DATES

Pub. L. 100-203, title IV, § 4091(a)(1), Dec. 22, 1987, 101 Stat. 1330-134, as amended by Pub. L. 100-360, title IV, § 411(j)(1), July 1, 1988, 102 Stat. 790, provided that:

"(A) IN GENERAL.—In order to permit the Secretary of Health and Human Services an adequate time to complete contract renewal negotiations with utilization and quality control peer review [now "quality improvement"] organizations under part B of title XI of the Social Security Act [this part] and to provide for a staggered period of contract expiration dates, notwithstanding section 1153(c) of such Act [subsec. (c) of this section], the Secretary may provide for extensions of existing contracts, but the total of such extensions may not exceed 24 months for any contract.

"(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall apply to contracts expiring on or after the date of the enactment of this Act [Dec. 22, 1987]."

§ 1320c-3. Functions of quality improvement organizations

(a) Review of professional activities; determination of payment; determination of review authority; consultation with professional health care practitioners; standards of health care; other duties

Subject to subsection (b), any quality improvement organization entering into a contract with the Secretary under this part must perform one or more of the following functions:

(1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under subchapter XVIII of this chapter (including where payment is made for such services to eligible organizations pursuant to contracts under section 1395mm of this title, to Medicare Advantage organizations pursuant to contracts under part C,¹ and to prescription drug sponsors pursuant to contracts under part D¹) for the purpose of determining whether—

(A) such services and items are or were reasonable and medically necessary and

¹ See References in Text note below.