

methods for providing coverage under part B of this subchapter for orthopedic shoes for individuals with disabling or deforming conditions requiring special fitting considerations, or requiring special shoes in conjunction with the use of an orthosis or foot support, report to be submitted no later than July 1, 1981; (f) a study of conditions under which services with respect to respiratory therapy could be covered as a home health benefit under this subchapter, report to be submitted within twenty-four months of Dec. 5, 1980; and (g) a study analyzing cost effects of alternative approaches to improving coverage under this subchapter for treatment of various types of foot conditions, report to be submitted within twenty-four months of Dec. 5, 1980. Payments and expenditures for such studies and projects were to be made in appropriate part from the Federal Hospital Insurance Trust Fund established by section 1395i of this title, and the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title.

DEMONSTRATION PROJECT RELATING TO THE
TERMINALLY ILL

Pub. L. 96-265, title V, §506, June 9, 1980, 94 Stat. 475, authorized Secretary of Health and Human Services to provide for participation, by Social Security Administration, in a demonstration project relating to the terminally ill then being conducted within the Department of Health and Human Services, the purpose of such participation to be to study impact on terminally ill of provisions of disability programs administered by Social Security Administration and to determine how best to provide services needed by persons who were terminally ill through programs over which the Social Security Administration had administrative responsibility, and authorized to be appropriated necessary sums not in excess of \$2,000,000 for any fiscal year.

REPORT TO CONGRESS WITH RESPECT TO URBAN OR
RURAL COMPREHENSIVE MENTAL HEALTH CENTERS
AND CENTERS FOR TREATMENT OF ALCOHOLISM AND
DRUG ABUSE; SUBMISSION NO LATER THAN JUNE 13,
1978

Pub. L. 95-210, §4, Dec. 13, 1977, 91 Stat. 1490, directed Secretary of Health, Education, and Welfare to submit to Congress, no later than six months after Dec. 13, 1977, a report on the advantages and disadvantages of extending coverage under this subchapter to urban or rural comprehensive mental health centers and to centers for treatment of alcoholism and drug abuse.

STUDY AND REVIEW BY COMPTROLLER GENERAL OF AD-
MINISTRATIVE STRUCTURE FOR PROCESSING MEDICARE
CLAIMS; REPORT TO CONGRESS

Pub. L. 95-142, §12, Oct. 25, 1977, 91 Stat. 1197, directed Comptroller General to conduct a comprehensive study and review of administrative structure established for processing of claims under this subchapter for purpose of determining whether and to what extent more efficient claims administration under this subchapter could be achieved and directed Comptroller General to submit to Congress no later than July 1, 1979, a complete report with respect to such study and review.

REPORT BY SECRETARY OF HEALTH, EDUCATION, AND
WELFARE ON DELIVERY OF HOME HEALTH AND OTHER
IN-HOME SERVICES; CONTENTS; CONSULTATION RE-
QUIREMENTS; SUBMISSION TO CONGRESS

Pub. L. 95-142, §18, Oct. 25, 1977, 91 Stat. 1202, directed Secretary of Health, Education, and Welfare, not later than one year after Oct. 25, 1977, to submit to appropriate committees of Congress a report analyzing, evaluating, and making recommendations with respect to all aspects of delivery of home health and other in-home services authorized to be provided under subchapters XVIII, XIX, and XX of this chapter.

§ 1395mm. Payments to health maintenance organizations and competitive medical plans

(a) Rates and adjustments

(1)(A) The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) not later than September 7 before the calendar year concerned—

(i) a per capita rate of payment for each class of individuals who are enrolled under this section with an eligible organization which has entered into a risk-sharing contract and who are entitled to benefits under part A and enrolled under part B, and

(ii) a per capita rate of payment for each class of individuals who are so enrolled with such an organization and who are enrolled under part B only.

For purposes of this section, the term “risk-sharing contract” means a contract entered into under subsection (g) and the term “reasonable cost reimbursement contract” means a contract entered into under subsection (h).

(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

(C) The annual per capita rate of payment for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in paragraph (4)) for that class.

(D) In the case of an eligible organization with a risk-sharing contract, the Secretary shall make monthly payments in advance and in accordance with the rate determined under subparagraph (C) and except as provided in subsection (g)(2), to the organization for each individual enrolled with the organization under this section.

(E)(i) The amount of payment under this paragraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(ii)(I) Subject to subclause (II), the Secretary may make retroactive adjustments under clause (i) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with an eligible organization (which has a risk-sharing contract under this section) under a health benefit plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the plan under this section, except that for purposes of making such retroactive adjustments under this clause, such period may not exceed 90 days.

(II) No adjustment may be made under subclause (I) with respect to any individual who does not certify that the organization provided the individual with the explanation described in subsection (c)(3)(E) at the time the individual enrolled with the organization.

(F)(i) At least 45 days before making the announcement under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall provide for notice to eligible organizations of proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(ii) In each announcement made under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall include an explanation of the assumptions (including any benefit coverage assumptions) and changes in methodology used in the announcement in sufficient detail so that eligible organizations can compute per capita rates of payment for classes of individuals located in each county (or equivalent area) which is in whole or in part within the service area of such an organization.

(2) With respect to any eligible organization which has entered into a reasonable cost reimbursement contract, payments shall be made to such plan in accordance with subsection (h)(2) rather than paragraph (1).

(3) Subject to subsections (c)(2)(B)(ii) and (c)(7), payments under a contract to an eligible organization under paragraph (1) or (2) shall be instead of the amounts which (in the absence of the contract) would be otherwise payable, pursuant to sections 1395f(b) and 1395f(a) of this title, for services furnished by or through the organization to individuals enrolled with the organization under this section.

(4) For purposes of this section, the term “adjusted average per capita cost” means the average per capita amount that the Secretary estimates in advance (on the basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for services covered under parts A and B, or part B only, and types of expenses otherwise reimbursable under parts A and B, or part B only (including administrative costs incurred by organizations described in sections 1395h and 1395u of this title), if the services were to be furnished by other than an eligible organization or, in the case of services covered only under section 1395x(s)(2)(H) of this title, if the services were to be furnished by a physician or as an incident to a physician’s service.

(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A and enrolled under part B shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The portion of that payment to the organization for a month to be paid by each trust fund shall be determined as follows:

(A) In regard to expenditures by eligible organizations having risk-sharing contracts, the allocation shall be determined each year by the Secretary based on the relative weight that benefits from each fund contribute to the adjusted average per capita cost.

(B) In regard to expenditures by eligible organizations operating under a reasonable cost reimbursement contract, the initial allocation shall be based on the plan’s most recent budget, such allocation to be adjusted, as needed, after cost settlement to reflect the distribution of actual expenditures.

The remainder of that payment shall be paid by the former trust fund.

(6) Subject to subsections (c)(2)(B)(ii) and (c)(7), if an individual is enrolled under this section with an eligible organization having a risk-sharing contract, only the eligible organization shall be entitled to receive payments from the Secretary under this subchapter for services furnished to the individual.

(b) Definitions; requirements

For purposes of this section, the term “eligible organization” means a public or private entity (which may be a health maintenance organization or a competitive medical plan), organized under the laws of any State, which—

(1) is a qualified health maintenance organization (as defined in section 300e-9(d)¹ of this title), or

(2) meets the following requirements:

(A) The entity provides to enrolled members at least the following health care services:

(i) Physicians’ services performed by physicians (as defined in section 1395x(r)(1) of this title).

(ii) Inpatient hospital services.

(iii) Laboratory, X-ray, emergency, and preventive services.

(iv) Out-of-area coverage.

(B) The entity is compensated (except for deductibles, coinsurance, and copayments) for the provision of health care services to enrolled members by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health care service actually provided to a member.

(C) The entity provides physicians’ services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through contracts with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(D) The entity assumes full financial risk on a prospective basis for the provision of the health care services listed in subparagraph (A), except that such entity may—

(i) obtain insurance or make other arrangements for the cost of providing to any enrolled member health care services listed in subparagraph (A) the aggregate value of which exceeds \$5,000 in any year,

(ii) obtain insurance or make other arrangements for the cost of health care service listed in subparagraph (A) provided to its enrolled members other than through the entity because medical necessity required their provision before they could be secured through the entity,

¹ See References in Text note below.

(iii) obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(iv) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(E) The entity has made adequate provision against the risk of insolvency, which provision is satisfactory to the Secretary.

Paragraph (2)(A)(ii) shall not apply to an entity which had contracted with a single State agency administering a State plan approved under subchapter XIX for the provision of services (other than inpatient hospital services) to individuals eligible for such services under such State plan on a prepaid risk basis prior to 1970.

(c) Enrollment in plan; duties of organization to enrollees

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI—

(i) only those services covered under parts A and B of this subchapter, for those members entitled to benefits under part A and enrolled under part B, or

(ii) only those services covered under part B, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(1)(A) and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period—

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period,

unless otherwise required by law.

(3)(A)(i) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year and including the period or periods specified under clause (ii), and must provide that at any time during which enrollments are accepted, the organization will accept up to the limits of its capacity (as determined by the Secretary) and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) in the order in which they apply for enrollment, unless to do so would result in failure to meet the requirements of subsection (f) or would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by the organization.

(ii)(I) If a risk-sharing contract under this section is not renewed or is otherwise terminated, eligible organizations with risk-sharing contracts under this section and serving a part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination. If a risk-sharing contract under this section is renewed in a manner that discontinues coverage for individuals residing in part of the service area, eligible organizations with risk-sharing contracts under this section and enrolling individuals residing in that part of the service area are required to have an open enrollment period for individuals residing in the part of the service area who were enrolled under the contract as of the date of notice of such discontinued coverage.

(II) The open enrollment periods required under subclause (I) shall be for 30 days and shall begin 30 days after the date that the Secretary provides notice of such requirement.

(III) Enrollment under this clause shall be effective 30 days after the end of the open enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations. In the case of an individual's termi-

nation of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this subchapter other than through the organization.

(C) The Secretary may prescribe the procedures and conditions under which an eligible organization that has entered into a contract with the Secretary under this subsection may inform individuals eligible to enroll under this section with the organization about the organization, or may enroll such individuals with the organization. No brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and (ii) the Secretary has not disapproved the distribution of the material. The Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary's discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(D) The organization must provide assurances to the Secretary that it will not expel or refuse to re-enroll any such individual because of the individual's health status or requirements for health care services, and that it will notify each such individual of such fact at the time of the individual's enrollment.

(E) Each eligible organization shall provide each enrollee, at the time of enrollment and not less frequently than annually thereafter, an explanation of the enrollee's rights under this section, including an explanation of—

- (i) the enrollee's rights to benefits from the organization,
- (ii) the restrictions on payments under this subchapter for services furnished other than by or through the organization,
- (iii) out-of-area coverage provided by the organization,
- (iv) the organization's coverage of emergency services and urgently needed care, and
- (v) appeal rights of enrollees.

(F) Each eligible organization that provides items and services pursuant to a contract under this section shall provide assurances to the Secretary that in the event the organization ceases to provide such items and services, the organization shall provide or arrange for supplemental coverage of benefits under this subchapter related to a pre-existing condition with respect to any exclusion period, to all individuals enrolled with the entity who receive benefits under this subchapter, for the lesser of six months or the duration of such period.

(G)(i) Each eligible organization having a risk-sharing contract under this section shall notify individuals eligible to enroll with the organization under this section and individuals enrolled with the organization under this section that—

- (I) the organization is authorized by law to terminate or refuse to renew the contract, and

(II) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the organization under this section.

(ii) The notice required by clause (i) shall be included in—

(I) any marketing materials described in subparagraph (C) that are distributed by an eligible organization to individuals eligible to enroll under this section with the organization, and

(II) any explanation provided to enrollees by the organization pursuant to subparagraph (E).

(4) The organization must—

(A) make the services described in paragraph (2) (and such other health care services as such individuals have contracted for) (i) available and accessible to each such individual, within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and

(B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is \$100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is \$1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 405(g) of this title, and both the individual and the eligible organization shall be entitled to be parties to that judicial review. In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1395ff(b)(1)(E)(iii) of this title shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar

amounts specified in section 1395ff(b)(1)(E)(i) of this title.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) as of the effective date of the individual's—

(A) enrollment with an eligible organization under this section—

(i) payment for such services until the date of the individual's discharge shall be made under this subchapter as if the individual were not enrolled with the organization,

(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge, and

(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or

(B) termination of enrollment with an eligible organization under this section—

(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge,

(ii) payment for such services during the stay shall not be made under section 1395ww(d) of this title, and

(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.

(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(d) Right to enroll with contracting organization in geographic area

Subject to the provisions of subsection (c)(3), every individual entitled to benefits under part A and enrolled under part B or enrolled under part B only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a contract under this section and which serves the geographic area in which the individual resides.

(e) Limitation on charges; election of coverage; “adjusted community rate” defined; workmen's compensation and insurance benefits

(1) In no case may—

(A) the portion of an eligible organization's premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered

under parts A and B) to individuals who are enrolled under this section with the organization and who are entitled to benefits under part A and enrolled under part B, or

(B) the portion of its premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under part B) to individuals who are enrolled under this section with the organization and enrolled under part B only

exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A and enrolled under part B, or enrolled under part B only, respectively, if they were not members of an eligible organization.

(2) If the eligible organization provides to its members enrolled under this section services in addition to services covered under parts A and B of this subchapter, election of coverage for such additional services (unless such services have been approved by the Secretary under subsection (c)(2)) shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of—

(A) the portion of such organization's premium rate charged, with respect to such additional services, to members enrolled under this section, and

(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members

exceed the adjusted community rate for such services.

(3) For purposes of this section, the term “adjusted community rate” for a service or services means, at the election of an eligible organization, either—

(A) the rate of payment for that service or services which the Secretary annually determines would apply to a member enrolled under this section with an eligible organization if the rate of payment were determined under a “community rating system” (as defined in section 300e-1(8) of this title, other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to a member enrolled under this section with the eligible organization, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the members enrolled with the eligible organization under this section and the utilization characteristics of the other members of the organization (or, if the Secretary finds that adequate data are not available to adjust for those differences, the dif-

ferences between the utilization characteristics of members in other eligible organizations, or individuals in the area, in the State, or in the United States, eligible to enroll under this section with an eligible organization and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Notwithstanding any other provision of law, the eligible organization may (in the case of the provision of services to a member enrolled under this section for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or plan of the United States or a State, under an automobile or liability insurance policy or plan, including a self-insured plan, or under no fault insurance) charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law or policy—

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such member to the extent that the member has been paid under such law, plan, or policy for such services.

(f) Membership requirements

(1) For contract periods beginning before January 1, 1999, each eligible organization with which the Secretary enters into a contract under this section shall have, for the duration of such contract, an enrolled membership at least one-half of which consists of individuals who are not entitled to benefits under this subchapter.

(2) Subject to paragraph (4), the Secretary may modify or waive the requirement imposed by paragraph (1) only—

(A) to the extent that more than 50 percent of the population of the area served by the organization consists of individuals who are entitled to benefits under this subchapter or under a State plan approved under subchapter XIX, or

(B) in the case of an eligible organization that is owned and operated by a governmental entity, only with respect to a period of three years beginning on the date the organization first enters into a contract under this section, and only if the organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this subchapter or under a State plan approved under subchapter XIX.

(3) If the Secretary determines that an eligible organization has failed to comply with the requirements of this subsection, the Secretary may provide for the suspension of enrollment of individuals under this section or of payment to the organization under this section for individuals newly enrolled with the organization, after the date the Secretary notifies the organization of such noncompliance.

(4) Effective for contract periods beginning after December 31, 1996, the Secretary may waive or modify the requirement imposed by paragraph (1) to the extent the Secretary finds that it is in the public interest.

(g) Risk-sharing contract

(1) The Secretary may enter a risk-sharing contract with any eligible organization, as de-

finied in subsection (b), which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that—

(A) if the adjusted community rate, as defined in subsection (e)(3), for services under parts A and B (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A and enrolled in part B, or

(B) if the adjusted community rate for services under part B (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits under part A and enrolled in part B, or enrolled in part B only, respectively, the eligible organization shall provide to members enrolled under a risk-sharing contract under this section with the organization and entitled to benefits under part A and enrolled in part B, or enrolled in part B only, respectively, the additional benefits described in paragraph (3) which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced); except that this paragraph shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced) and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5). If the Secretary finds that there is insufficient enrollment experience to determine an average of the per capita rates of payment to be made under subsection (a)(1) at the beginning of a contract period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

(3) The additional benefits referred to in paragraph (2) are—

(A) the reduction of the premium rate or other charges made with respect to services furnished by the organization to members enrolled under this section, or

(B) the provision of additional health benefits,

or both.

(4) Repealed. Pub. L. 100-203, title IV, § 4012(b), Dec. 22, 1987, 101 Stat. 1330-61.

(5) An organization having a risk-sharing contract under this section may (with the approval

of the Secretary) provide that a part of the value of additional benefits otherwise required to be provided by reason of paragraph (2) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to stabilize and prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with paragraph (3). Any of such value of additional benefits which is not provided to members of the organization in accordance with paragraph (3) prior to the end of such period, shall revert for the use of such trust funds.

(6)(A) A risk-sharing contract under this section shall require the eligible organization to provide prompt payment (consistent with the provisions of sections 1395h(c)(2) and 1395u(c)(2) of this title) of claims submitted for services and supplies furnished to individuals pursuant to such contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier.

(B) In the case of an eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with subparagraph (A), the Secretary may provide for direct payment of the amounts owed to providers and suppliers for such covered services furnished to individuals enrolled under this section under the contract. If the Secretary provides for such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this section to reflect the amount of the Secretary's payments (and costs incurred by the Secretary in making such payments).

(h) Reasonable cost reimbursement contract; requirements

(1) If—

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1),

the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1395x(v) of this title) in the manner prescribed in paragraph (3).

(2) A reasonable cost reimbursement contract under this subsection may, at the option of such organization, provide that the Secretary—

(A) will reimburse hospitals and skilled nursing facilities either for the reasonable cost (as determined under section 1395x(v) of this title) or for payment amounts determined in accordance with section 1395ww of this title, as applicable, of services furnished to individ-

uals enrolled with such organization pursuant to subsection (d), and

(B) will deduct the amount of such reimbursement from payment which would otherwise be made to such organization.

If such an eligible organization pays a hospital or skilled nursing facility directly, the amount paid shall not exceed the reasonable cost of the services (as determined under section 1395x(v) of this title) or the amount determined under section 1395ww of this title, as applicable, unless such organization demonstrates to the satisfaction of the Secretary that such excess payments are justified on the basis of advantages gained by the organization.

(3) Payments made to an organization with a reasonable cost reimbursement contract shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) or the amounts otherwise determined under section 1395ww of this title for the types of expenses otherwise reimbursable under this subchapter for providing services covered under this subchapter to individuals described in subsection (a)(1).

(4) Any reasonable cost reimbursement contract with an eligible organization under this subsection shall provide that the Secretary shall require, at such time following the expiration of each accounting period of the eligible organization (and in such form and in such detail) as he may prescribe—

(A) that the organization report to him in an independently certified financial statement its per capita incurred cost based on the types of components of expenses otherwise reimbursable under this subchapter for providing services described in subsection (a)(1), including therein, in accordance with accounting procedures prescribed by the Secretary, its methods of allocating costs between individuals enrolled under this section and other individuals enrolled with such organization;

(B) that failure to report such information as may be required may be deemed to constitute evidence of likely overpayment on the basis of which appropriate collection action may be taken;

(C) that in any case in which an eligible organization is related to another organization by common ownership or control, a consolidated financial statement shall be filed and that the allowable costs for such organization may not include costs for the types of expense otherwise reimbursable under this subchapter, in excess of those which would be determined to be reasonable in accordance with regulations (providing for limiting reimbursement to costs rather than charges to the eligible organization by related organizations and owners) issued by the Secretary; and

(D) that in any case in which compensation is paid by an eligible organization substantially in excess of what is normally paid for similar services by similar practitioners (regardless of method of compensation), such compensation may as appropriate be considered to constitute a distribution of profits.

(5)(A) After August 5, 1997, the Secretary may not enter into a reasonable cost reimbursement contract under this subsection (if the contract is not in effect as of August 5, 1997), except for a contract with an eligible organization which, immediately previous to entering into such contract, had an agreement in effect under section 1395l(a)(1)(A) of this title.

(B) Subject to subparagraph (C), the Secretary shall approve an application for a modification to a reasonable cost contract under this section in order to expand the service area of such contract if—

(i) such application is submitted to the Secretary on or before September 1, 2003; and

(ii) the Secretary determines that the organization with the contract continues to meet the requirements applicable to such organizations and contracts under this section.

(C)(i) Subject to clause (ii), a reasonable cost reimbursement contract under this subsection may be extended or renewed indefinitely.

(ii) Subject to clause (iv), for any period beginning on or after January 1, 2016, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area of—

(I) 2 or more MA regional plans described in clause (iii), provided that all such plans are not offered by the same Medicare Advantage organization; or

(II) 2 or more MA local plans described in clause (iii), provided that all such plans are not offered by the same Medicare Advantage organization.

(iii) A plan described in this clause for a year for a service area is a plan described in section 1395w-21(a)(2)(A)(i) of this title if the service area for the year meets the following minimum enrollment requirements:

(I) With respect to any portion of the cost plan service area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area that are not in another Metropolitan Statistical Area with a population of more than 250,000, 5,000 individuals. If the service area includes a portion in more than 1 Metropolitan Statistical Area with a population of more than 250,000, the minimum enrollment determination under the preceding sentence shall be made with respect to each such Metropolitan Statistical Area (and such applicable contiguous counties to such Metropolitan Statistical Area).

(II) With respect to any other portion of such cost plan service area, 1,500 individuals.

(iv) In the case of an eligible organization that is offering a reasonable cost reimbursement contract that may no longer be extended or renewed because of the application of clause (ii), or where such contract has been extended or renewed but the eligible organization has informed the Secretary in writing not later than a date determined appropriate by the Secretary that such organization voluntarily plans not to seek renewal of the reasonable cost reimbursement contract, the following shall apply:

(I) Notwithstanding such clause, such contract may be extended or renewed for the two years subsequent to 2016. The final year in which such contract is extended or renewed is referred to in this subsection as the “last reasonable cost reimbursement contract year for the contract”.

(II) The organization may not enroll a new enrollee under such contract during the last reasonable cost reimbursement contract year for the contract (but may continue to enroll new enrollees through the end of the year immediately preceding such year) unless such enrollee is any of the following:

(aa) An individual who chooses enrollment in the reasonable cost contract during the annual election period with respect to such last year.

(bb) An individual whose spouse, at the time of the individual’s enrollment² is an enrollee under the reasonable cost reimbursement contract.

(cc) An individual who is covered under an employer group health plan that offers coverage through the reasonable cost reimbursement contract.

(dd) An individual who becomes entitled to benefits under part A, or enrolled under part B, and was enrolled in a plan offered by the eligible organization immediately prior to the individual’s enrollment under the reasonable cost reimbursement contract.

(III) Not later than a date determined appropriate by the Secretary prior to the beginning of the last reasonable cost reimbursement contract year for the contract, the organization shall provide notice to the Secretary as to whether the organization will apply to have the contract converted over, in whole or in part, and offered as a Medicare Advantage plan under part C for the year following the last reasonable cost reimbursement contract year for the contract.

(IV) If the organization provides the notice described in subclause (III) that the contract will be converted, in whole or in part, the organization shall, not later than a date determined appropriate by the Secretary, provide the Secretary with such information as the Secretary determines appropriate in order to carry out section 1395w-21(c)(4) of this title and to carry out section 1395w-24(a)(5) of this title, including subparagraph (C)(ii) of such section.

(V) In the case that the organization enrolls a new enrollee under such contract during the last reasonable cost reimbursement contract year for the contract, the organization shall provide the individual with a notification that such year is the last year for such contract.

(v) If an eligible organization that is offering a reasonable cost reimbursement contract that is extended or renewed pursuant to clause (iv) provides the notice described in clause (iv)(III) that the contract will be converted, in whole or in part, the following shall apply:

(I) The deemed enrollment under section 1395w-21(c)(4) of this title.

² So in original. Probably should be followed by a comma.

(II) The special rule for quality increase under section 1395w-23(o)(4)(C) of this title.

(III) During the last reasonable cost reimbursement contract year for the contract and the year immediately preceding such year, the eligible organization, or the corporate parent organization of the eligible organization, shall be permitted to offer an MA plan in the area that such contract is being offered and enroll Medicare Advantage eligible individuals in such MA plan and such cost plan.

(i) Duration, termination, effective date, and terms of contract; powers and duties of Secretary

(1) Each contract under this section shall be for a term of at least one year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).

(2) The effective date of any contract executed pursuant to this section shall be specified in the contract.

(3) Each contract under this section—

(A) shall provide that the Secretary, or any person or organization designated by him—

(i) shall have the right to inspect or otherwise evaluate (I) the quality, appropriateness, and timeliness of services performed under the contract and (II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(ii) shall have the right to audit and inspect any books and records of the eligible organization that pertain (I) to the ability of the organization to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(B) shall require the organization with a risk-sharing contract to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this subchapter, to each individual enrolled under this section with the organization; and

(C)(i) shall require the organization to comply with subsections (a) and (c) of section 300e-17 of this title (relating to disclosure of certain financial information) and with the requirement of section 300e(c)(8)¹ of this title (relating to liability arrangements to protect members);

(ii) shall require the organization to provide and supply information (described in section 1395cc(b)(2)(C)(ii) of this title) in the manner such information is required to be provided or supplied under that section;

(iii) shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties; and

(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(4) The Secretary may not enter into a risk-sharing contract with an eligible organization if a previous risk-sharing contract with that organization under this section was terminated at the request of the organization within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

(5) The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this subchapter.

(6)(A) If the Secretary determines that an eligible organization with a contract under this section—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(v) misrepresents or falsifies information that is furnished—

(I) to the Secretary under this section, or

(II) to an individual or to any other entity under this section;

(vi) fails to comply with the requirements of subsection (g)(6)(A) or paragraph (8); or

(vii) in the case of a risk-sharing contract, employs or contracts with any individual or entity that is excluded from participation under this subchapter under section 1320a-7 or 1320a-7a of this title for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than \$25,000 for each determination under subparagraph (A) or, with respect to a determination under clause (iv) or (v)(I) of such subparagraph, of not more than \$100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iv), \$15,000 for each individual not enrolled as a result of the practice involved,

(ii) suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(iii) suspension of payment to the organization under this section for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

(i) Civil money penalties of not more than \$25,000 for each determination under paragraph (1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(ii) Civil money penalties of not more than \$10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1320a-7a(a) of this title.

(7)(A) Each risk-sharing contract with an eligible organization under this section shall provide that the organization will maintain a written agreement with a quality improvement organization (which has a contract with the Sec-

retary under part B of subchapter XI for the area in which the eligible organization is located) or with an entity selected by the Secretary under section 1320c-3(a)(4)(C)¹ of this title under which the review organization will perform functions under section 1320c-3(a)(4)(B) of this title and section 1320c-3(a)(14) of this title (other than those performed under contracts described in section 1395cc(a)(1)(F) of this title) with respect to services, furnished by the eligible organization, for which payment may be made under this subchapter.

(B) For purposes of payment under this subchapter, the cost of such agreement to the eligible organization shall be considered a cost incurred by a provider of services in providing covered services under this subchapter and shall be paid directly by the Secretary to the review organization on behalf of such eligible organization in accordance with a schedule established by the Secretary.

(C) Such payments—

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for such organizations for a fiscal year than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' conducting activities described in subparagraph (A) with respect to such eligible organizations under part B of subchapter XI.

(8)(A) Each contract with an eligible organization under this section shall provide that the organization may not operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization—

(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

(B) In this paragraph, the term “physician incentive plan” means any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary’s determination under paragraph (1) and the organization fails to develop or implement such a plan;

(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization’s attention;

(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.

(j) Payment in full and limitation on actual charges; physicians, providers of services, or renal dialysis facilities not under contract with organization

(1)(A) In the case of physicians’ services or renal dialysis services described in paragraph (2) which are furnished by a participating physician or provider of services or renal dialysis facility to an individual enrolled with an eligible organization under this section and enrolled under part B, the applicable participation agreement is deemed to provide that the physician or provider of services or renal dialysis facility will accept as payment in full from the eligible organization the amount that would be payable to the physician or provider of services or renal dialysis facility under part B and from the individual under such part, if the individual were not enrolled with an eligible organization under this section.

(B) In the case of physicians’ services described in paragraph (2) which are furnished by a nonparticipating physician, the limitations on actual charges for such services otherwise applicable under part B (to services furnished by individuals not enrolled with an eligible organization under this section) shall apply in the same manner as such limitations apply to services furnished to individuals not enrolled with such an organization.

(2) The physicians’ services or renal dialysis services described in this paragraph are physicians’ services or renal dialysis services which are furnished to an enrollee of an eligible organization under this section by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.

(k) Risk-sharing contracts

(1) Except as provided in paragraph (2)—

(A) on or after the date standards for Medicare+Choice organizations and plans are first established under section 1395w-26(b)(1) of this title, the Secretary shall not enter into any risk-sharing contract under this section with an eligible organization; and

(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

(2) An individual who is enrolled in part B only and is enrolled in an eligible organization with a risk-sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1395w-26(b)(1) of this title.

(3) Notwithstanding subsection (a), the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed—

(A) with respect to individuals entitled to benefits under both parts A and B, by substituting payment rates under section 1395w-23(a) of this title for the payment rates otherwise established under subsection (a), and

(B) with respect to individuals only entitled to benefits under part B, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this subchapter attributable to such part) for the payment rates otherwise established under subsection (a).

(4) The following requirements shall apply to eligible organizations with risk-sharing contracts under this section in the same manner as they apply to Medicare+Choice organizations under part C:

(A) Data collection requirements under section 1395w-23(a)(3)(B) of this title.

(B) Restrictions on imposition of premium taxes under section 1395w-24(g) of this title in relating to payments to such organizations under this section.

(C) The requirement to accept enrollment of new enrollees during November 1998 under section 1395w-21(e)(6) of this title.

(D) Payments under section 1395w-27(e)(2) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1876, as added and amended Pub. L. 92-603, title II, §§ 226(a), 278(b)(3), Oct. 30, 1972, 86 Stat. 1396, 1453; Pub. L. 93-233, § 18(m), (n), Dec. 31, 1973, 87 Stat. 970, 971; Pub. L. 94-460, title II, § 201(a)-(d), Oct. 8, 1976, 90 Stat. 1956, 1957; Pub. L. 95-292, § 5, June 13, 1978, 92 Stat. 315; Pub. L. 97-248, title I, § 114(a), Sept. 3, 1982, 96 Stat. 341; Pub. L. 97-448, title III, § 309(b)(12), Jan. 12, 1983, 96 Stat. 2409; Pub. L. 98-21, title VI, §§ 602(g), 606(a)(3)(H), Apr. 20, 1983,

97 Stat. 164, 171; Pub. L. 98-369, div. B, title III, §§ 2350(a)(1), (b)(1), (2), (c), 2354(b)(37), (38), July 18, 1984, 98 Stat. 1097, 1098, 1102; Pub. L. 99-272, title IX, § 9211(a)-(d), Apr. 7, 1986, 100 Stat. 178, 179; Pub. L. 99-509, title IX, §§ 9312(b)(1), (c)(1), (2), (d)(1), (e)(1), (f), 9353(e)(2), Oct. 21, 1986, 100 Stat. 1999-2001, 2048; Pub. L. 99-514, title XVIII, § 1895(b)(11)(A), Oct. 22, 1986, 100 Stat. 2934; Pub. L. 100-203, title IV, §§ 4011(a)(1), (b)(1), 4012(b), 4013(a), 4014, 4018(a), 4039(h)(8), Dec. 22, 1987, 101 Stat. 1330-60, 1330-61, 1330-65, as amended Pub. L. 100-360, title IV, § 411(c)(3), (e)(3), July 1, 1988, 102 Stat. 773, 776; Pub. L. 100-360, title II, §§ 202(f), 211(c)(3), 224, title IV, § 411(c)(1), (4), (6), formerly (5), July 1, 1988, 102 Stat. 717, 738, 748, 772, 773, as amended Pub. L. 100-485, title VI, § 608(d)(19)(B), (C), Oct. 13, 1988, 102 Stat. 2419; Pub. L. 100-647, title VIII, § 8412(a)(1), Nov. 10, 1988, 102 Stat. 3801; Pub. L. 101-234, title II, §§ 201(a), 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-239, title VI, §§ 6206(a)(1), (b)(1), 6212(b)(1), (c)(2), 6411(d)(3)(A), Dec. 19, 1989, 103 Stat. 2244, 2250, 2271; Pub. L. 101-508, title IV, §§ 4204(a)(1), (2), (c)(1), (2), (d)(1), (e)(1), 4206(b)(1), Nov. 5, 1990, 104 Stat. 1388-108 to 1388-111, 1388-116; Pub. L. 103-296, title I, § 108(c)(6), Aug. 15, 1994, 108 Stat. 1486; Pub. L. 103-432, title I, § 157(b)(1), (4), Oct. 31, 1994, 108 Stat. 4442; Pub. L. 104-191, title II, §§ 215(a), (b), 231(g), Aug. 21, 1996, 110 Stat. 2005-2007, 2014; Pub. L. 105-33, title IV, § 4002(a)-(b)(2)(A), Aug. 5, 1997, 111 Stat. 328, 329; Pub. L. 106-113, div. B, 1000(a)(6) [title V, § 503], Nov. 29, 1999, 113 Stat. 1536, 1501A-380; Pub. L. 106-554, § 1(a)(6) [title VI, § 634], Dec. 21, 2000, 114 Stat. 2763, 2763A-568; Pub. L. 108-173, title II, § 234, title VII, § 736(d)(2), title IX, § 940(b)(2)(B), Dec. 8, 2003, 117 Stat. 2209, 2357, 2417; Pub. L. 110-173, title I, § 109, Dec. 29, 2007, 121 Stat. 2497; Pub. L. 110-275, title I, § 167(a)-(c), July 15, 2008, 122 Stat. 2575, 2576; Pub. L. 111-148, title III, § 3206, Mar. 23, 2010, 124 Stat. 459; Pub. L. 112-40, title II, § 261(a)(3)(A), Oct. 21, 2011, 125 Stat. 423; Pub. L. 112-240, title VI, § 608, Jan. 2, 2013, 126 Stat. 2349; Pub. L. 113-67, div. B, title I, § 1108, Dec. 26, 2013, 127 Stat. 1197; Pub. L. 113-93, title I, § 108, Apr. 1, 2014, 128 Stat. 1043; Pub. L. 114-10, title II, § 209(a), Apr. 16, 2015, 129 Stat. 146.)

Editorial Notes

REFERENCES IN TEXT

Section 300e-9(d) of this title, referred to in subsec. (b)(1), was redesignated section 300e-9(c) of this title by Pub. L. 100-517, § 7(b), Oct. 24, 1988, 102 Stat. 2580.

Section 300e(c)(8) of this title, referred to in subsec. (i)(3)(C)(i), was redesignated section 300e(c)(7) of this title by Pub. L. 100-517, § 5(b), Oct. 24, 1988, 102 Stat. 2579.

Section 1320c-3(a)(4)(C) of this title, referred to in subsec. (i)(7)(A), was repealed by Pub. L. 112-40, title II, § 261(c)(2)(A)(ii), Oct. 21, 2011, 125 Stat. 425.

AMENDMENTS

2015—Subsec. (h)(5)(C)(ii). Pub. L. 114-10, § 209(a)(1), substituted “Subject to clause (iv), for any” for “For any” in introductory provisions.

Subsec. (h)(5)(C)(iii)(I). Pub. L. 114-10, § 209(a)(2), inserted “cost plan service” after “With respect to any portion of the”.

Subsec. (h)(5)(C)(iii)(II). Pub. L. 114-10, § 209(a)(3), inserted “cost plan service” after “With respect to any other portion of such” in introductory provisions.

Subsec. (h)(5)(C)(iv), (v). Pub. L. 114-10, § 209(a)(4), added cls. (iv) and (v).

2014—Subsec. (h)(5)(C)(ii). Pub. L. 113-93 substituted “January 1, 2016” for “January 1, 2015” in introductory provisions.

2013—Subsec. (h)(5)(C)(ii). Pub. L. 113-67 substituted “January 1, 2015” for “January 1, 2014” in introductory provisions.

Pub. L. 112-240 substituted “January 1, 2014” for “January 1, 2013” in introductory provisions.

2011—Subsec. (i)(7)(A). Pub. L. 112-40 substituted “quality improvement” for “utilization and quality control peer review”.

2010—Subsec. (h)(5)(C)(ii). Pub. L. 111-148 substituted “January 1, 2013” for “January 1, 2010” in introductory provisions.

2008—Subsec. (h)(5)(C)(ii). Pub. L. 110-275, § 167(a), substituted “January 1, 2010” for “January 1, 2009” in introductory provisions.

Subsec. (h)(5)(C)(ii)(I), (II). Pub. L. 110-275, § 167(b), inserted “, provided that all such plans are not offered by the same Medicare Advantage organization” after “clause (iii)”.

Subsec. (h)(5)(C)(iii)(I). Pub. L. 110-275, § 167(c), inserted “that are not in another Metropolitan Statistical Area with a population of more than 250,000” after “such Metropolitan Statistical Area” and inserted “If the service area includes a portion in more than 1 Metropolitan Statistical Area with a population of more than 250,000, the minimum enrollment determination under the preceding sentence shall be made with respect to each such Metropolitan Statistical Area (and such applicable contiguous counties to such Metropolitan Statistical Area).” at end.

2007—Subsec. (h)(5)(C)(ii). Pub. L. 110-173 substituted “January 1, 2009” for “January 1, 2008” in introductory provisions.

2003—Subsec. (c)(2)(B). Pub. L. 108-173, § 736(d)(2)(A), substituted “significant” for “signficant” in introductory provisions.

Subsec. (c)(5)(B). Pub. L. 108-173, § 940(b)(2)(B), which directed amendment of subsec. (b)(5)(B) by inserting at end “The provisions of section 1395ff(b)(1)(E)(iii) of this title shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar amounts specified in section 1395ff(b)(1)(E)(i) of this title.”, was executed by making the insertion at end of subsec. (c)(5)(B), to reflect the probable intent of Congress. Subsec. (b) does not contain a par. (5)(B).

Subsec. (h)(5)(C). Pub. L. 108-173, § 234, amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: “The Secretary may not extend or renew a reasonable cost reimbursement contract under this subsection for any period beyond December 31, 2004.”

Subsec. (j)(2). Pub. L. 108-173, § 736(d)(2)(B), substituted “this section” for “this setion”.

2000—Subsec. (h)(5)(B), (C). Pub. L. 106-554 added subpar. (B) and redesignated former subpar. (B) as (C).

1999—Subsec. (h)(5)(B). Pub. L. 106-113 substituted “2004” for “2002”.

1997—Subsec. (f)(1). Pub. L. 105-33, § 4002(a)(1), substituted “For contract periods beginning before January 1, 1999, each” for “Each” and struck out “or under a State plan approved under subchapter XIX of this chapter” before period at end.

Subsec. (f)(2). Pub. L. 105-33, § 4002(a)(2), substituted “Subject to paragraph (4), the Secretary” for “The Secretary”.

Subsec. (f)(4). Pub. L. 105-33, § 4002(a)(3), added par. (4).

Subsec. (h)(5). Pub. L. 105-33, § 4002(b)(2)(A), added par. (5).

Subsec. (k). Pub. L. 105-33, § 4002(b)(1), added subsec. (k).

1996—Subsec. (i)(1). Pub. L. 104-191, § 215(a)(1), substituted “in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organiza-

tion if the Secretary determines that the organization—” for “the Secretary may terminate any such contract at any time (after such reasonable notice and opportunity for hearing to the eligible organization involved as he may provide in regulations), if he finds that the organization—” in introductory provisions, added subpars. (A) to (C), and struck out former subpars. (A) to (C) which read as follows:

“(A) has failed substantially to carry out the contract,

“(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this section, or

“(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f) of this section.”

Subsec. (i)(6)(B). Pub. L. 104-191, § 215(a)(4), struck out concluding provisions which read as follows: “The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as they apply to a civil money penalty or proceeding under section 1320a-7a(a) of this title.”

Subsec. (i)(6)(C). Pub. L. 104-191, § 215(a)(2), added subpar. (C).

Subsec. (i)(6)(D). Pub. L. 104-191, § 231(g), added subpar. (D).

Subsec. (i)(7)(A). Pub. L. 104-191, § 215(b), substituted “a written agreement” for “an agreement”.

Subsec. (i)(9). Pub. L. 104-191, § 215(a)(3), added par. (9).

1994—Subsec. (a)(1)(E)(ii)(I). Pub. L. 103-432, § 157(b)(4), struck out comma after “contributed to”.

Subsec. (a)(3). Pub. L. 103-432, § 157(b)(1), substituted “subsections (c)(2)(B)(ii) and (c)(7)” for “subsection (c)(7)”.

Subsec. (c)(5)(B). Pub. L. 103-296 inserted at end “In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.”

1990—Subsec. (a)(1)(E). Pub. L. 101-508, § 4204(e)(1), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (a)(6). Pub. L. 101-508, § 4204(c)(2), substituted “subsections (c)(2)(B)(ii) and (c)(7)” for “subsection (c)(7)”.

Subsec. (c)(2). Pub. L. 101-508, § 4204(c)(1), designated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) and former cls. (i) and (ii) as cls. (i) and (ii) and subcls. (I) and (II), respectively, and added subpar. (B).

Subsec. (c)(8). Pub. L. 101-508, § 4206(b)(1), added par. (8).

Subsec. (i)(6)(A)(vi). Pub. L. 101-508, § 4204(a)(2), inserted “or paragraph (8)” after “(g)(6)(A)”.

Subsec. (i)(8). Pub. L. 101-508, § 4204(a)(1), added par. (8).

Subsec. (j)(1)(A). Pub. L. 101-508, § 4204(d)(1)(A), substituted “physicians’ services or renal dialysis services” for “physicians’ services”, “physician or provider of services or renal dialysis facility” for “physician” in three places, and “applicable participation agreement” for “participation agreement under section 1395u(h)(1) of this title”.

Subsec. (j)(2). Pub. L. 101-508, § 4204(d)(1)(B), substituted “physicians’ services or renal dialysis services” for “physicians’ services” in two places and “which are furnished to an enrollee of an eligible organization under this section [sic] by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.” for “which—” and subpars. (A) and (B) which read as follows:

“(A) are emergency services or out-of-area coverage (described in clauses (iii) and (iv) of subsection (b)(2)(A) of this section), and

“(B) are furnished to an enrollee of an eligible organization under this section by a person who is not under a contract with the organization.”

1989—Subsec. (a)(1)(F). Pub. L. 101-239, § 6206(a)(1), added subpar. (F).

Subsec. (a)(5). Pub. L. 101-234, § 202(a), repealed Pub. L. 100-360, § 211(c)(3)(A), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (c)(3)(A)(i). Pub. L. 101-239, § 6206(b)(1)(A), substituted “period or periods” for “30-day period”.

Subsec. (c)(3)(A)(ii). Pub. L. 101-239, § 6206(b)(1)(B), added cl. (ii) and struck out former cl. (ii) which read as follows: “For each area served by more than one eligible organization under this section, the Secretary (after consultation with such organizations) shall establish a single 30-day period each year during which all eligible organizations serving the area must provide for open enrollment under this section. The Secretary shall determine annual per capita rates under subsection (a)(1)(A) of this section in a manner that assures that individuals enrolling during such a 30-day period will not have premium charges increased or any additional benefits decreased for 12 months beginning on the date the individual’s enrollment becomes effective. An eligible organization may provide for such other open enrollment period or periods as it deems appropriate consistent with this section.”

Subsecs. (e)(1), (g)(3)(A). Pub. L. 101-234, § 201(a), repealed Pub. L. 100-360, § 202(f), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment notes below.

Subsec. (g)(5). Pub. L. 101-239, § 6212(c)(2), struck out “and during a period of not longer than four years” after first reference to “Secretary”.

Subsec. (i)(6)(A)(vii). Pub. L. 101-239, § 6411(d)(3)(A), added cl. (vii).

Subsec. (j). Pub. L. 101-239, § 6212(b)(1), added subsec. (j).

1988—Subsec. (a)(5). Pub. L. 100-360, § 211(c)(3)(B), amended second sentence generally. Prior to amendment, second sentence read as follows: “The portion of that payment to the organization for a month to be paid by the latter trust fund shall be equal to 200 percent of the sum of—

“(A) the product of (i) the number of such individuals for the month who have attained age 65, and (ii) the monthly actuarial rate for supplementary medical insurance for the month as determined under section 1395r(a)(1) of this title, and

“(B) the product of (i) the number of such individuals for the month who have not attained age 65, and (ii) the monthly actuarial rate for supplementary medical insurance for the month as determined under section 1395r(a)(4) of this title.”

Pub. L. 100-360, § 211(c)(3)(A), substituted “, the Federal Supplementary Medical Insurance Trust Fund, and the Federal Catastrophic Drug Insurance Trust Fund” for “and the Federal Supplementary Medical Insurance Trust Fund” in first sentence.

Subsec. (c)(3)(F). Pub. L. 100-360, § 411(c)(1), realigned margin with left margin of subpar. (G).

Subsec. (e)(1). Pub. L. 100-360, § 202(f)(1), inserted at end “The preceding sentence shall be applied separately with respect to covered outpatient drugs.”

Subsec. (f)(3). Pub. L. 100-647 redesignated par. (4) as (3) and struck out former par. (3) which read as follows:

“(A) An eligible organization described in subparagraph (B) may elect, for purposes of enrollment and residency requirements under this section and for determining the compliance of a subdivision, subsidiary, or affiliate described in subparagraph (B)(iii) with the requirement of paragraph (1) for the period before October 1, 1992, to have members described in subparagraph (B)(iii) who receive services through the subdivision, subsidiary, or affiliate considered to be members of the parent organization.

“(B) An eligible organization described in this subparagraph is an eligible organization which—

“(i) is described in section 1396b(m)(2)(B)(iii) of this title;

“(ii) has members who have a collectively bargained contractual right to obtain health benefits from the organization;

“(iii) elects to provide benefits under a risk-sharing contract to individuals residing in a service area, who have a collectively bargained contractual right to obtain benefits from the organization, through a subdivision, subsidiary, or affiliate which itself is an eligible organization serving the area and which is owned or controlled by the parent eligible organization; and

“(iv) has assumed any risk of insolvency and quality assurance with respect to individuals receiving benefits through such a subdivision, subsidiary, or affiliate.”

Subsec. (f)(3)(A). Pub. L. 100-360, § 411(c)(6), formerly § 411(c)(5), as redesignated by Pub. L. 100-485, § 608(d)(19)(C), inserted “enrollment and residency requirements under this section and for” after “for purposes of” and substituted “described in subparagraph (B)(iii) who receives services through the subdivision” for “of the subdivision”.

Subsec. (f)(4). Pub. L. 100-647 redesignated par. (4) as (3).

Subsec. (g)(3)(A). Pub. L. 100-360, § 202(f)(2), substituted “rates” for “rate”.

Subsec. (g)(5). Pub. L. 100-360, § 411(c)(3), amended Pub. L. 100-203, § 4013, see 1987 Amendment note below.

Subsec. (i)(6)(A). Pub. L. 100-360, § 411(c)(4)(A), inserted “, in addition to any other remedies authorized by law,” after “the Secretary may provide” in concluding provisions.

Subsec. (i)(6)(B). Pub. L. 100-360, § 411(c)(4)(C), formerly § 411(c)(4)(B), as redesignated by Pub. L. 100-485, § 608(d)(19)(B)(ii), substituted “or proceeding under section 1320a-7a(a) of this title” for “under that section” in last sentence.

Subsec. (i)(6)(B)(i). Pub. L. 100-360, § 411(c)(4)(B), as added by Pub. L. 100-485, § 608(d)(19)(B)(i), (iii), inserted “of such subparagraph” after “(v)(I)”.

Pub. L. 100-360, § 224, inserted at end “plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iv), \$15,000 for each individual not enrolled as a result of the practice involved.”

Subsec. (i)(7)(A). Pub. L. 100-360, § 411(e)(3), added Pub. L. 100-203, § 4039(h)(8)(A), (B), see 1987 Amendment note below.

Subsec. (i)(7)(B). Pub. L. 100-360, § 411(e)(3), added Pub. L. 100-203, § 4039(h)(8)(C), see 1987 Amendment note below.

1987—Subsec. (c)(3)(F). Pub. L. 100-203, § 4011(a)(1), added subpar. (F).

Subsec. (c)(3)(G). Pub. L. 100-203, § 4011(b)(1), added subpar. (G).

Subsec. (f)(3), (4). Pub. L. 100-203, § 4018(a), added par. (3) and redesignated former par. (3) as (4).

Subsec. (g)(4). Pub. L. 100-203, § 4012(b), struck out par. (4) which read as follows: “A risk-sharing contract under this subsection may, at the option of an eligible organization, provide that the Secretary—

“(A) will reimburse hospitals and skilled nursing facilities either for payment amounts determined in accordance with section 1395ww of this title, or, if applicable, for the reasonable cost (as determined under section 1395x(v) of this title) or other appropriate basis for payment established under this subchapter, of inpatient services furnished to individuals enrolled with such organization pursuant to subsection (d) of this section, and

“(B) will deduct the amount of such reimbursement for payment which would otherwise be made to such organization.”

Subsec. (g)(5). Pub. L. 100-203, § 4013, which directed amendment of par. (5) by substituting “six years” for “four years”, was amended generally by Pub. L. 100-360, § 411(c)(3), so that it does not amend this section.

Subsec. (i)(6). Pub. L. 100-203, § 4014, amended par. (6) generally. Prior to amendment, par. (6) read as follows:

“(6)(A) Any eligible organization with a risk-sharing contract under this section that fails substantially to provide medically necessary items and services that are required (under law or such contract) to be provided to individuals covered under such contract, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals, is subject to a civil money penalty of not more than \$10,000 for each such failure.

“(B) The provisions of section 1320a-7a of this title (other than subsection (a)) shall apply to a civil money penalty under subparagraph (A) in the same manner as they apply to a civil money penalty under that section.”

Subsec. (i)(7)(A). Pub. L. 100-203, § 4039(h)(8)(A), (B), as added by Pub. L. 100-360, § 411(e)(3), substituted “Each” for “Except as provided under section 1320c-3(a)(4)(C) of this title, each”, inserted “or with an entity selected by the Secretary under section 1320c-3(a)(4)(C) of this title” after “located”, and substituted “which the review organization” for “which the peer review organization”.

Subsec. (i)(7)(B). Pub. L. 100-203, § 4039(h)(8)(C), as added by Pub. L. 100-360, § 411(e)(3), substituted “the review organization” for “the peer review organization”.

1986—Subsec. (a)(1)(A). Pub. L. 99-514 substituted “announce (in a manner intended to provide notice to interested parties)” for “publish” in introductory provisions.

Pub. L. 99-272, § 9211(d), inserted “, and shall publish not later than September 7 before the calendar year concerned” after “The Secretary shall annually determine” in introductory provisions.

Subsec. (a)(3). Pub. L. 99-272, § 9211(a)(2), substituted “Subject to subsection (c)(7), payments” for “Payments”.

Subsec. (a)(6). Pub. L. 99-272, § 9211(a)(3), substituted “Subject to subsection (c)(7), if” for “If”.

Subsec. (c)(3)(B). Pub. L. 99-272, § 9211(b), substituted “the date on which” for “a full calendar month after”, and inserted provision at end that in the case of an individual’s termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this subchapter other than through the organization.

Subsec. (c)(3)(C). Pub. L. 99-272, § 9211(c), inserted provisions at end that no brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and the Secretary has not disapproved the distribution of the material, and that Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary’s discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

Subsec. (c)(7). Pub. L. 99-272, § 9211(a)(1), added par. (7).

Subsec. (c)(3)(E). Pub. L. 99-509, § 9312(b)(1), added subpar. (E).

Subsec. (f)(2). Pub. L. 99-509, § 9312(c)(1), struck out “if the Secretary determines that” after “imposed by paragraph (1) only”, added new subpars. (A) and (B), and struck out former subpars. (A) and (B) which read as follows:

“(A) special circumstances warrant such modification or waiver, and

“(B) the eligible organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this subchapter or under a State plan approved under subchapter XIX of this chapter.”

Subsec. (f)(3). Pub. L. 99-509, §9312(c)(2)(A), added par. (3).

Subsec. (g)(6). Pub. L. 99-509, §9312(d)(1), added par. (6).

Subsec. (i)(1)(C). Pub. L. 99-509, §9312(c)(3)(B), substituted “(e), and (f)” for “and (e)”.

Subsec. (i)(3)(C). Pub. L. 99-509, §9312(e)(1), designated existing provisions as cl. (i) and added cls. (ii) and (iii).

Subsec. (i)(6). Pub. L. 99-509, §9312(f), added par. (6).

Subsec. (i)(7). Pub. L. 99-509, §9353(e)(2), added par. (7). 1984—Subsec. (b)(2)(D). Pub. L. 98-369, §2354(b)(37), substituted “subparagraph (A)” for “paragraph (1)”.

Subsec. (c)(3)(A). Pub. L. 98-369, §2350(a)(1), designated existing provisions as cl. (i), inserted “and including the 30-day period specified under clause (ii)” after “30 days duration every year”, and added cl. (ii).

Subsec. (c)(4)(A)(i). Pub. L. 98-369, §2354(b)(38), substituted “with reasonable promptness” for “promptly as appropriate”.

Subsec. (g)(2). Pub. L. 98-369, §2350(b)(1), inserted “and except that an organization (with the approval of the Secretary) may provide that a part of the value of such additional benefits be withheld and reserved by the Secretary as provided in paragraph (5)” at end of first sentence.

Subsec. (g)(4)(A). Pub. L. 98-369, §2350(c), inserted “and skilled nursing facilities” after “hospitals”, inserted “or the appropriate basis for payment established under this subchapter” after “section 1395x(v) of this title”, and struck out “hospital” before “services furnished to individuals”.

Subsec. (g)(5). Pub. L. 98-369, §2350(b)(2), added par. (5).

1983—Subsec. (a)(5)(A)(ii). Pub. L. 98-21, §606(a)(3)(H)(i), substituted “1395r(a)(1)” for “1395r(c)(1)”.

Subsec. (a)(5)(B)(ii). Pub. L. 98-21, §606(a)(3)(H)(ii), substituted “1395r(a)(4)” for “1395r(c)(4)”.

Subsec. (g)(1). Pub. L. 97-448 substituted “subsection (b)” for “subsection (b)(1)”.

Subsec. (g)(4). Pub. L. 98-21, §602(g), added par. (4).

1982—Pub. L. 97-248 completely revised section, expanding its coverage to permit payments to both health maintenance organizations and competitive medical plans.

1978—Subsec. (b)(2)(B). Pub. L. 95-292 substituted “Administrator of the Health Care Financing Administration” for “Commissioner of Social Security”.

1976—Subsec. (b). Pub. L. 94-460, §201(a), struck out provisions defining a health maintenance organization as a public or private organization which provides physicians’ services and a sufficient number of primary care and specialty care physicians, assures its members access to qualified practitioners in specialties available in area served by such organization, demonstrates financial responsibility and means to provide comprehensive health care services, has at least half of its enrolled members under age 65, assures prompt and qualified health service, and has an open enrollment period at least every year, and revised the definition and requirements of an health maintenance organization to conform to those set forth in the Public Health Service Act, except that the services which such an organization must provide are those covered in parts A and B of this subchapter rather than the basic health services defined in the Public Health Service Act, and inserted provisions requiring Secretary to administer determinations of whether an organization is a health maintenance organization through and in the office of the Assistant Secretary for Health, to integrate the administration of such functions and duties with the administration of provisions requiring the continued regulation of health maintenance organizations under the Public Health Service Act, and to administer other provisions of this section through the Commissioner of Social Security.

Subsec. (h). Pub. L. 94-460, §201(b), substituted provisions that each health maintenance organization with which the Secretary enters into a contract under this section have an enrolled membership at least half of

which consists of individuals who have not attained age 65, with the Secretary empowered to waive that requirement for a period of not more than three years from the date a health maintenance organization first enters into an agreement with the Secretary pursuant to subsection (i) of this section for provisions that such requirement not apply with respect to any health maintenance organization for such period not to exceed three years from the date such organization enters into an agreement with the Secretary pursuant to subsection (i) of this section, as the Secretary might permit.

Subsec. (i)(6)(B). Pub. L. 94-460, §201(c), substituted “(other than costs with respect to out-of-area services and, in the case of an organization which has entered into a risk-sharing contract with the Secretary pursuant to paragraph (2)(A), the cost of providing any member with basic health services the aggregate value of which exceeds \$5,000 in any year)” for “(Other than those with respect to out-of-area services)”.

Subsec. (k). Pub. L. 94-460, §201(d), added subsec. (k). 1973—Subsec. (a)(3)(A)(ii). Pub. L. 93-233, §18(m), struck out “, with the apportionment of savings being proportional to the losses absorbed and not yet offset” at end.

Subsec. (g)(2). Pub. L. 93-233, §18(n), substituted “portion of its premium rate or other charges” for “portion” and “shall not exceed” for “may not exceed”, and struck out cl. (i) designation preceding “the actuarial value” and provisions reading “less (ii) the actuarial value of other charges made in lieu of such deductible and coinsurance”, respectively.

1972—Subsec. (i). Pub. L. 92-603, §278(b)(3), substituted “skilled nursing facility” for “extended care facility” and “skilled nursing facilities” for “extended care facilities”.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108-173, set out as a note under section 1395w-21 of this title.

EFFECTIVE DATE OF 2011 AMENDMENT

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

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104-191, title II, §215(c), Aug. 21, 1996, 110 Stat. 2007, provided that: “The amendments made by this section [amending this section] shall apply with respect to contract years beginning on or after January 1, 1997.”

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

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-432 effective as if included in the enactment of Pub. L. 101-508, see section 157(b)(8) of Pub. L. 103-432, set out as a note under section 1395y of this title.

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

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101-508, title IV, §4204(a)(4), Nov. 5, 1990, 104 Stat. 1388-109, provided that: “The amendments made by paragraphs (1) and (2) [amending this section] shall apply with respect to contract years beginning on or

after January 1, 1992, and the amendments made by paragraph (3) [amending section 1320a-7a of this title] shall take effect on the date of the enactment of this Act [Nov. 5, 1990].”

Pub. L. 101-508, title IV, § 4204(c)(3), Nov. 5, 1990, 104 Stat. 1388-111, as amended by Pub. L. 103-432, title I, § 157(b)(2), Oct. 31, 1994, 108 Stat. 4442, provided that: “The amendments made by this subsection [amending this section] shall apply with respect to national coverage determinations that are not incorporated in the determination of the per capita rate of payment for individuals enrolled for years beginning with 1991 with an eligible organization which has entered into a risk-sharing contract under section 1876 of the Social Security Act [42 U.S.C. 1395mm].”

Pub. L. 101-508, title IV, § 4204(d)(2), Nov. 5, 1990, 104 Stat. 1388-111, as amended by Pub. L. 103-432, title I, § 157(b)(3), Oct. 31, 1994, 108 Stat. 4442, provided that: “The amendments made by paragraph (1) [amending this section] shall apply with respect to items and services furnished on or after January 1, 1991.”

Pub. L. 101-508, title IV, § 4204(e)(2), Nov. 5, 1990, 104 Stat. 1388-111, as amended by Pub. L. 103-432, title I, § 157(b)(5), Oct. 31, 1994, 108 Stat. 4442, provided that: “The amendments made by paragraph (1) [amending this section] shall apply with respect to individuals enrolling with an eligible organization under a health benefit plan operated, sponsored, or contributed to, by the individual’s employer or former employer (or the employer or former employer of the individual’s spouse) on or after January 1, 1991.”

Amendment by section 4206(b)(1) of Pub. L. 101-508 applicable to contracts under this section and payments under section 1395f(a)(1)(A) of this title as of the first day of the first month beginning more than 1 year after Nov. 5, 1990, see section 4206(e)(2) of Pub. L. 101-508, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 1989 AMENDMENTS

Pub. L. 101-239, title VI, § 6206(b)(2), Dec. 19, 1989, 103 Stat. 2245, provided that: “The amendments made by paragraph (1) [amending this section] shall take effect 60 days after the date of the enactment of this Act [Dec. 19, 1989].”

Pub. L. 101-239, title VI, § 6212(b)(2), Dec. 19, 1989, 103 Stat. 2250, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after April 1, 1990.”

Pub. L. 101-239, title VI, § 6212(c)(3), Dec. 19, 1989, 103 Stat. 2250, provided that: “The amendments made by this subsection [amending this section and repealing provisions set out as notes below] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].”

Pub. L. 101-239, title VI, § 6411(d)(4)(B), Dec. 19, 1989, 103 Stat. 2271, provided that: “The amendments made by paragraph (3) [amending this section and section 1396a of this title] shall apply to employment and contracts as of 90 days after the date of the enactment of this Act [Dec. 19, 1989].”

Amendment by section 201(a) of 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.

Amendment by section 202(a) of Pub. L. 101-234 effective Jan. 1, 1990, and applicable to premiums for months beginning after Dec. 31, 1989, see section 202(b) of Pub. L. 101-234, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Pub. L. 100-647, title VIII, § 8412(b), Nov. 10, 1988, 102 Stat. 3801, provided that: “The amendments made by subsection (a) [amending this section] shall not apply to contracts in effect on the date of the enactment of this Act [Nov. 10, 1988] or extensions (not exceeding 90 days) thereof.”

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 608(g)(1) of Pub. L. 100-485, set out as a note under section 704 of this title.

Amendment by section 202(f) of Pub. L. 100-360 applicable to enrollments effected on or after Jan. 1, 1990, see section 202(m)(3) of Pub. L. 100-360, set out as a note under section 1395u of this title.

Amendment by section 211(c)(3) of Pub. L. 100-360 applicable, except as specified in such amendment, to monthly premiums for months beginning with January 1989, see section 211(d) of Pub. L. 100-360, set out as a note under section 1395r of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(c)(1), (3), (4), (6), (e)(3) 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 1, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100-203, title IV, § 4011(a)(2), Dec. 22, 1987, 101 Stat. 1330-60, provided that: “The amendment made by paragraph (1) [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].”

Pub. L. 100-203, title IV, § 4011(b)(2), Dec. 22, 1987, 101 Stat. 1330-60, provided that: “The amendment 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 [Dec. 22, 1987].”

Pub. L. 100-203, title IV, § 4012(d), Dec. 22, 1987, 101 Stat. 1330-61, provided that: “The amendments made by subsections (a) and (b) [amending this section and section 1395cc this title] shall apply to admissions occurring on or after April 1, 1988, or, if later, the earliest date the Secretary can provide the information required under subsection (c) [set out as a note below] in machine readable form.”

Pub. L. 100-203, title IV, § 4013(b), Dec. 22, 1987, 101 Stat. 1330-61, which provided the effective date for amendment made by section 4013(a) of Pub. L. 100-203, was omitted in the general amendment of section 4013 of Pub. L. 100-203 by Pub. L. 100-360, title IV, § 411(c)(3), July 1, 1988, 102 Stat. 773.

EFFECTIVE DATE OF 1986 AMENDMENTS

Pub. L. 99-514, title XVIII, § 1895(b)(1)(B), Oct. 22, 1986, 100 Stat. 2934, provided that: “The amendment made by subparagraph (A) [amending this section] shall apply to determinations of per capita payment rates for 1987 and subsequent years.”

Pub. L. 99-509, title IX, § 9312(b)(2), Oct. 21, 1986, 100 Stat. 1999, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on January 1, 1987, and shall apply to enrollments effected on or after such date.”

Pub. L. 99-509, title IX, § 9312(c)(3), Oct. 21, 1986, 100 Stat. 2000, as amended by Pub. L. 100-203, title IV, § 4018(d), Dec. 22, 1987, 101 Stat. 1330-66; Pub. L. 101-239, title VI, § 6212(a), Dec. 19, 1989, 103 Stat. 2249; Pub. L. 103-66, title XIII, § 13569, Aug. 10, 1993, 107 Stat. 608, provided that:

“(A) NEW RESTRICTION.—The amendment made by paragraph (1) [amending this section] shall apply to modifications and waivers granted after the date of the enactment of this Act [Oct. 21, 1986].

“(B) SANCTIONS FOR NONCOMPLIANCE.—The amendments made by paragraph (2) [amending this section] shall take effect on the date of the enactment of this Act.

“(C) TREATMENT OF CURRENT WAIVERS.—In the case of an eligible organization (or successor organization) that—

“(i) as of the date of the enactment of this Act, has been granted, under paragraph (2) of section 1876(f) of the Social Security Act [42 U.S.C. 1395mm(f)(2)], a modification or waiver of the requirement imposed by paragraph (1) of that section, but

“(ii) does not meet the requirement for such modification or waiver under the amendment made by paragraph (1) of this subsection,

the organization shall make, and continue to make, reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by the Secretary of Health and Human Services. If the Secretary determines that the organization has complied, or made significant progress towards compliance, with such schedule of compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has not complied with such schedule, the Secretary may provide for a sanction described in section 1876(f)(3) of the Social Security Act [42 U.S.C. 1395mm(f)(3)] (as amended by this section) effective with respect to individuals enrolling with the organization after the date the Secretary notifies the organization of such noncompliance.

“(D) TREATMENT OF CERTAIN WAIVERS.—In the case of an eligible organization (or successor organization) that is described in clauses (i) and (ii) of subparagraph (C) and that received a grant or grants totaling at least \$3,000,000 in fiscal year 1987 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act [42 U.S.C. 254b(d)(1)(A), 254c(d)(1)]—

“(i) before January 1, 1996, section 1876(f) of the Social Security Act [42 U.S.C. 1395mm(f)] shall not apply to the organization;

“(ii) beginning on January 1, 1990, the Secretary of Health and Human Services shall conduct an annual review of the organization to determine the organization's compliance with the quality assurance requirements of section 1876(c)(6) of such Act [42 U.S.C. 1395mm(c)(6)]; and

“(iii) after January 1, 1990, if the organization receives an unfavorable review under clause (ii), the Secretary, after notice to the organization of the unfavorable review and an opportunity to correct any deficiencies identified during the review, may provide for the sanction described in section 1876(f)(3) of such Act [42 U.S.C. 1395mm(f)(3)] effective with respect to individuals enrolling with the organization after the date the Secretary notifies the organization that the organization is not in compliance with the requirements of section 1876(c)(6) of such Act.”

Pub. L. 99-509, title IX, §9312(d)(2), Oct. 21, 1986, 100 Stat. 2001, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to risk-sharing contracts under section 1876 of the Social Security Act [42 U.S.C. 1395mm] with respect to services furnished on or after January 1, 1987.”

Pub. L. 99-509, title IX, §9312(e)(2), Oct. 21, 1986, 100 Stat. 2001, provided that: “The amendments made by paragraph (1) [amending this section] shall apply to contracts as of January 1, 1987.”

Pub. L. 99-509, title IX, §9353(e)(3)(B), Oct. 21, 1986, 100 Stat. 2049, as amended by Pub. L. 100-203, title IV, §4039(h)(9)(C), as added by Pub. L. 100-360, title IV, §411(e)(3), July 1, 1988, 102 Stat. 776, provided that: “The amendment made by paragraph (2) [amending this section] shall apply to risk-sharing contracts with eligible organizations, under section 1876 of the Social Security Act [42 U.S.C. 1395mm], as of April 1, 1987. The provisions of section 1876(i)(7) of the Social Security Act [42 U.S.C. 1395mm(i)(7)] (added by such amendment) shall apply to health maintenance organizations with contracts in effect under section 1876 of such Act (as in effect before the date of the enactment of Public Law 97-248 [Sept. 3, 1982]) in the same manner as it applies to eligible organizations with risk-sharing contracts in effect under section 1876 of such Act (as in effect on the date of the enactment of this Act [Dec. 22, 1987]).”

Pub. L. 99-272, title IX, §9211(e), Apr. 7, 1986, 100 Stat. 179, provided that:

“(1) FINANCIAL RESPONSIBILITY.—The amendments made by subsection (a) [amending this section] shall apply to enrollments and disenrollments that become effective on or after the date of the enactment of this Act [Apr. 7, 1986].

“(2) DISENROLLMENTS.—The amendments made by subsection (b) [amending this section] shall apply to requests for termination of enrollment submitted on or after May 1, 1986.

“(3) MATERIAL REVIEW.—(A) The amendment made by subsection (c) [amending this section] shall not apply to material which has been distributed before July 1, 1986.

“(B) Such amendment also shall not apply so as to require the submission of material which is distributed before July 1, 1986.

“(C) Such amendment shall also not apply to material which the Secretary determines has been prepared before the date of the enactment of this Act [Apr. 7, 1986] and for which a commitment for distribution has been made, if the application of such amendment would constitute a hardship for the organization involved.

“(4) PUBLICATION.—The amendment made by subsection (d) [amending this section] shall apply to determinations of per capita rates of payment for 1987 and subsequent years.

“(5) NECESSARY MODIFICATION OF CONTRACTS.—The Secretary of Health and Human Services shall provide for such changes in the risk-sharing contracts which have been entered into under section 1876 of the Social Security Act [42 U.S.C. 1395mm] as may be necessary to conform to the requirements imposed by the amendments made by this section [amending this section] on a timely basis.”

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98-369, div. B, title III, §2350(d), July 18, 1984, 98 Stat. 1098, provided that: “The amendments made by this section [amending this section and enacting provisions set out as notes under this section] shall become effective on the date of the enactment of this Act [July 18, 1984].”

Amendment by section 2354(b)(37), (38) of Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

EFFECTIVE DATE OF 1983 AMENDMENTS; TRANSITIONAL RULE

Amendment by section 602(g) of Pub. L. 98-21 applicable to items and services furnished by or under arrangement with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, see section 604(a)(1) of Pub. L. 98-21, set out as a note under section 1395ww of this title.

Amendment by section 606(a)(3)(H) of Pub. L. 98-21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the monthly premium for June 1983 shall apply to individuals enrolled under parts A and B of this subchapter, see section 606(c) of Pub. L. 98-21, set out as a note under section 1395r of this title.

Amendment by section 309(b)(12) of Pub. L. 97-448 effective as if originally included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248, see section 309(c)(2) of Pub. L. 97-448, set out as a note under section 426-1 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Pub. L. 97-248, title I, §114(c), Sept. 3, 1982, 96 Stat. 350, as amended by Pub. L. 98-369, div. B, title III, §2354(c)(3)(A), (B), July 18, 1984, 98 Stat. 1102; Pub. L. 98-617, §3(a)(5), Nov. 8, 1984, 98 Stat. 3295; Pub. L. 99-509, title IX, §9312(a), Oct. 21, 1986, 100 Stat. 1999, provided that:

“(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply with respect to services furnished on or after the initial effective date (as defined in paragraph (4)), except that such amendment shall not apply—

“(A) with respect to services furnished by an eligible organization to any individual who is enrolled

with that organization under an existing cost contract (as defined in paragraph (3)(A)) and entitled to benefits under part A [42 U.S.C. 1395c et seq.], or enrolled in part B [42 U.S.C. 1395j et seq.], of title XVIII of the Social Security Act at the time the organization first enters into a new risk-sharing contract (as defined in paragraph (3)(D)) unless—

“(i) the individual requests at any time that the amendment apply, or

“(ii) the Secretary determines at any time that the amendment should apply to all members of the organization because of administrative costs or other administrative burdens involved and so informs in advance each affected member of the eligible organization;

“(B) with respect to services furnished by an eligible organization during the five-year period beginning on the initial effective date, if—

“(i) the organization has an existing risk-sharing contract (as defined in paragraph (3)(B)) on the initial effective date, or

“(ii) on the date of the enactment of this Act [Sept. 3, 1982] the organization was furnishing services pursuant to an existing demonstration project (as defined in paragraph (3)(C)), such demonstration project is concluded before the initial effective date, and before such initial effective date the organization enters into an existing risk-sharing contract,

unless the organization requests that the amendment apply earlier; or

“(C) with respect to services furnished by an eligible organization during the period of an existing demonstration project if on the initial effective date the organization was furnishing services pursuant to the project and if the project concludes after such date.

“(2)(A) In the case of an eligible organization which has in effect an existing cost contract (as defined in paragraph (3)(A)) on the initial effective date, the organization may receive payment under a new risk-sharing contract with respect to a current, nonrisk medicare enrollee (as defined in subparagraph (C)) only to the extent that the organization enrolls, for each such enrollee, two new medicare enrollees (as defined in subparagraph (D)). The selection of those current nonrisk medicare enrollees with respect to whom payment may be so received under a new risk-sharing contract shall be made in a nonbiased manner.

“(B) Subparagraph (A) shall not be construed to prevent an eligible organization from providing for enrollment, on a basis described in subsection (a)(6) of section 1876 of the Social Security Act [42 U.S.C. 1395mm(a)(6)] (as amended by this Act [Pub. L. 97-248], other than under a reasonable cost reimbursement contract), of current, nonrisk medicare enrollees and from providing such enrollees with some or all of the additional benefits described in section 1876(g)(2) of the Social Security Act [42 U.S.C. 1395mm(g)(2)] (as amended by this Act [Pub. L. 97-248]), but (except as provided in subparagraph (A))—

“(i) payment to the organization with respect to such enrollees shall only be made in accordance with the terms of a reasonable cost reimbursement contract, and

“(ii) no payment may be made under section 1876 of such Act [42 U.S.C. 1395mm] with respect to such enrollees for any such additional benefits.

Individuals enrolled with the organization under this subparagraph shall be considered to be individuals enrolled with the organization for the purpose of meeting the requirement of section 1876(g)(2) of the Social Security Act [42 U.S.C. 1395mm(g)(2)] (as amended by this Act [Pub. L. 97-248]).

“(C) For purposes of this paragraph, the term ‘current, nonrisk medicare enrollee’ means, with respect to an organization, an individual who on the initial effective date—

“(i) is enrolled with that organization under an existing cost contract, and

“(ii) is entitled to benefits under part A [42 U.S.C. 1395c et seq.] and enrolled under part B [42 U.S.C.

1395j et seq.], or enrolled in part B, of title XVIII of the Social Security Act.

“(D) For purposes of this paragraph, the term ‘new medicare enrollee’ means, with respect to an organization, an individual who—

“(i) is enrolled with the organization after the date the organization first enters into a new risk-sharing contract,

“(ii) at the time of such enrollment is entitled to benefits under part A, or enrolled in part B, of title XVIII of the Social Security Act, and

“(iii) was not enrolled with the organization at the time the individual became entitled to benefits under part A, or to enroll in part B, of such title.

“(E) The preceding provisions of this paragraph shall not to [sic] apply to payments made for current, nonrisk medicare enrollees for months beginning with April 1987.

“(3) For purposes of this subsection:

“(A) The term ‘existing cost contract’ means a contract which is entered into under section 1876 of the Social Security Act [42 U.S.C. 1395mm], as in effect before the initial effective date, or reimbursement on a reasonable cost basis under section 1833(a)(1)(A) of such Act [42 U.S.C. 1395(a)(1)(A)], and which is not an existing risk-sharing contract or an existing demonstration project.

“(B) The term ‘existing risk-sharing contract’ means a contract entered into under section 1876(i)(2)(A) of the Social Security Act [42 U.S.C. 1395mm(i)(2)(A)], as in effect before the initial effective date.

“(C) The term ‘existing demonstration project’ means a demonstration project under section 402(a) of the Social Security Amendments of 1967 [42 U.S.C. 1395b-1(a)] or under section 222(a) of the Social Security Amendments of 1972 [section 222(a) of Pub. L. 92-603, set out as a note under section 1395b-1 of this title], relating to the provision of services for which payment may be made under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

“(D) The term ‘new risk-sharing contract’ means a contract entered into under section 1876(g) of the Social Security Act [42 U.S.C. 1395mm(g)], as amended by this Act [Pub. L. 97-248].

“(E) The term ‘reasonable cost reimbursement contract’ means a contract entered into under section 1876(h) of such Act [42 U.S.C. 1395mm(h)], as amended by this Act, or reimbursement on a reasonable cost basis under section 1833(a)(1)(A) of such Act [42 U.S.C. 1395(a)(1)(A)].

“(4) As used in this section, the term ‘initial effective date’ means—

“(A) the first day of the thirteenth month which begins after the date of the enactment of this Act [Sept. 3, 1982], or

“(B) the first day of the first month [Feb. 1, 1985] after the month in which the Secretary of Health and Human Services notifies the Committee on Finance of the Senate and the Committees on Ways and Means and on Energy and Commerce of the House of Representatives that he is reasonably certain that the methodology to make appropriate adjustments (referred to in section 1876(a)(4) of the Social Security Act [42 U.S.C. 1395mm(a)(4)], as amended by this Act [Pub. L. 97-248]) has been developed and can be implemented to assure actuarial equivalence in the estimation of adjusted average per capita costs under that section, whichever is later.”

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility's or provider's first accounting period beginning after the last day of the twelfth

month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95-292, set out as a note under section 426 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94-460, title II, § 201(e), Oct. 8, 1976, 90 Stat. 1957, provided that: "The amendments made by this section [amending this section] shall be effective with respect to contracts entered into between the Secretary and health maintenance organizations under section 1876 of the Social Security Act [42 U.S.C. 1395mm] on and after the first day of the first calendar month which begins more than 30 days after the date of enactment of this Act [Oct. 8, 1976]."

EFFECTIVE DATE OF 1973 AMENDMENT

Pub. L. 93-233, § 18(z-3)(3), Dec. 31, 1973, 87 Stat. 974, provided that: "The amendments made by subsections (m) and (n) [amending this section] shall be effective with respect to services provided after June 30, 1973."

EFFECTIVE DATE

Pub. L. 92-603, title II, § 226(f), Oct. 30, 1972, 86 Stat. 1404, provided that: "The amendments made by this section [enacting this section, amending sections 1395f, 1395l, 1395ll, and 1396b of this title, and enacting provisions set out as notes under this section] shall be effective with respect to services provided on or after July 1, 1973."

REPORT ON IMPACT

Pub. L. 105-33, title IV, § 4002(b)(2)(B), Aug. 5, 1997, 111 Stat. 329, provided that: "By not later than January 1, 2001, the Secretary of Health and Human Services shall submit to Congress a report that analyzes the potential impact of termination of reasonable cost reimbursement contracts, pursuant to the amendment made by subparagraph (A), on medicare beneficiaries enrolled under such contracts and on the medicare program. The report shall include such recommendations regarding any extension or transition with respect to such contracts as the Secretary deems appropriate."

TRANSITION RULE FOR PSO ENROLLMENT

Pub. L. 105-33, title IV, § 4002(h), Aug. 5, 1997, 111 Stat. 330, provided that: "In applying subsection (g)(1) of section 1876 of the Social Security Act (42 U.S.C. 1395mm) to a risk-sharing contract entered into with an eligible organization that is a provider-sponsored organization (as defined in section 1855(d)(1) of such Act [42 U.S.C. 1395w-25(d)(1)], as inserted by section 5001 [4001]) for a contract year beginning on or after January 1, 1998, there shall be substituted for the minimum number of enrollees provided under such section the minimum number of enrollees permitted under section 1857(b)(1) of such Act [42 U.S.C. 1395w-27(b)(1)] (as so inserted)."

REQUIREMENTS WITH RESPECT TO ACTUARIAL EQUIVALENCE OF AAPCC

Pub. L. 101-508, title IV, § 4204(b), Nov. 5, 1990, 104 Stat. 1388-109, as amended by Pub. L. 103-432, title I, § 157(a), Oct. 31, 1994, 108 Stat. 4441; Pub. L. 104-316, title I, § 122(g), Oct. 19, 1996, 110 Stat. 3837, provided that:

"(1)(A) Not later than October 1, 1995, the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall submit a proposal to the Congress that provides for revisions to the payment method to be applied in years beginning with 1997 for organizations with a risk-sharing contract under section 1876(g) of the Social Security Act [42 U.S.C. 1395mm(g)].

"(B) In proposing the revisions required under subparagraph (A), the Secretary shall consider—

"(i) the difference in costs associated with medicare beneficiaries with differing health status and demographic characteristics; and

"(ii) the effects of using alternative geographic classifications on the determinations of costs associated with beneficiaries residing in different areas.

"(2) Not later than 3 months after the date of submittal of the proposal under paragraph (1), the Comptroller General shall review the proposal and shall report to Congress on the appropriateness of the proposed modifications."

[Amendment by section 122(g) of Pub. L. 104-316 to section 4204(b)(4), (5) of Pub. L. 101-508, set out above, could not be executed, because section 4204(b) of Pub. L. 101-508 did not contain pars. (4) and (5) subsequent to amendment by Pub. L. 103-432.]

STUDY OF CHIROPRACTIC SERVICES

Pub. L. 101-508, title IV, § 4204(f), Nov. 5, 1990, 104 Stat. 1388-112, as amended by Pub. L. 103-432, title I, § 157(b)(6), Oct. 31, 1994, 108 Stat. 4442, directed Secretary to conduct a study of the extent to which health maintenance organizations with contracts under section 1876 of the Social Security Act (this section) make available to enrollees entitled to benefits under title XVIII of such Act (this subchapter) chiropractic services that are covered under such title, such study to examine the arrangements under which such services are made available and the types of practitioners furnishing such services to such enrollees and to be based on contracts entered into or renewed on or after Jan. 1, 1991, and before Jan. 1, 1993, with Secretary to issue a report to Congress on results of the study not later than Jan. 1, 1993, including recommendations with respect to any legislative and regulatory changes determined necessary by Secretary to ensure access to such services.

EFFECT ON STATE LAW

Conscientious objections of health care provider under State law unaffected by enactment of subsec. (c)(8) of this section, see section 4206(c) of Pub. L. 101-508, set out as a note under section 1395cc of this title.

NOTICE OF METHODOLOGY USED IN MAKING ANNOUNCEMENTS UNDER SUBSECTION (a)(1)(A)

Pub. L. 101-239, title VI, § 6206(a)(2), Dec. 19, 1989, 103 Stat. 2244, provided that: "Before July 1, 1990, the Secretary of Health and Human Services shall provide for notice to eligible organizations of the methodology used in making the announcement under section 1876(a)(1)(A) of the Social Security Act [42 U.S.C. 1395mm(a)(1)(A)] for 1990."

ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

Pub. L. 101-234, title II, § 203(b), Dec. 13, 1989, 103 Stat. 1984, provided that: "Notwithstanding any other provision of this Act [see Tables for classification], the amendments made by this Act (other than the repeal of sections 1833(c)(5) and 1834(c)(6) of the Social Security Act [42 U.S.C. 1395l(c)(5), 1395m(c)(6)]) shall not apply to risk-sharing contracts, for contract year 1990—

"(1) with eligible organizations under section 1876 of the Social Security Act [42 U.S.C. 1395mm], or

"(2) with health maintenance organizations under section 1876(i)(2)(A) of such Act [42 U.S.C. 1395mm(i)(2)(A)] (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967 [42 U.S.C. 1395b-1(a)], or under section 222(a) of the Social Security Amendments of 1972 [Pub. L. 92-603, set out as a note under section 1395b-1 of this title]."

ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

Pub. L. 100-360, title II, § 222, July 1, 1988, 102 Stat. 746, as amended by Pub. L. 100-485, title VI, § 608(d)(13), Oct. 13, 1988, 102 Stat. 2415, provided that: "The Secretary of Health and Human Services shall—

"(1) modify contracts under section 1876 of the Social Security Act [42 U.S.C. 1395mm], for portions of

contract years occurring after December 31, 1988, to take into account the amendments made by this Act [see Short Title of 1988 Amendment note under section 1305 of this title]; and

“(2) require such organizations and organizations paid under section 1833(a)(1)(A) of such Act [42 U.S.C. 1395l(a)(1)(A)] to make appropriate adjustments (including adjustments in premiums and benefits) in the terms of their agreements with medicare beneficiaries to take into account such amendments. The Secretary shall also provide for appropriate modifications of contracts with health maintenance organizations under section 1876(i)(2)(A) of the Social Security Act [42 U.S.C. 1395mm(i)(2)(A)] (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967 [42 U.S.C. 1395b-1(a)], or under section 222(a) of the Social Security Amendments of 1972 [42 U.S.C. 1395b-1 note], for portions of contract years occurring after December 31, 1988, so as to apply to such organizations and contracts the requirements imposed by the amendments made by this Act upon an organization with a risk-sharing contract under section 1876 of the Social Security Act.”

PROVISION OF MEDICARE DRG RATES FOR CERTAIN PAYMENTS AND DATA ON INPATIENT COST PASS-THROUGH ITEMS

Pub. L. 100-203, title IV, §4012(c), Dec. 22, 1987, 101 Stat. 1330-61, as amended by Pub. L. 100-360, title IV, §411(c)(2)(B), July 1, 1988, 102 Stat. 773, provided that: “The Secretary of Health and Human Services shall provide (in machine readable form) to eligible organizations under section 1876 of the Social Security Act [42 U.S.C. 1395mm] medicare DRG rates for payments required by the amendment made by subsection (a) [amending section 1395cc of this title] and data on cost pass-through items for all inpatient services provided to medicare beneficiaries enrolled with such organizations.”

MEDICARE PAYMENT DEMONSTRATION PROJECTS

Pub. L. 100-203, title IV, §4015, Dec. 22, 1987, 101 Stat. 1330-62, as amended by Pub. L. 100-360, title IV, §411(c)(5), as added by Pub. L. 100-485, title VI, §608(d)(19)(C), Oct. 13, 1988, 102 Stat. 2419, provided that:

“(a) MEDICARE INSURED GROUP DEMONSTRATION PROJECTS.—

“(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) may provide for capitation demonstration projects (in this subsection referred to as ‘projects’) with an entity which is an eligible organization with a contract with the Secretary under section 1876 of the Social Security Act [42 U.S.C. 1395mm] or which meets the restrictions and requirements of this subsection. The Secretary may not approve a project unless it meets the requirements of this subsection.

“(2) The Secretary may not conduct more than 3 projects and may not expend, from funds under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], more than \$600,000,000 in any fiscal year for all such projects.

“(3) The per capita rate of payment under a project—

“(A) may be based on the adjusted average per capita cost (as defined in section 1876(a)(4) of the Social Security Act [42 U.S.C. 1395mm(a)(4)]) determined only with respect to the group of individuals involved (rather than with respect to medicare beneficiaries generally), but

“(B) the rate of payment may not exceed the lesser of—

“(i) 95 percent of the adjusted average per capita cost described in subparagraph (A), or

“(ii) (I) in the 4th year or 5th year of a project, 115 percent of the adjusted average per capita cost (as defined in section 1876(a)(4) of such Act [42 U.S.C. 1395mm(a)(4)]) for classes of individuals described in section 1876(a)(1)(B) of that Act [42 U.S.C. 1395mm(a)(1)(B)], or

“(II) in any subsequent year of a project, 95 percent of the adjusted average per capita cost (as defined in section 1876(a)(4) [42 U.S.C. 1395mm(a)(4)]) for such classes.

“(4) If the payment amounts made to a project are greater than the costs of the project (as determined by the Secretary or, if applicable, on the basis of adjusted community rates described in section 1876(e)(3) of the Social Security Act [42 U.S.C. 1395mm(e)(3)]), the project—

“(A) may retain the surplus, but not to exceed 5 percent of the average adjusted per capita cost determined in accordance with paragraph (3)(A), and

“(B) with respect to any additional surplus not retained by the project, shall apply such surplus to additional benefits for individuals served by the project or return such surplus to the Secretary.

“(5) Enrollment under the project shall be voluntary. Individuals enrolled with the project may terminate such enrollment as of the beginning of the first calendar month following the date on which the request is made for such termination. Upon such termination, such individuals shall retain the same rights to other health benefits that such individuals would have had if they had never enrolled with the project without any exclusion or waiting period for pre-existing conditions.

“(6) The requirements of—

“(A) subsection (c)(3)(C) (relating to dissemination of information),

“(B) subsection (c)(3)(E) (annual statement of rights),

“(C) subsection (c)(5) (grievance procedures),

“(D) subsection (c)(6) (on-going quality),

“(E) subsection (g)(6) (relating to prompt payment of claims),

“(F) subsection (i)(3)(A) and (B) (relating to access to information and termination notices),

“(G) subsection (i)(6) (relating to providing necessary services), and

“(H) subsection (i)(7) (relating to agreements with peer review [now “quality improvement”] organizations),

of section 1876 of the Social Security Act [42 U.S.C. 1395mm] shall apply to a project in the same manner as they apply to eligible organizations with risk-sharing contracts under such section.

“(7) The benefits provided under a project must be at least actuarially equivalent to the combination of the benefits available under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] and the benefits available through any alternative plans in which the individual can enroll through the employer. The project shall guarantee the actuarial value of benefits available under the employer plan for the duration of the project.

“(8) A project shall comply with all applicable State laws.

“(9) The Secretary may not authorize a project unless the entity offering the project demonstrates to the satisfaction of the Secretary that it has the necessary financial reserves to pay for any liability for benefits under the project (including those liabilities for health benefits under medicare and any supplemental benefits).

“(10) The Comptroller General shall monitor projects under this subsection and shall report periodically (not less often than once every year) to the Committee on Finance of the Senate and the Committee on Energy and Commerce and Committee on Ways and Means of the House of Representatives on the status of such projects and the effect on such projects of the requirements of this section and shall submit a final report to each such committee on the results of such projects.

“(b) PAYMENT METHODOLOGY REFORM DEMONSTRATION PROJECTS.—

“(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) is specifically authorized to conduct demonstration

projects under this subsection for the purpose of testing alternative payment methodologies pertaining to capitation payments under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], including—

“(A) computing adjustments to the average per capita cost under section 1876 of such Act [42 U.S.C. 1395mm] on the basis of health status or prior utilization of services, and

“(B) accounting for geographic variations in cost in the adjusted average per capita costs applicable to an eligible organization under such section which differs from payments currently provided on a county-by-county basis.

“(2) No project may be conducted under this subsection—

“(A) with an entity which is not an eligible organization (as defined in section 1876(b) of the Social Security Act [42 U.S.C. 1395mm(b)]), and

“(B) unless the project meets all the requirements of subsections (c) and (i)(3) of section 1876 of such Act [42 U.S.C. 1395mm(c), (i)(3)].

“(3) There are authorized to be appropriated to carry out projects under this subsection \$5,000,000 in each of fiscal years 1989 and 1990.

“(c) APPLICATION OF PROVISIONS.—The provisions of subsection (a)(2) and the first sentence of subsection (b) of section 402 of the Social Security Amendments of 1967 [42 U.S.C. 1395b-1(a)(2), (b)] shall apply to the demonstration projects under this section in the same manner as they apply to experiments under subsection (a)(1) of that section.”

[For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103-7 (in which the requirement to report not less than once every year to certain committees of Congress under section 4015(a)(10) of Pub. L. 100-203, set out above, is listed on page 9), see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.]

GAO STUDY AND REPORTS ON MEDICARE CAPITATION

Pub. L. 100-203, title IV, §4017, Dec. 22, 1987, 101 Stat. 1330-64, directed Comptroller General to conduct a study on medicare capitation rates that would include an analysis and assessment of the current method for computing per capita rates of payment under section 1876 of the Social Security Act (this section), including the method for determining the United States per capita cost; the method for establishing relative costs for geographic areas and the data used to establish age, sex, and other weighting factors; ways to refine the calculation of adjusted average per capita costs under section 1876 of such Act, including making adjustments for health status or prior utilization of services and improvements in the definition of geographic areas; the extent to which individuals enrolled with organizations with a risk-sharing contract with the Secretary under section 1876 of such Act differ in utilization and cost from fee-for-service beneficiaries and ways for modifying enrollment patterns through program changes or for reflecting the differences in rates through group experience rating or other means; approaches for limiting the liability of the contracting organization under section 1876 of such Act in catastrophic cases; ways of establishing capitation rates on a basis other than fee-for-service experience in areas with high prepaid market penetration; and methods for providing the rate levels necessary to maintain access to quality prepaid services in rural or medically underserved areas, while maintaining cost savings; and directed Comptroller General, not later than January 1 of 1989 and 1990, to submit to Congress interim reports on the progress of

the study and, not later than Jan. 1, 1991, a final report on the results of such study.

DEMONSTRATION PROJECTS TO PROVIDE PAYMENT ON A PREPAID, CAPITATED BASIS FOR COMMUNITY NURSING AND AMBULATORY CARE FURNISHED TO MEDICARE BENEFICIARIES

Pub. L. 106-113, div. B, §1000(a)(6) [title V, §532], Nov. 29, 1999, 113 Stat. 1536, 1501A-388, as amended by Pub. L. 106-554, §1(a)(6) [title VI, §632(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-566, provided that:

“(a) EXTENSION.—Notwithstanding any other provision of law, any demonstration project conducted under section 4079 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-123 [Pub. L. 100-203]; 42 U.S.C. 1395mm note) and conducted for the additional period of 2 years as provided for under section 4019 of BBA [Pub. L. 105-33, set out as a note below], shall be conducted for an additional period of 2 years.

“(b) TERMS AND CONDITIONS.—

“(1) JANUARY THROUGH SEPTEMBER 2000.—For the 9-month period beginning with January 2000, any such demonstration project shall be conducted under the same terms and conditions as applied to such demonstration during 1999.

“(2) OCTOBER 2000 THROUGH DECEMBER 2001.—For the 15-month period beginning with October 2000, any such demonstration project shall be conducted under the same terms and conditions as applied to such demonstration during 1999, except that the following modifications shall apply:

“(A) BASIC CAPITATION RATE.—The basic capitation rate paid for services covered under the project (other than case management services) per enrollee per month and furnished during—

“(i) the period beginning with October 1, 2000, and ending with December 31, 2000, shall be determined by actuarially adjusting the actual capitation rate paid for such services in 1999 for inflation, utilization, and other changes to the CNO service package, and by reducing such adjusted capitation rate by 10 percent in the case of the demonstration sites located in Arizona, Minnesota, and Illinois, and 15 percent for the demonstration site located in New York; and

“(ii) 2001 shall be determined by actuarially adjusting the capitation rate determined under clause (i) for inflation, utilization, and other changes to the CNO service package.

“(B) TARGETED CASE MANAGEMENT FEE.—Effective October 1, 2000—

“(i) the case management fee per enrollee per month for—

“(I) the period described in subparagraph (A)(i) shall be determined by actuarially adjusting the case management fee for 1999 for inflation; and

“(II) 2001 shall be determined by actuarially adjusting the amount determined under subclause (I) for inflation; and

“(ii) such case management fee shall be paid only for enrollees who are classified as moderately frail or frail pursuant to criteria established by the Secretary.

“(C) GREATER UNIFORMITY IN CLINICAL FEATURES AMONG SITES.—Each project shall implement for each site—

“(i) protocols for periodic telephonic contact with enrollees based on—

“(I) the results of such standardized written health assessment; and

“(II) the application of appropriate care planning approaches;

“(ii) disease management programs for targeted diseases (such as congestive heart failure, arthritis, diabetes, and hypertension) that are highly prevalent in the enrolled populations;

“(iii) systems and protocols to track enrollees through hospitalizations, including pre-admission planning, concurrent management during inpa-

tient hospital stays, and post-discharge assessment, planning, and follow-up; and

“(iv) standardized patient educational materials for specified diseases and health conditions.

“(D) QUALITY IMPROVEMENT.—Each project shall implement at each site once during the 15-month period—

“(i) enrollee satisfaction surveys; and

“(ii) reporting on specified quality indicators for the enrolled population.

“(c) EVALUATION.—

“(1) PRELIMINARY REPORT.—Not later than July 1, 2001, the Secretary of Health and Human Services shall submit to the Committees on Ways and Means and Commerce [now Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate a preliminary report that—

“(A) evaluates such demonstration projects for the period beginning July 1, 1997, and ending December 31, 1999, on a site-specific basis with respect to the impact on per beneficiary spending, specific health utilization measures, and enrollee satisfaction; and

“(B) includes a similar evaluation of such projects for the portion of the extension period that occurs after September 30, 2000.

“(2) FINAL REPORT.—The Secretary shall submit a final report to such Committees on such demonstration projects not later than July 1, 2002. Such report shall include the same elements as the preliminary report required by paragraph (1), but for the period after December 31, 1999.

“(3) METHODOLOGY FOR SPENDING COMPARISONS.—Any evaluation of the impact of the demonstration projects on per beneficiary spending included in such reports shall include a comparison of—

“(A) data for all individuals who—

“(i) were enrolled in such demonstration projects as of the first day of the period under evaluation; and

“(ii) were enrolled for a minimum of 6 months thereafter; with

“(B) data for a matched sample of individuals who are enrolled under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] and are not enrolled in such a project, or in a Medicare+Choice plan under part C of such title [42 U.S.C. 1395w–21 et seq.], a plan offered by an eligible organization under section 1876 of such Act [42 U.S.C. 1395mm], or a health care prepayment plan under section 1833(a)(1)(A) of such Act [42 U.S.C. 1395l(a)(1)(A)].”

[Pub. L. 106–554, §1(a)(6) [title VI, §632(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–568, provided that: “The amendments made by subsection (a) [amending section 1000(a)(6) [title V, §532] of Pub. L. 106–113, set out above] shall be effective as if included in the enactment of section 532 of BBRA [Pub. L. 106–113, §1000(a)(6) [title V, §532] [113 Stat. 1501A–388)].”]

Pub. L. 105–33, title IV, §4019, Aug. 5, 1997, 111 Stat. 347, provided that: “Notwithstanding any other provision of law, demonstration projects conducted under section 4079 of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203, set out as a note below] may be conducted for an additional period of 2 years, and the deadline for any report required relating to the results of such projects shall be not later than 6 months before the end of such additional period.”

Pub. L. 100–203, title IV, §4079, Dec. 22, 1987, 101 Stat. 1330–121, as amended by Pub. L. 100–360, title IV, §411(h)(8), July 1, 1988, 102 Stat. 787, provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall enter into an agreement with not less than four eligible organizations submitting applications under this section to conduct demonstration projects to provide payment on a prepaid, capitated basis for community nursing and ambulatory care furnished to any individual entitled to benefits under part A and enrolled under part B of title XVIII of the Social

Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] (other than an individual medically determined to have end-stage renal disease) who resides in the geographic area served by the organization and enrolls with such organization (in accordance with subsection (c)(2)).

“(b) DEFINITIONS OF COMMUNITY NURSING AND AMBULATORY CARE AND ELIGIBLE ORGANIZATION.—As used in this section:

“(1) The term ‘community nursing and ambulatory care’ means the following services:

“(A) Part-time or intermittent nursing care furnished by or under the supervision of registered professional nurses.

“(B) Physical, occupational, or speech therapy.

“(C) Social and related services supportive of a plan of ambulatory care.

“(D) Part-time or intermittent services of a home health aide.

“(E) Medical supplies (other than drugs and biologicals) and durable medical equipment while under a plan of care.

“(F) Medical and other health services described in paragraphs (2)(H)(ii) and (5) through (9) of section 1861(s) of the Social Security Act [42 U.S.C. 1395x(s)(2)(H)(ii), (5)–(9)].

“(G) Rural health clinic services described in section 1861(aa)(1)(C) of such Act [42 U.S.C. 1395x(aa)(1)(C)].

“(H) Certain other related services listed in section 1915(c)(4)(B) of such Act [42 U.S.C. 1396n(c)(4)(B)] to the extent the Secretary finds such services are appropriate to prevent the need for institutionalization of a patient.

“(2) The term ‘eligible organization’ means a public or private entity, organized under the laws of any State, which meets the following requirements:

“(A) The entity (or a division or part of such entity) is primarily engaged in the direct provision of community nursing and ambulatory care.

“(B) The entity provides directly, or through arrangements with other qualified personnel, the services described in paragraph (1).

“(C) The entity provides that all nursing care (including services of home health aids) is furnished by or under the supervision of a registered nurse.

“(D) The entity provides that all services are furnished by qualified staff and are coordinated by a registered professional nurse.

“(E) The entity has policies governing the furnishing of community nursing and ambulatory care that are developed by registered professional nurses in cooperation with (as appropriate) other professionals.

“(F) The entity maintains clinical records on all patients.

“(G) The entity has protocols and procedures to assure, when appropriate, timely referral to or consultation with other health care providers or professionals.

“(H) The entity complies with applicable State and local laws governing the provision of community nursing and ambulatory care to patients.

“(I) The requirements of subparagraphs (B), (D), and (E) of section 1876(b)(2) of the Social Security Act [42 U.S.C. 1395mm(b)(2)(B), (D), (E)].

“(c) AGREEMENTS WITH ELIGIBLE ORGANIZATIONS TO CONDUCT DEMONSTRATION PROJECTS.—

“(1) The Secretary may not enter into an agreement with an eligible organization to conduct a demonstration project under this section unless the organization meets the requirements of this subsection and subsection (e) with respect to members enrolled with the organization under this section.

“(2) The organization shall have an open enrollment period for the enrollment of individuals under this section. The duration of such period of enrollment and any other requirement pertaining to enrollment or termination of enrollment shall be specified in the agreement with the organization.

“(3) The organization must provide to members enrolled with the organization under this section,

through providers and other persons that meet the applicable requirements of titles XVIII and XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.], community nursing and ambulatory care (as defined in subsection (b)(1)) which is generally available to individuals residing in the geographic area served by the organization, except that the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered.

“(4) The organization must make community nursing and ambulatory care (and such other health care services as such individuals have contracted for) available and accessible to each individual enrolled with the organization under this section, within the area served by the organization, with reasonable promptness and in a manner which assures continuity.

“(5) Section 1876(c)(5) of the Social Security Act [42 U.S.C. 1395mm(c)(5)] shall apply to organizations under this section in the same manner as it applies to organizations under section 1876 of such Act.

“(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals under the demonstration project conducted under this section, which program (A) stresses health outcomes and (B) provides review by health care professionals of the process followed in the provision of such health care services.

“(7) Under a demonstration project under this section—

“(A) the Secretary could require the organization to provide financial or other assurances (including financial risk-sharing) that minimize the inappropriate substitution of other services under title XVIII of such Act [42 U.S.C. 1395 et seq.] for community nursing services; and

“(B) if the Secretary determines that the organization has failed to perform in accordance with the requirements of the project (including meeting financial responsibility requirements under the project, any pattern of disproportionate or inappropriate institutionalization) the Secretary shall, after notice, terminate the project.

“(d) DETERMINATION OF PER CAPITA PAYMENT RATES.—

“(1) The Secretary shall determine for each 12-month period in which a demonstration project is conducted under this section, and shall announce (in a manner intended to provide notice to interested parties) not later than three months before the beginning of such period, with respect to each eligible organization conducting a demonstration project under this section, a per capita rate of payment for each class of individuals who are enrolled with such organization who are entitled to benefits under part A and enrolled under part B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.].

“(2)(A) Except as provided in paragraph (3), the per capita rate of payment under paragraph (1) shall be determined in accordance with this paragraph.

“(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

“(C) The per capita rate of payment under paragraph (1) for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in subparagraph (D)) for that class.

“(D) For purposes of subparagraph (C), the term ‘adjusted average per capita cost’ means the average per capita amount that the Secretary estimates in advance (on the basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geo-

graphic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for those services covered under parts A and B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] and types of expenses otherwise reimbursable under such parts A and B which are described in subparagraphs (A) through (G) of subsection (b)(1) (including administrative costs incurred by organizations described in sections 1816 and 1842 of such Act [42 U.S.C. 1395h, 1395u]), if the services were to be furnished by other than an eligible organization.

“(3) The Secretary shall, in consultation with providers, health policy experts, and consumer groups develop capitation-based reimbursement rates for such classes of individuals entitled to benefits under part A and enrolled under part B of the Social Security Act [probably means parts A and B of title XVIII of that Act, 42 U.S.C. 1395c et seq., 1395j et seq.] as the Secretary shall determine. Such rates shall be applied in determining per capita rates of payment under paragraph (1) with respect to at least one eligible organization conducting a demonstration project under this section.

“(4)(A) In the case of an eligible organization conducting a demonstration project under this section, the Secretary shall make monthly payments in advance and in accordance with the rate determined under paragraph (2) or (3), except as provided in subsection (e)(3)(B), to the organization for each individual enrolled with the organization.

“(B) The amount of payment under paragraph (2) or (3) may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

“(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A and enrolled under part B of the Social Security Act shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under such Act [42 U.S.C. 301 et seq.] in such proportions from each such trust fund as the Secretary deems to be fair and equitable taking into consideration benefits attributable to such parts A and B, respectively.

“(6) During any period in which an individual is enrolled with an eligible organization conducting a demonstration project under this section, only the eligible organization (and no other individual or person) shall be entitled to receive payments from the Secretary under this title [probably means title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.] for community nursing and ambulatory care (as defined in subsection (b)(1)) furnished to the individual.

“(e) RESTRICTION ON PREMIUMS, DEDUCTIBLES, COPAYMENTS, AND COINSURANCE.—

“(1) In no case may the portion of an eligible organization’s premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to community nursing and ambulatory care) to individuals who are enrolled under this section with the organization, exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A and enrolled under part B of the Social Security Act [probably

means parts A and B of title XVIII of that Act, 42 U.S.C. 1395c et seq., 1395j et seq., if they were not members of an eligible organization.

“(2) If the eligible organization provides to its members enrolled under this section services in addition to community nursing and ambulatory care, election of coverage for such additional services shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of—

“(A) the portion of such organization’s premium rate charged, with respect to such additional services, to members enrolled under this section, and

“(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members

exceed the adjusted community rate for such services (as defined in section 1876(e)(3) of the Social Security Act [42 U.S.C. 1395mm(e)(3)]).

“(3)(A) Subject to subparagraphs (B) and (C), each agreement to conduct a demonstration project under this section shall provide that if—

“(i) the adjusted community rate, referred to in paragraph (2), for community nursing and ambulatory care covered under parts A and B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization,

is less than

“(ii) the average of the per capita rates of payment to be made under subsection (d)(1) at the beginning of the 12-month period (as determined on such basis as the Secretary determines appropriate) described in such subsection for members enrolled under this section with the organization,

the eligible organization shall provide to such members the additional benefits described in section 1876(g)(3) of the Social Security Act [42 U.S.C. 1395mm(g)(3)] which are selected by the eligible organization and which the Secretary finds are at least equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced).

“(B) Subparagraph (A) shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced).

“(C) An organization conducting a demonstration project under this section may provide (with the approval of the Secretary) that a part of the value of such additional benefits under subparagraph (A) be withheld and reserved by the Secretary as provided in section 1876(g)(5) of the Social Security Act [42 U.S.C. 1395mm(g)(5)].

“(4) The provisions of paragraphs (3), (5), and (6) of section 1876(g) of the Social Security Act [42 U.S.C. 1395mm(g)(3), (5), (6)] shall apply in the same manner to agreements under this section as they apply to risk-sharing contracts under section 1876 of such Act, and, for this purpose, any reference in such paragraphs to paragraph (2) is deemed a reference to paragraph (3) of this subsection.

“(5) Section 1876(e)(4) of the Social Security Act [42 U.S.C. 1395mm(e)(4)] shall apply to eligible organizations under this section in the same manner as it applies to eligible organizations under section 1876 of such Act.

“(f) COMMENCEMENT AND DURATION OF PROJECTS.—Each demonstration project under this section shall begin not later than July 1, 1989, and shall be conducted for a period of three years.

“(g) REPORT.—Not later than January 1, 1992, the Secretary shall submit to the Congress a report on the results of the demonstration projects conducted under this section.”

STUDY OF AAPCC AND ACR

Pub. L. 99-509, title IX, §9312(g), Oct. 21, 1986, 100 Stat. 2001, directed Secretary of Health and Human Services to provide, through contract with an appropriate organization, for a study of the methods by which the adjusted average per capita cost (“AAPCC”, as defined in subsec. (a)(4) of this section) can be refined to more accurately reflect the average cost of providing care to different classes of patients, and the adjusted community rate (“ACR”, as defined in subsec. (e)(3) of this section) can be refined, with Secretary to submit to Congress, by not later than Jan. 1, 1988, specific legislative recommendations concerning methods by which the calculation of the AAPCC and the ACR could be refined.

ALLOWING MEDICARE BENEFICIARIES TO DISENROLL AT LOCAL SOCIAL SECURITY OFFICES

Pub. L. 99-509, title IX, §9312(h), Oct. 21, 1986, 100 Stat. 2002, provided that: “The Secretary of Health and Human Services shall provide that individuals enrolled with an eligible organization under section 1876 of the Social Security Act [42 U.S.C. 1395mm] may disenroll, on and after June 1, 1987, at any local office of the Social Security Administration.”

USE OF RESERVE FUNDS

Pub. L. 99-509, title IX, §9312(i), Oct. 21, 1986, 100 Stat. 2002, provided that: “Notwithstanding any provision of section 1876(g)(5) of the Social Security Act (42 U.S.C. 1395mm(g)(5)) to the contrary, funds reserved by an eligible organization under such section before the date of the enactment of this Act [Oct. 21, 1986] may be applied, at the organization’s option, to offset the amount of any reduction in payment amounts to the organization effected under Public Law 99-177 [Dec. 12, 1985, 99 Stat. 1037, see Tables for classification] during fiscal year 1986.”

PHASE-IN OF ENROLLMENT PERIOD BY SECRETARY

Pub. L. 98-369, div. B, title III, §2350(a)(2), July 18, 1984, 98 Stat. 1098, provided that: “The Secretary of Health and Human Services may phase in, over a period of not longer than three years, the application of the amendments made by paragraph (1) [amending this section] to all applicable areas in the United States if the Secretary determines that it is not administratively feasible to establish a single 30-day open enrollment period for all such applicable areas before the end of the period.”

STABILIZATION FUND; ESTABLISHMENT LIMITATION; USES; REPORT TO CONGRESS

Pub. L. 98-369, div. B, title III, §2350(b)(3), (4), July 18, 1984, 98 Stat. 1098, as amended by Pub. L. 100-203, title IV, §4013, Dec. 22, 1987, 101 Stat. 1330-61; Pub. L. 100-360, title IV, §411(c)(3), July 1, 1988, 102 Stat. 773, prohibited Secretary of Health and Human Services from approving the establishment of a stabilization fund by an eligible organization under subsec. (g)(5) of this section for any contract period beginning later than Sept. 30, 1990, and directed Secretary to report to Congress with respect to use of stabilization funds by eligible organizations under subsec. (g)(5) of this section and to assess the need for such funds not later than 54 months after July 1984, prior to repeal by Pub. L. 101-239, title VI, §6212(c)(1), Dec. 19, 1989, 103 Stat. 2250.

STUDY OF ADDITIONAL BENEFITS SELECTED BY ELIGIBLE ORGANIZATIONS

Pub. L. 97-248, title I, §114(d), Sept. 3, 1982, 96 Stat. 352, directed Secretary of Health and Human Services to conduct a study of the additional benefits selected by eligible organizations pursuant to subsec. (g)(2) of this section, with Secretary to report to Congress within 24 months of the initial effective date (as defined in subsec. (c)(4) of section 114 of Pub. L. 97-248) with re-

spect to the findings and conclusions made as a result of such study.

STUDY EVALUATING THE EXTENT OF, AND REASONS FOR, TERMINATION BY MEDICARE BENEFICIARIES OF MEMBERSHIP IN ORGANIZATIONS WITH CONTRACTS UNDER THIS SECTION

Pub. L. 97-248, title I, §114(e), Sept. 3, 1982, 96 Stat. 352, directed Secretary of Health and Human Services to conduct a study evaluating the extent of, and reasons for, the termination by medicare beneficiaries of their memberships in organizations with contracts under section 1876 of the Social Security Act (this section), with Secretary to submit an interim report to Congress, within two years after the initial effective date (as defined in subsec. (c)(4) of section 114 of Pub. L. 97-248), and a final report within five years after such date containing the respective interim and final findings and conclusions made as a result of such study.

REIMBURSEMENT FOR SERVICES

Pub. L. 92-603, title II, §226(b), Oct. 30, 1972, 86 Stat. 1403, provided that:

“(1) Notwithstanding the provisions of section 1814 and section 1833 of the Social Security Act [42 U.S.C. 1395f, 1395l], any health maintenance organization which has entered into a contract with the Secretary pursuant to section 1876 of such Act [42 U.S.C. 1395mm] shall, for the duration of such contract, (except as provided in paragraph (2)) be entitled to reimbursement only as provided in section 1876 of such Act [42 U.S.C. 1395mm] for individuals who are members of such organizations.

“(2) With respect to individuals who are members of organizations which have entered into a risk-sharing contract with the Secretary pursuant to subsection (i)(2)(A) [of this section] prior to July 1, 1973, and who, although eligible to have payment made pursuant to section 1876 of such Act [42 U.S.C. 1395mm] for services rendered to them, chose (in accordance with regulations) not to have such payment made pursuant to such section, the Secretary shall, for a period not to exceed three years commencing on July 1, 1973, pay to such organization on the basis of an interim per capita rate, determined in accordance with the provisions of section 1876(a)(2) of such Act [42 U.S.C. 1395mm(a)(2)], with appropriate actuarial adjustments to reflect the difference in utilization of out-of-plan services, which would have been considered sufficiently reasonable and necessary under the rules of the health maintenance organization to be provided by that organization, between such individuals and individuals who are enrolled with such organization pursuant to section 1876 of such Act [42 U.S.C. 1395mm]. Payments under this paragraph shall be subject to retroactive adjustment at the end of each contract year as provided in paragraph (3).

“(3) If the Secretary determines that the per capita cost of any such organization in any contract year for providing services to individuals described in paragraph (2), when combined with the cost of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such year for providing out-of-plan services to such individuals, is less than or greater than the adjusted average per capita cost (as defined in section 1876(a)(3) of such Act [42 U.S.C. 1395mm(a)(3)]) of providing such services, the resulting savings shall be apportioned between such organization and such Trust Funds, or the resulting losses shall be absorbed by such organization, in the manner prescribed in section 1876(a)(3) of such Act [42 U.S.C. 1395mm(a)(3)].”

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b), if a physician (or an immediate family member of

such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d), an ownership or investment interest in the entity, or

(B) except as provided in subsection (e), a compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(b) General exceptions to both ownership and compensation arrangement prohibitions

Subsection (a)(1) shall not apply in the following cases:

(1) Physicians' services

In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4)) as the referring physician.

(2) In-office ancillary services

In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)—

(A) that are furnished—

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice—

(aa) for the provision of some or all of the group's clinical laboratory services, or