(in a form specified by the Secretary) specifying the rights of employees under this section. Such sign shall include a statement that an employee may file a complaint with the Secretary against a long-term care facility that violates the provisions of this subsection and information with respect to the manner of filing such a complaint.

(e) Procedure
The provisions of section 1320a–7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty or exclusion under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320c–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.


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 1395yy of this title, including the definition of the utilization and quality control peer review organizations with which the Secretary shall contract, the functions such peer review organizations are to perform, the confidentiality of medical records, and related administrative matters to facilitate the carrying out of the purposes of this part.


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[This part] 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.

(a) Establishment and consolidation of geographic areas

(1) The Secretary shall establish throughout the United States geographic areas with respect to which contracts under this part will be made. In establishing such areas, the Secretary shall use the same areas as established under section 1320c–1 of this title as in effect immediately prior to September 3, 1982, but subject to the provisions of paragraph (2).

(b) Organizations entitled to contract with Secretary

(1) The Secretary shall enter into a contract with a utilization and quality control peer review organization for each area established under subsection (a) of this section if a qualified professional standards review organization is 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 1320c–1 of such Act [section 1320c–11 of this title] after the end of such 30-day period.

§ 1320c–1. “Utilization and quality control peer review organization” defined

The term “utilization and quality control peer review organization” means an entity which—

(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; and

(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

(3) has at least one individual who is a representative of consumers on its governing body.


PRIOR PROVISIONS


AMENDMENTS


EFFECTIVE DATE OF 1986 AMENDMENT

Section 9353(b)(2) of Pub. L. 99–509 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 utilization and quality control peer review organizations

(a) Establishment and consolidation of geographic areas

(1) The Secretary shall establish throughout the United States geographic areas with respect to agreements with professional standards review organizations, prior to the general revision of this part.
in a manner consistent with the efficient and effective administration of this part. If more than one such qualified organization meets the requirements of the preceding sentence, priority shall be given to any such organization which is described in section 1320c–1 of this title.

(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, 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, or association of such facilities, 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 or association of facilities 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 or associations.

(c) Terms of contract

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

(1) the organization shall perform the functions described in section 1320c–3(a) of this section, or may subcontract for the performance of all or some of such 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 three years and shall be renewable on a triennial basis thereafter;

(4) 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 contract 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;

(5) the organization may terminate the contract upon 90 days notice to the Secretary;

(6) 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;

(7) 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

(8) 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.

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.

(d) Review prior to termination of contract; modification and termination; reviewing panel

(1) Prior to making any termination under subsection (c)(6)(B) of this section, the Secretary must provide the organization with an opportunity to provide data, interpretations of data, and other information pertinent to its performance under the contract. Such data and other information shall be reviewed in a timely manner by a panel appointed by the Secretary, and the panel shall submit a report of its findings to the Secretary in a timely manner. The Secretary shall make a copy of the report available to the organization.

(A) The Secretary may accept or not accept the findings of the panel. After the panel has submitted a report with respect to an organization, the Secretary may, with the concurrence of the organization, amend the contract to mod-
ify the scope of the functions to be carried out by the organization, or in any other manner. The Secretary may terminate a contract under the authority of subsection (c)(6)(B) of this section upon 90 days notice after the panel has submitted a report, or earlier if the organization so agrees. 

(3) A panel appointed by the Secretary under this subsection shall consist of not more than five individuals, each of whom shall be a member of a utilization and quality control peer review organization, having a contract with the Secretary under this part. While serving on such panel individuals shall be paid at a per diem rate not to exceed the current per diem equivalent at the time that service on the panel is rendered for grade GS–18 under section 5332 of title 5. Appointments shall be made without regard to title 5.

(4) During the period after the Secretary has given notice of intent to terminate a contract, and prior to the time that the Secretary enters into a contract with another utilization and quality control peer review organization, the Secretary may transfer review responsibilities of the organization under the contract being terminated to another utilization and quality control peer review organization, or to an intermediary or carrier having an agreement under section 1395w of this title or a contract under section 1965u of this title.

(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 peer review 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 peer review organizations

The Secretary shall provide that fiscal intermediaries furnish to peer review organizations, each month on a timely basis, data necessary to initiate the review process under section 1320c–8(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 peer review 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.

(i) Preference in contracting with in-State organizations

(1) Notwithstanding any other provision of this section, the Secretary shall not renew a contract with any organization that is not an in-State organization (as defined in paragraph (3)) unless the Secretary has first complied with the requirements of paragraph (2).

(2)(A) Not later than six months before the date on which a contract period ends with respect to an organization that is not an in-State organization, the Secretary shall publish in the Federal Register—

(i) the date on which such period ends; and

(ii) the period of time in which an in-State organization may submit a proposal for the contract ending on such date.

(B) If one or more qualified in-State organizations submits a proposal within the period of time specified under subparagraph (A)(ii), the Secretary shall not automatically renew the current contract on a noncompetitive basis, but shall provide for competition for the contract in the same manner as a new contract under subsection (b) of this section.

(3) For purposes of this subsection, an in-State organization is an organization that has its primary place of business in the State in which review will be conducted (or, which is owned by a parent corporation the headquarters of which is located in such State).


Prior Provisions

$1320c-2
Title 42—The Public Health and Welfare

1987—Subsec. (c). Pub. L. 100–203, §4909(d)(1), inserted after and above 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, §4909(a)(2)(A), substituted "three" for "two" and "triennial" for "biennial."

Subsec. (e). Pub. L. 100–203, §4901(b)(2), designated existing provisions as par. (1), substituted "Except as provided in paragraph (2), contracting" for "Contracting", and added par. (2).


Subsec. (i). Pub. L. 100–203, §4902(a), added subsec. (i).

1986—Subsec. (b)(2)(A). Pub. L. 99–272, §4904(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, §4902(b), amended par. (8) generally. Prior to amendment, par. (8) read as follows: "The reimbursement shall be made to the organization in accordance with the terms of the contract."


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, 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.


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 subparagraph (A) would be deemed to have begun not later than October 1983.

Subsec. (b)(3). Pub. L. 98–369, §2354(a), designated existing provisions as subpar. (A) and added subpar. (B).


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 1987 Amendment
Section 4901(a)(2)(B) of Pub. L. 100–203 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 enactment of this Act [Dec. 22, 1987]."

Section 4902(b) of Pub. L. 100–203 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 [Oct. 21, 1986]."

Effective Date of 1986 Amendments
Section 9320(c)(1) of Pub. L. 99–509 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]."

Section 9402(c)(2) of Pub. L. 99–272 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 enactment of this Act [Apr. 7, 1986]."

Section 9404(b) of Pub. L. 99–272 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]."

Section 9406(b) of Pub. L. 99–272 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
Section 2334(c) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section] shall become effective on the date of enactment of this Act [July 18, 1984]."

Section 2347(d) of Pub. L. 98–369 provided that: "The provisions of, and 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 [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. 100–203, set out as a note under section 1395ww of this title.

Amendment by Pub. L. 97–488 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. 97–488, set out as a note under section 4261 of this title.

References in Other Laws to GS–16, 17, or 18 Pay Rates
References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 329 (title I, §101(c)(1)) of Pub. L. 100–509, set out in a note under section 5376 of Title 5.
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 1138(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 peer review 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

Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform 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, and to prescription drug sponsors pursuant to contracts under part D) for the purpose of determining whether—

(A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

If the organization performs such reviews with respect to a type of health care practitioner other than medical doctors, the organization shall establish procedures for the involvement of health care practitioners of that type in such reviews.

(2) The organization shall determine, on the basis of the review carried out under subparagraphs (A), (B), and (C) of paragraph (1), whether payment shall be made for services under subchapter XVIII of this chapter. Such determination shall constitute the conclusive determination on those issues for purposes of payment under subchapter XVIII of this chapter, except that payment may be made if—

(A) such payment is allowed by reason of section 1395pp of this title;

(B) in the case of inpatient hospital services or extended care services, the peer review organization determines that additional time is required in order to arrange for postdischarge care, but payment may be continued under this subparagraph for not more than six days after the date of the disapproval, but only in the case where the provider of such services did not know and could not reasonably have been expected to know (as determined under section 1395pp of this title) that payment would not otherwise be made for such services under subchapter XVIII of this chapter prior to notification by the organization under paragraph (3);

(C) such determination is changed as the result of any hearing or review of the determination under section 1320c–4 of this title; or

(D) such payment is authorized under section 1395x(v)(1)(G) of this title.

The organization shall identify cases for which payment should not be made by reason of paragraph (1)(B) only through the use of criteria developed pursuant to guidelines established by the Secretary.

(3)(A) Subject to subparagraphs (B) and (D), whenever the organization makes a determination that any health care services or items furnished or to be furnished to a patient by any practitioner or provider are disapproved, the organization shall promptly notify such patient and the agency or organization responsible for the payment of claims under subchapter XVIII of this chapter of such determination.

(B) The notification under subparagraph (A) with respect to services or items disapproved by reason of subparagraph (A) or (C) of paragraph (1) shall not occur until 20 days after the date that the organization has—

(i) made a preliminary notification to such practitioner or provider of such proposed determination, and

(ii) provided such practitioner or provider an opportunity for discussion and review of the proposed determination.

(C) The discussion and review conducted under subparagraph (B)(ii) shall affect the rights of a practitioner or provider to a formal reconsideration of a determination under this part (as provided under section 1320c–4 of this title).

(D) The notification under subparagraph (A) with respect to services or items disapproved by reason of paragraph (1)(B) shall not occur until after—

(i) the organization has notified the practitioner or provider involved of the determination and of the practitioner’s or provider’s right to a formal reconsideration of the determination under section 1320c–4 of this title, and

(ii) if the provider or practitioner requests such a reconsideration, the organization has made such a reconsideration.
If a provider or practitioner is provided a reconsideration, such reconsideration shall be in lieu of any subsequent reconsideration to which the provider or practitioner may be otherwise entitled under section 1320c-4 of this title, but shall not affect the right of a beneficiary from seeking reconsideration under such section of the organization’s determination (after any reconsideration requested by the provider or physician under clause (ii)).

(4)(A) The organization shall, after consultation with the Secretary, determine the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order to most effectively carry out the purposes of this part, exercise review authority under the contract. The organization shall notify the Secretary periodically with respect to such determinations. Each peer review organization shall provide that a reasonable proportion of its activities are involved with reviewing, under paragraph (1)(B), the quality of services and that a reasonable allocation of such activities is made among the different cases and settings (including post-acute-care settings, ambulatory settings, and health maintenance organizations). In establishing such allocation, the organization shall consider (i) whether there is reason to believe that there is a particular need for reviews of particular cases or settings because of previous problems regarding quality of care, (ii) the cost of such reviews and the likely yield of such reviews in terms of number and seriousness of quality of care problems likely to be discovered as a result of such reviews, and (iii) the availability and adequacy of alternative quality review and assurance mechanisms.

(B) The contract of each organization shall provide for the review of services (including both inpatient and outpatient services) provided by eligible organizations pursuant to a risk-sharing contract under section 1395mm of this title (or that is subject to review under section 1395ss(t)(3) of this title) for the purpose of determining whether the quality of such services meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings and whether individuals enrolled with an eligible organization have adequate access to health care services provided by or through such organization (as determined, in part, by a survey of individuals enrolled with the organization who have not yet used the organization to receive such services). The contract of each organization shall also provide that with respect to health care provided by a health maintenance organization or competitive medical plan under section 1395mm of this title, the organization shall maintain a beneficiary outreach program designed to apprise individuals receiving care under such section of the role of the peer review system, of the rights of the individual under such system, and of the method and purposes for contacting the organization. The previous two sentences shall not apply with respect to a contract year if another entity has been awarded a contract under subparagraph (C). Under the contract the level of effort expended by the organization on utilization and quality reviews performed with respect to individuals not enrolled with an eligible organization.

(C) The Secretary may provide, by contract under competitive procurement procedures on a State-by-State basis in up to 25 States, for the review described in subparagraph (B) by an appropriate entity (which may be a peer review organization described in that subparagraph). In selecting among States in which to conduct such competitive procurement procedures, the Secretary may not select States which, as a group, have more than 50 percent of the total number of individuals enrolled with eligible organizations under section 1395mm of this title. Under a contract with an entity under this subparagraph—

(i) the entity must be, or must meet all the requirements under section 1320c-1 of this title to be, a utilization and quality control peer review organization (other than the ability to perform review functions under this section that are not described in subparagraph (B)),

(ii) the contract must meet the requirement of section 1320c-2(b)(3) of this title, and

(iii) the level of effort expended under the contract shall be, to the extent practicable, not less than the level of effort that would otherwise be required under the third sentence of subparagraph (B) if this subparagraph did not apply.

(5) The organization shall consult with nurses and other professional health care practitioners (other than physicians described in section 1395x(r)(1) of this title) and with representatives of institutional and noninstitutional providers of health care services, with respect to the organization’s responsibility for the review under paragraph (1) of the professional activities of such practitioners and providers.

(6)(A) The organization shall, consistent with the provisions of its contract under this part, apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice within the geographic area served by the organization as principal points of evaluation and review, taking into consideration national norms where appro-
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priate. Such norms with respect to treatment for particular illnesses or health conditions shall include—

(i) the types and extent of the health care services which, taking into account differences in acceptable modes of treatment and methods of organizing and delivering care, are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care; and

(ii) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

As a component of the norms described in clause (i) or (ii), the organization shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and other appropriate factors (such as the distance from a patient’s residence to the site of care, family support, availability of proximate alternative sites of care, and the patient’s ability to carry out necessary or prescribed self-care regimens) that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis.

(B) The organization shall—

(i) offer to provide, several times each year, for a physician representing the organization to meet (at a hospital or at a regional meeting) with medical and administrative staff of each hospital (the services of which are reviewed by the organization) respecting the organization’s review of the hospital’s services for which payment may be made under subchapter XVIII of this chapter, and

(ii) publish (not less often than annually) and distribute to providers and practitioners whose services are subject to review a report that describes the organization’s findings with respect to the types of cases in which the organization has frequently determined that (I) inappropriate or unnecessary care has been provided, (II) services were rendered in an inappropriate setting, or (III) services did not meet professionally recognized standards of health care.

(7) The organization, to the extent necessary and appropriate to the performance of the contract, shall—

(A)(i) make arrangements to utilize the services of persons who are practitioners of, or specialists in, the various areas of medicine (including dentistry, optometry, and podiatry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization; and

(ii) in the case of psychiatric and physical rehabilitation services, make arrangements to ensure that (to the extent possible) initial review of such services be made by a physician who is trained in psychiatry or physical rehabilitation (as appropriate).2

(B) undertake such professional inquiries either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review which in the judgment of such organization will facilitate its activities;

(C) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1); and

(D) inspect the facilities in which care is rendered or services are provided (which are located in such area) of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1).

(8) The organization shall perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part or as may be required to carry out section 1395y(a)(15) of this title.

(9)(A) The organization shall collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1320c–9 of this title.

(B) If the organization finds, after reasonable notice to and opportunity for discussion with the physician or practitioner concerned, that the physician or practitioner has furnished services in violation of section 1320c–5(c) or (d) of this title, the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding.

(10) The organization shall coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations including—

(A) agencies under contract pursuant to sections 1395l and 1395a of this title;

(B) other peer review organizations having contracts under this part; and

(C) other public or private review organizations as may be appropriate.

(11) The organization shall make available its facilities and resources for contracting with private and public entities paying for health care in its area for review, as feasible and appropriate, of services reimbursed by such entities.

2So in original. The period probably should be a semicolon.

(13) Notwithstanding paragraph (4), the organization shall perform the review described in paragraph (1) with respect to early readmission cases to determine if the previous inpatient hospital services and the post-hospital services met professionally recognized standards of health care. Such reviews may be performed on a sample basis if the organization and the Secretary determine it to be appropriate. In this paragraph, an “early readmission case” is a case in which an individual, after discharge from a hospital, is readmitted to a hospital less than 31 days after the date of the most recent previous discharge.

(14) The organization shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under subchapter XVIII of this chapter) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such subchapter (or a person acting on the individual’s behalf). The organization shall inform the individual (or representative) of the organization’s final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.

(15) During each year of the contract entered into under section 1320c–2(b) of this title, the organization shall perform significant on-site review activities, including on-site review in at least 20 percent of the rural hospitals in the organization’s area.

(16) The organization shall provide for a review and report to the Secretary when requested by the Secretary under section 1395ddd(d)(3) of this title. The organization shall provide reasonable notice of the review to the physician and hospital involved. Within the time period permitted by the Secretary, the organization shall provide a reasonable opportunity for discussion with the physician and hospital involved, and an opportunity for the physician and hospital to submit additional information, before issuing its report to the Secretary under such section.

(17) The organization shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and subchapter XVIII of this chapter, the functions described in this paragraph shall be treated as a review function.

(b) Review by physicians; physician’s family defined

(1) No physician shall be permitted to review—

(A) health care services provided to a patient if he was directly responsible for providing such services; or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

(2) For purposes of this subsection, a physician’s family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(c) Utilization of services of physicians to make final determinations of denial decisions with respect to professional conduct of other physicians

No utilization and quality control peer review organization shall utilize the services of any individual who is not a duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry to make final determinations of denial decisions in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry, or any act performed by any duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry in the exercise of his profession.

(d) Review of ambulatory surgical procedures

Each contract under this part shall require that the utilization and quality control peer review organization’s review responsibility pursuant to subsection (a)(1) of this section will include review of all ambulatory surgical procedures specified pursuant to section 1395ddd(i)(1)(A) of this title which are performed in the area, or, at the discretion of the Secretary a sample of such procedures.

(e) Review of hospital denial notices

(1) If—

(A) a hospital has determined that a patient no longer requires inpatient hospital care, and

(B) the attending physician has agreed with the hospital’s determination,

the hospital may provide the patient (or the patient’s representative) with a notice (meeting conditions prescribed by the Secretary under section 1395ddp of this title) of the determination.


(f) Identification of methods for identifying cases of substandard care

The Secretary, in consultation with appropriate experts, shall identify methods that would be available to assist peer review organizations (under subsection (a)(4) of this section) in identifying those cases which are more likely than others to be associated with a quality of services which does not meet professionally recognized standards of health care.


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3See References in Text note below.

REFERENCES IN TEXT

Parts C and D, referred to in subsec. (a)(1), (17), probably means parts C and D of title XVIII of act Aug. 14, 1935, ch. 531, which are classified to parts C (§ 1395w–21 et seq.) and D (§ 1395w–181 et seq.) of subpart XVIII of this chapter.

PRIOR PROVISIONS


AMENDMENTS

2003—Subsec. (a)(1). Pub. L. 108–173, § 109(a), inserted "to Medicare Advantage organizations pursuant to contracts under part C, and to prescription drug sponsors pursuant to contracts under part D after "under section 1395mm of this title".


Subsec. (c)(5). Pub. L. 108–173, § 948(d), struck out par. (5) which read as follows: "In any review conducted under paragraph (2) or (3), the organization shall solicit the views of the patient involved (or the patient's representative)."

2000—Subsec. (a)(2) to (4), Pub. L. 100–504 struck out paras. (2) to (4), which had, in par. (2), authorized peer review organization review of validity of hospital's determination that a patient no longer required inpatient hospital care but attending physician had not agreed with the hospital's determination; in par. (3), authorized review of the determination where patient or patient's representative had received notice under paragraph (1) and requested the review; and in par. (4), directed that hospital could not charge patient for inpatient services furnished before noon of the first day after the date the patient or patient's representative received notice of the decision where request for review had been made not later than noon of the first working day after notice under paragraph (1) had been received and section 1385pp(a)(2) conditions had been met.

1994—Subsec. (a)(4)(B). Pub. L. 103–432, § 171(h)(2), substituted "(or subject to review under section 1395ss(t)(3) of this title)" for "(or subject to review under section 1395ss(t)(3) of this title)".

Subsec. (a)(9)(B). Pub. L. 103–432, § 156(g)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "If the organization finds, after notice and hearing, that a physician has furnished services in violation of this subsection, the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician of its finding and decision."


Subsec. (d). Pub. L. 103–432, § 156(a)(2)(A)(ii), struck out paragraph (3) which read as follows: "Determinations that payment should not be made by reason of subparagraph (B) of paragraph (1) shall be made only on the basis of criteria which are consistent with guidelines established by the Secretary."
Section 156(a)(3) of Pub. L. 103–322 provided that: "The amendments made by this subsection (amending this section and sections 1395f, 1395m, 1395y, and 1395cc of this title and repealing section 1320c–13 of this title) shall apply to services provided on or after the date of the enactment of this Act [Oct. 31, 1994]." Amendment by section 171(h)(2) of Pub. L. 103–322 effective as if included in the enactment of Pub. L. 103–322, set out as a note under section 1395ss of this title.

Section 4205(b)(2) of Pub. L. 101–508 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to contracts entered into or renewed on or after the date of the enactment of this Act [Nov. 5, 1990]."

Section 4205(d)(1)(C) of Pub. L. 101–508 provided that: "The amendments made by this paragraph [amending this section and section 1323c–9 of this title] shall apply to notices of proposed sanctions issued more than 60 days after the date of the enactment of this Act [Nov. 5, 1990]."

Section 4205(g)(1)(B) of Pub. L. 101–508 provided that: "The amendments made by subparagraph (A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1985 [Pub. L. 101–508]."

Section 4205(g)(2)(B) of Pub. L. 101–508 provided that: "The amendment made by subparagraph (A) [amending section 1395dd of this title] shall take effect on the first day of the first month beginning more than 60 days after the date of the enactment of this Act [Oct. 31, 1994]."

Section 4205(h)(1)(B) of Pub. L. 101–508 provided that: "The amendment made by subparagraph (A) [amending section 1385dd of this title] shall take effect as if included in the enactment of this Act [Nov. 5, 1990]." The amendment made by subparagraph (B) [amending this section] shall apply to contracts under part B of title XI of the Social Security Act (this part) as of the first day of the first month beginning more than 60 days after the date of the enactment of this Act."

Section 4358(c) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, § 160(d)(4), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 104–18, § 1, July 7, 1995, 109 Stat. 192, provided that: "(1) The amendments made by this section [amending this section and section 1395ss of this title] shall only apply—"(A) in 15 States (as determined by the Secretary of Health and Human Services) and such other States as elect such amendments to apply to them, and"(B) subject to paragraph (2), during the 6½-year period beginning with 1992.

For purposes of this paragraph, the term 'State' has the meaning given such term by section 210(h) of the Social Security Act (42 U.S.C. 410(h))." "(2)(A) The Secretary of Health and Human Services shall conduct a study that compares the health care costs, quality of care, and access to services under medicare supplemental policies with that under other medicare supplemental policies. The study shall be based on surveys of appropriate age-adjusted sample populations. The study shall be completed by June 30, 1997. "(B) Not later than December 31, 1997, the Secretary shall determine, based on the results of the study under subparagraph (A), if any of the following findings are true:"

"(i) The amendments made by this section have not resulted in savings of premium costs to those enrolled in medicare select policies (in comparison to the enrollment in medicare policies that are not medicare select policies and that provide comparable coverage)."

"(ii) There have been significant additional expenditures under the medicare program as a result of such amendments."

"(iii) Access to and quality of care has been significantly diminished as a result of such amendments."

"(C) The amendments made by this section shall remain in effect beyond the 6½-year period described in paragraph (1)(B) unless the Secretary determines that—any of the findings described in clause (i), (ii), or (iii) of subparagraph (B) are true.

"(3) The Comptroller General shall conduct a study to determine the extent to which individuals who are continuously covered under a medicare supplemental policy are subject to medical underwriting if they change the policy under which they are covered, and to identify options, if necessary, for modifying the medicare supplemental insurance market to make sure that continuously insured beneficiaries are able to switch plans without medical underwriting. By not later than June 30, 1996, the Comptroller General shall submit to the Congress a report on the study. The report shall include a description of the potential impact on the cost and availability of medicare supplemental policies of each option identified in the study."

Section 172(b) of Pub. L. 101–322 provided that: "The amendment made by subsection (a) [amending section 455c(b) of Pub. L. 101–508, set out above] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101–508]."

Section 6224(a)(2) of Pub. L. 101–239 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to contracts entered into after the date of the enactment of this Act [Dec. 19, 1989]."

Section 6224(b)(3) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section and section 1323c–4 of this title] shall apply to determinations by utilization and quality control peer review organizations with respect to which preliminary notifications were made under section 1154(a)(3)(B) of the Social Security Act [subsec. (a)(3)(B) of this section] more than 30 days after the date of the enactment of this Act [Dec. 19, 1989]."

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

Section 203(g) of Pub. L. 100–360, which had provided that the amendments made by section 203 of Pub. L. 100–360 (amending this section and sections 1395f, 1395x, and 1395aa of this title) were to apply to items and services furnished on or after January 1, 1990, was repealed by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981. Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(e)(2), (3), (4)(C) of 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 I, General Provisions.

Section 4094(c)(1)(B) of Pub. L. 100–203 provided that: "The amendment made by subparagraph (A) [amending this section] shall apply to contracts under part B of title XI of the Social Security Act (42 U.S.C. 1320c et

Effective Date of 1989 Amendments

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 203(g) of Pub. L. 100–360, set out as a note under section 704 of this title.

Section 203(g) of Pub. L. 100–360, which had provided that the amendments made by section 203 of Pub. L. 100–360 (amending this section and sections 1395f, 1395x, and 1395aa of this title) were to apply to items and services furnished on or after January 1, 1990, was repealed by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981. Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(e)(2), (3), (4)(C) of 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 I, General Provisions.

Effective Date of 1987 Amendment

Section 4093(b) of Pub. L. 100–203 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to determinations made on or after April 1, 1988."

Section 4094(c)(1)(B) of Pub. L. 100–203 provided that: "The amendments made by subparagraph (A) [amending this section] shall apply to contracts under part B of title XI of the Social Security Act (42 U.S.C. 1320c et
section and section 1395cc of this title] shall become effective on the date of the enactment of this Act [Apr. 7, 1986].''


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 4261 of this title.

State Regulatory Programs
For provisions relating to changes required to conform State regulatory programs to amendments by sec. 171 of Pub. L. 103–432, see section 171(m) of Pub. L. 103–432, set out as a note under section 1396s of this title.

Review and Analysis of Variations in Utilization of Hospital and Other Health Care Services
Section 9353(a)(4) of Pub. L. 99–509 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 [this part], 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 [subchapter XVIII of this chapter]."

§ 1320c–4. Right to hearing and judicial review
Any beneficiary who is entitled to benefits under subchapter XVIII of this chapter, 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 peer review 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 of this chapter 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 (f) 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.


Prior Provisions
1989—Pub. L. 103–296 substituted ``(to the same extent as beneficiaries under subchapter II of this chapter 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 (i) 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 the Secretary's final decision.''

(b) Sanctions and penalties; hearings and review

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, medically necessary;

(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 peer review 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) of this section, 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 provider from eligibility shall be final.

(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 such case 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.

1 So in original. Probably should be "pay".
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 a 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 utilization and quality control peer review 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) of this section) furnishing health care services in such area shall comply with all obligations imposed by him on him under subsection (a) of this section.


PRIOR PROVISIONS


AMENDMENTS

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 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 (i) 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”.


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 whether [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. 101-397 substituted “health professional shortage area” for “health manpower shortage area (HMSA)”.


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 “services under this section”.

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 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. 103–422 effective as if included in the enactment of Pub. L. 101–508, see section 156(b)(6)(A) of Pub. L. 103–422, set out as a note under title 1320c–9 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT
Section 4205(a)(2) of Pub. L. 101–508 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].’’

EFFECTIVE DATE OF 1988 AMENDMENT
Except as specifically provided in section 411 of Pub. L. 99–360, 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 166 of Title I, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENTS
Section 4095(b) of Pub. L. 100–203 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 [subsec. (b) (of this section) 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
Section 4094(e) of Pub. L. 100–203, as amended by Pub. L. 103–354, title IV, §411(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 which is classified to this subchapter). 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
Section 4096(c), (d) of Pub. L. 100–203 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 [subsec. (b) of this section] 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 [subchapter XVIII of this chapter] if permitted to continue 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 [subsec. (b) of this section] 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 osteopath or provider took such action; but only if—
§ 1320c–7. Application of this part to certain State programs receiving Federal financial assistance

(a) State plan provision that functions of peer review 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 utilization and quality control peer review 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) of this section, 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).

§ 1320c–8. Authorization for use of certain funds to administer provisions of this part

Expenses incurred in the administration of the contracts described in section 1395y(g) of this title shall be payable from—

(1) funds in the Federal Hospital Insurance Trust Fund; and

(2) funds in the Federal Supplementary Medical Insurance Trust Fund,

in such amounts from each of such Trust Funds as the Secretary shall deem to be fair and equitable after taking into consideration the expenses attributable to the administration of this part with respect to each of such programs. The Secretary shall make such transfers of money from such Trust Funds as may be appropriate to settle accounts between them in cases where expenses properly payable from one such Trust Fund have been paid from the other such Trust Fund.

§ 1320c–9. Prohibition against disclosure of information

(a) Freedom of Information Act inapplicable; exceptions to nondisclosure

An organization, in carrying out its functions under a contract entered into under this part, shall not be a Federal agency for purposes of the provisions of section 552 of title 5 (commonly referred to as the Freedom of Information Act). Any data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person except—

(1) to the extent that may be necessary to carry out the purposes of this part,

(2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care, or

(3) in accordance with subsection (b) of this section.

(b) Disclosure of information permitted

An organization having a contract with the Secretary under this part shall provide in accordance with procedures and safeguards established by the Secretary, data and information—
§ 1320c–9  TITLE 42—THE PUBLIC HEALTH AND WELFARE

(1) which may identify specific providers or practitioners as may be necessary—

(A) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns involving risks to the public health, which data and information shall be provided by the peer review organization to any such agency at the request of such agency relating to a specific case or pattern;

(B) to assist appropriate Federal and State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health, which data and information shall be provided by the peer review organization to any such agency—

(i) at the discretion of the peer review organization, at the request of such agency relating to a specific case or pattern with respect to which such agency has made a finding, or has a reasonable belief, that there may be a substantial risk to the public health, or

(ii) upon a finding by, or the reasonable belief of, the peer review organization that there may be a substantial risk to the public health;

(C) to assist appropriate State agencies recognized by the Secretary as having responsibility for licensing or certification of providers or practitioners or to assist national accreditation bodies acting pursuant to section 1395bb of this title in accrediting providers for purposes of meeting the conditions described in subchapter XVIII of this chapter, which data and information shall be provided by the peer review organization to any such agency or body at the request of such agency or body relating to a specific case or to a possible pattern of substandard care, but only to the extent that such data and information are required by the agency or body to carry out its respective function which is within the jurisdiction of the agency or body under State law or under section 1395bb of this title; and

(D) to provide notice in accordance with section 1320c–3(a)(9)(B) of this title;

(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such organization, and shall be in the form of aggregate statistical data (without explicitly identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such organization.

The penalty provided in subsection (c) of this section shall not apply to the disclosure of any information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such information) of any such information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the information. An organization may require payment of a reasonable fee for providing information under this subsection in response to a request for such information.

(c) Penalties

It shall be unlawful for any person to disclose any such information described in paragraph (1) of this section other than for the purposes provided in subsections (a) and (b) of this section, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than 6 months, or both, and shall be required to pay the costs of prosecution.

(d) Subpoena and discovery proceedings regarding patient records

No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under section 1320c–3(a)(1)(B) or 1320c–5(a)(2) of this title shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization’s findings and conclusions in making the determination.

(e) Organizations with contracts

For purposes of this section and section 1320c–6 of this title, the term ‘‘organization with a contract with the Secretary under this part’’ includes an entity with a contract with the Secretary under section 1320c–3(a)(4)(C) of this title.


Prior Provisions


Amendments

1994—Subsec. (b)(1)(D). Pub. L. 103–432, §156(b)(2)(B), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: ‘‘to provide notice to the
State medical board in accordance with section 1320c–3(a)(9)(B) of this title when the organization submits a report and recommendations to the Secretary under section 1320c–5(a)(1) of this title with respect to a physician whom the board is responsible for licensing.''


Subsec. (g). Pub. L. 100–360, added Pub. L. 99–509 amended subpar. (G) generally. Prior to amendment, subpar. (C) read as follows: 'to assist appropriate State agencies recognized by the Secretary as having responsibility for licensing the certification of providers or practitioners, which data and information shall be provided by the peer review organization to any such agency at the request of such agency relating to a specific case, but only to the extent that such data and information is required by the agency in carrying out a function which is within the jurisdiction of such agency under State law; and'.

**Effective Date of 1994 Amendment**

Section 156(b)(6) of Pub. L. 103–432 provided that:

'(A) Except as provided in subparagraph (B), the amendments made by this subsection [amending this section, sections 1320c–3 and 1320c–5 of this title, and provisions set out as notes under this section and section 1320c–5 of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].

'(B) The amendments made by paragraph (2) [amending this section and section 1320c–3 of this title] (relating to the requirement on reporting of information to State boards) shall take effect on the date of the enactment of this Act [Oct. 31, 1994].'

**Effective Date of 1990 Amendment**

Amendment by section 4205(d)(1)(B) of Pub. L. 101–508 applicable to notices of proposed sanctions issued more than 60 days after Nov. 5, 1990, see section 4205(d)(1)(C) of Pub. L. 101–508, set out as a note under section 1320c–3 of this title.

Section 4205(e)(2) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, § 156(b)(5), Oct. 31, 1994, 108 Stat. 441, provided that: 'The amendment made by paragraph (1) [amending this section] shall apply to proceedings as of 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 1986 Amendment**

Section 9353(d)(2) of Pub. L. 99–509 provided that: 'The amendments made by paragraph (1) [amending this section] shall apply to requests for data and information made on and after the end of the 6-month period beginning on the date of the enactment of this Act [Oct. 21, 1986].'

**Freedom of Information Act Request**

Pub. L. 96–499, title IX, § 928, Dec. 5, 1980, 94 Stat. 2660, provided that: 'No Professional Standards Review Organization designated (conditionally or otherwise) under part B of title XI of the Social Security Act [this part] shall be required to make available any records pursuant to a request made under section 552 of title 5, United States Code, until the later of (1) one year after the date of entry of a final court order requiring that such records be made available, or (2) the last date of the Congress during which the court order was entered.'

§ 1320c–10. Annual reports

The Secretary shall submit to the Congress not later than April 1 of each year, a full and complete report on the administration, impact, and cost of the program under this part during the preceding fiscal year, including data and information on—

(1) the number, status, and service areas of all utilization and quality control peer review organizations participating in the program;

(2) the number of health care institutions and practitioners whose services are subject to review by such organizations, and the number of beneficiaries and recipients who received services subject to such review during such year;

(3) the various methods of reimbursement utilized in contracts under this part, and the relative efficiency of each such method of reimbursement;

(4) the imposition of penalties and sanctions under this title for violations of law and for failure to comply with the obligations imposed by this part;

(5) the total costs incurred under subchapters XVIII and XIX of this chapter in the implementation and operation of all procedures required by such subchapters for the review of services to determine their medical necessity, appropriateness of use, and quality; and

(6) descriptions of the criteria upon which decisions are made, and the selection and relative weights of such criteria.


**Prior Provisions**


**Performance of Professional Standards Review Organizations; Report to Congress**

Pub. L. 97–35, title XXI, § 2112(a)(2)(D), Aug. 13, 1981, 95 Stat. 793, provided that the Secretary of Health and Human Services, not later than September 30, 1982, was to report to the Congress on his assessment (under former section 1320c–3(g) of this title) of the relative performance of Professional Standards Review Organi-
zations and on any determinations made not to renew agreements with such Organizations on the basis of such performance.

§ 1320c–11. Exemptions for religious nonmedical health care institutions

The provisions of this part shall not apply with respect to a religious nonmedical health care institution (as defined in section 1395x(aa)(1) of this title).


PRIOR PROVISIONS


§ 1320c–12. Medical officers in American Samoa, Northern Mariana Islands, and Trust Territory of the Pacific Islands to be included in utilization and quality control peer review program

For purposes of applying this part to American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, individuals licensed to practice medicine in those places shall be considered to be physicians and doctors of medicine.


PRIOR PROVISIONS


TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.


EFFECTIVE DATE OF REPEAL

Repeal applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103–432, set out as an Effective Date of 1994 Amendment note under section 1320c–3 of this title.

§§ 1320c–14 to 1320c–19. Omitted

CODIFICATION

Sections 1320c–14 to 1320c–19 were omitted in the general revision of this part by Pub. L. 97–248, title I, §143, Sept. 3, 1982, 96 Stat. 382.


EFFECTIVE DATE OF REPEAL

Repeal applicable to agreements with Professional Standards Review Organizations entered into on or after Oct. 1, 1981, see section 2113(o) of Pub. L. 97–35, set out as an Effective Date of 1981 Amendment note under section 1396a of this title.
§§ 1320c–21, 1320c–22. Omitted

CODIFICATION

Sections 1320c–21 and 1320c–22 were omitted in the general revision of this part by Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 382.


PART C—ADMINISTRATIVE SIMPLIFICATION

§ 1320d. Definitions

For purposes of this part:

(1) Code set

The term "code set" means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(2) Health care clearinghouse

The term "health care clearinghouse" means a public or private entity that processes or facilitates the processing of non-standard data elements of health information into standard data elements.

(3) Health care provider

The term "health care provider" includes a provider of services (as defined in section 1395s(s) of this title), a provider of medical or other health services (as defined in section 1395x(s) of this title), and any other person furnishing health care services or supplies.

(4) Health information

The term "health information" means any information, whether oral or recorded in any form or medium, that—

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

(5) Health plan

The term "health plan" means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 300gg–91 of this title). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 300gg–91(a) of this title), but only if the plan—

(i) has 50 or more participants (as defined in section 1002(7) of title 29); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

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

(C) A health maintenance organization (as defined in section 300gg–91(b) of this title).

(D) Parts A, B, C, or D of the Medicare program under subchapter XVIII of this chapter.

(E) The Medicaid program under subchapter XIX of this chapter.

(F) A Medicare supplemental policy (as defined in section 1395ss(g)(1) of this title).

(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10.

(J) The veterans health care program under chapter 17 of title 38.

(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefits Plan under chapter 89 of title 5.

(6) Individually identifiable health information

The term "individually identifiable health information" means any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(7) Standard

The term "standard", when used with reference to a data element of health information or a transaction referred to in section 1320d–2(a)(1) of this title, means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1320d–1 through 1320d–3 of this title.

\(^{1}\) So in original. Probably should be "Part".