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time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

[80 FR 70604, Nov. 13, 2015, as amended at 88 FR 82180, Nov. 22, 2023]

§ 416.330 Reconsiderations under the ASCQR Program.

(a) *Reconsiderations of ASCQR Program decisions.* An ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year. An ASC must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year.

(b) *Requirements for reconsideration requests.* A reconsideration request must contain the following information:

(1) The ASC CCN and related NPI(s);

(2) The name of the ASC;

(3) The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;

(4) The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;

(5) The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and

(6) A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

(c) *Reconsideration process.* Upon receipt of a request for reconsideration, CMS will do the following:

(1) Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and

(2) Provide a formal response to the ASC contact using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

(d) *Final ASCQR Program payment determination.* For an ASC that submits a timely reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For an ASC that does not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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AUTHORITY: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

Subpart A—General Provisions

§ 417.1 Definitions.

As used in this part, unless the context indicates otherwise—

Basic health services means health services described in § 417.101(a).

Community rating system means a system of fixing rates of payments for health services that meets the requirements of § 417.104(a)(3).

Comprehensive health services means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 417.101(a)(1));

(2) Outpatient services and inpatient hospital services (§ 417.101(a)(2));

(3) Medically necessary emergency health services (§ 417.101(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 417.101(a)(6)).

Direct service contract means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

Enrollee means an individual for whom an HMO, CMP, or HCPP assumes the responsibility, under a contract or agreement, for the furnishing of health care services on a prepaid basis.

Full-time student means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Furnished, when used in connection with prepaid health care services, means services that are maid available to an enrollee either dierctly by, or under arrangements made by, the HMO, CMP, or HCPP.

Health maintenance organization (HMO) means a legal entity that provides or arranges for the provision of basic and supplemental health services to its enrollees in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the PHS Act and the regulations in subparts B and C of this part.

Health professionals means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

Individual practice association (IPA) means a partnership, association, corporation, or other legal entity that delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement must provide:

(1) That these health professionals will provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

Medical group means a partnership, association, corporation, or other group:

(1) That is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a

qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to enrollees of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby an enrollee's enrollment status is not known to the health professional who provides health services to the enrollee.

Medical group members means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Medically underserved population means the population of an urban or rural area as described in Sec. 417.912(d).

Nonmetropolitan area means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

Party in interest means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

Policymaking body of an HMO means a board of directors, governing body, or other body of individuals that has the authority to establish policy for the HMO.

Qualified HMO means an HMO found by CMS to be qualified within the meaning of section 1310 of the PHS Act and subpart D of this part.

Rural area means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, ''Number of Inhabitants,'' Table VI, ''Population of Places,'' and not listed as an urbanized area in Table XI, ''Population of Urbanized Areas'' of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with §417.106(b). Facilities in which individuals are incarcerated are not included in the geographic service area of an HMO or CMP plan.

Significant business transaction means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

Staff of the HMO means health professionals who are employees of the HMO and who—

(1) Provide services to HMO enrollees at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to enrollees of the HMO the health services that the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO; and

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

Subscriber means an enrollee who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Supplemental health services means the health services described in § 417.102(a).

Unusual or infrequently used health services means:

(1) Those health services that are projected to involve fewer than 1 percent of the encounters per year for the entire HMO enrollment, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987. Redesignated and amended at 56 FR 51985, Oct. 17, 1991; 58 FR 38067, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45674, Sept. 1, 1995; 79 FR 29955, May 23, 2014]

§ 417.2 Basis and scope.

(a) Subparts B through F of this part pertain to the Federal qualification of HMOs under title XIII of the Public Health Service (PHS) Act.

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act and 8 U.S.C. 1611.

(c) Subpart U of this part pertains to Medicare payment to health care prepayment plans under section 1833(a)(1)(A) of the Act.

(d) Subpart V of this part applies to the administration of outstanding loans and loan guarantees previously granted under title XIII of the PHS Act.

[56 FR 51985, Oct. 17, 1991, as amended at 60 FR 45675, Sept. 1, 1995; 80 FR 7958, Feb. 12, 2015]

Subpart B—Qualified Health Maintenance Organizations: Services

§ 417.101 Health benefits plan: Basic health services.

(a) An HMO must provide or arrange for the provision of basic health services to its enrollees as needed and without limitations as to time and cost other than those prescribed in the PHS Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which must be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which must include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital;

(ii) Inpatient hospital services, which must include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;

(iii) Outpatient services and inpatient hospital services must include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its enrollees on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per enrollee per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs must include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services must be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at an enrollee's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which must be made available to members and must include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in §417.102 as a supplemental health service in the basic health services that it provides or arranges for its enrollees for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§417.101 through 417.106 and §§417.168 and 417.169, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the PHS Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the enrollee is legally entitled to services and for which facilities are reasonably available to this enrollee;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and

1302(1)(H)(vi) of the PHS Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services that are unusual and infrequently provided and not necessary for the protection of individual health, as approved by CMS upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis that do not include all the basic health services set forth in paragraph (a) of this section or that are limited as to time and cost except in a manner prescribed by this subpart.

[45 FR 72528, Oct. 31, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38077, July 15, 1993]

§ 417.102 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its enrollees any health service that is not included as a basic health service under § 417.101(a). These health services may be limited as to time and cost.

(b) An HMO must determine the level and scope of supplemental health services included with basic health services provided to its enrollees for a basic health services payment or those services offered to its enrollees as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.103 Providers of basic and supplemental health services.

(a)(1) The HMO must provide that the services of health professionals that are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, CMS approves the sharing as being consistent with the purposes of section 1310(b) of the PHS Act.

(3) After the 4 year period beginning with the month following the month in that an HMO becomes a qualified HMO, an entity that meets the requirements of the definition of medical group in § 417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if CMS determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of CMS that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the ''substantial responsibility'' requirement of subdivision (3)(i) of the definition of ''medical group'' in § 417.100. The HMO must update the plan annually and must demonstrate to the satisfaction of CMS that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of ''medical group,'' or

(ii) Demonstrating that compliance by the entity with the ''substantial responsibility'' requirement is unreasonable or impractical because (A) the

HMO serves a non-metropolitan or rural area as defined in §417.100, or (B) the entity is a multi-speciality group that provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of enrollees to require utilization of at least 35 percent of the entity's services.

(b) HMOs must have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the enrollee other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services must be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO must:

(1) Pay the provider, or reimburse its enrollees for the payment of reasonable charges for basic health services (or supplemental health services that the HMO agreed to provide on a prepayment basis) for which its enrollees have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from enrollees for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its enrollees on procedures to be followed to secure these health services.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO must provide or arrange for the provision of basic health services for a basic health services payment that:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its enrollees, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or enrollment in the HMO, an HMO may not impose copayment charges on any subscriber (or enrollees covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or enrollees) in that calendar year total 200 percent of the total annual premium cost which that

subscriber (or enrollees) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or enrollees) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates will be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue that would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers must be calculated to yield revenues substantially equivalent to the product of the total number of enrollees (or subscribers) expected to be enrolled from the group and the per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment that are established for new enrollments or re-enrollments and that do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates will be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it must:

(i) Classify all of the enrollees of the organization into classes based on factors that the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by CMS,

(ii) Determine its revenue requirements for providing services to the enrollees of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. CMS will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If CMS determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, CMS will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 (''Contracts for Medical Care for

Spouses and Children: Plans'') or section 1086 (''Contracts for Health Benefits for Certain Members, Former Members and their Dependents'') of title 10 (''Armed Forces''), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 (''Health Insurance'') of title 5 (''Government Organization and Employees''), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to CMS of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its enrollees, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided an enrollee who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable that are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*[1] An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915–0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

§417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in §417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-

[1] Further information entitled ''Guidelines for Rating by Class'' may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

service. Supplemental health services payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.

(a) *Quality assurance program.* Each HMO or CMP must have an ongoing quality assurance program for its health services that meets the following conditions:

(1) Stresses health outcomes to the extent consistent with the state of the art.

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services.

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change.

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.

(b) *Availability and accessibility of health care services.* Basic health services and those supplemental health services for which enrollees have contracted must be provided or arranged for by the HMO in accordance with the following rules:

(1) Except as provided in paragraph (b)(2) of this section, the services must be available to each enrollee within the HMO's service area.

(2) *Exception.* If the HMO's service area is located wholly within a nonmetropolitan area, the HMO may make available outside its service area any basic health service that is not a primary care or emergency care service, if the number of providers of that basic health service who will provide the service to the HMO's enrollees is insufficient to meet the demand. As used in this paragraph, primary care includes general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO that provides the services covered by these fields through at least a general or family practitioner, or a pediatrician and a general internist, is considered to be providing primary care.

(3) The services must be available and accessible with reasonable promptness to each of the HMO's enrollees as ensured through—

(i) Staffing patterns within generally accepted norms for meeting the projected enrollment needs; and

(ii) Geographic location, hours of operation, and arrangements for afterhours services. (Medically necessary emergency services must be available 24 hours a day, 7 days a week.)

(c) *Continuity of care.* The HMO must ensure continuity or care through arrangements that include but are not limited to the following:

(1) Use of a health professional who is primarily responsible for coordinating the enrollee's overall health care.

(2) A system of health and medical records that accumulates pertinent information about the enrollee's health care and makes it available to appropriate professionals.

(3) Arrangements made directly or through the HMO's providers to ensure that the HMO or the health professional who coordinates the enrollee's overall health care is kept informed about the services that the referral resources furnish to the enrollee.

(d) *Confidentiality of health records.* Each HMO must establish adequate procedures to ensure the confidentiality of the health and medical records of its enrollees.

[58 FR 38068, July 15, 1993]

Subpart C—Qualified Health Maintenance Organizations: Organization and Operation

SOURCE: 58 FR 38068, July 15, 1993, unless otherwise noted.

§417.120 Fiscally sound operation and assumption of financial risk.

(a) *Fiscally sound operation*—(1) *General requirements.* Each HMO must have a fiscally sound operation, as demonstrated by the following:

(i) Total assets greater than total unsubordinated liabilities. In evaluating assets and liabilities, loan funds awarded or guaranteed under section 1306 of the PHS Act are not included as liabilities.

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(iii) A net operating surplus, or a financial plan that meets the requirements of paragraph (a)(2) of this section.

(iv) An insolvency protection plan that meets the requirements of §417.122(b) for protection of enrollees.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO.

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by CMS to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(2) *Financial plan requirement.* (i) If an HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year or does not have positive net worth, the HMO must submit a financial plan satisfactory to CMS to achieve net operating surplus within available fiscal resources.

(ii) This plan must include—

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds statements; and

(D) Balance sheets.

(b) *Assumption of financial risk.* Each HMO must assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements as follows:

(1) For the cost of providing to any enrollee basic health services with an aggregate value of more than $5,000 in any year.

(2) For the cost of basic health services obtained by its enrollees from sources other than the HMO because medical necessity required that they be furnished before they could be secured through the HMO.

(3) 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 that fiscal year.

(4) For physicians or other health professionals, health care institutions, or any other combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for their furnishing of basic health services to the HMO's enrollees.

§417.122 Protection of enrollees.

(a) *Liability protection.* (1) Each HMO must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the HMO. These arrangements may include any of the following:

(i) Contractual arrangements that prohibit health care providers used by the enrollees from holding any enrollee liable for payment of any fees that are the legal obligation of the HMO.

(ii) Insurance, acceptable to CMS.

(iii) Financial reserves, acceptable to CMS, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to CMS.

(2) The requirements of this paragraph do not apply to an HMO if CMS determines that State law protects the HMO enrollees from liability for payment of any fees that are the legal obligation of the HMO.

(b) *Protection against loss of benefits if the HMO becomes insolvent.* The insolvency protection plan required under §417.120(a) must provide for continuation of benefits as follows:

(1) For all enrollees, for the duration of the contract period for which payment has been made.

(2) For enrollees who are in an inpatient facility on the date of insolvency, until they are discharged from the facility.

§ 417.124 Administration and management.

(a) *General requirements.* Each HMO must have administrative and managerial arrangements satisfactory to CMS, as demonstrated by at least the following:

(1) A policymaking body that exercises oversight and control over the HMO's policies and personnel to ensure that management actions are in the best interest of the HMO and its enrollees.

(2) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO.

(3) At a minimum, management by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Full and fair disclosure*—(1) *Basic rule.* Each HMO must prepare a written description of the following:

(i) Benefits (including limitations and exclusions).

(ii) Coverage (including a statement of conditions on eligibility for benefits).

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied.

(iv) Rates.

(v) Grievance procedures.

(vi) Service area.

(vii) Participating providers.

(viii) Financial condition including at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Requirements for the description.* (i) The description must be written in a way that can be easily understood by the average person who might enroll in the HMO.

(ii) The description of benefits and coverage may be in general terms if reference is made to a detailed statement of benefits and coverage that is available without cost to any person who enrolls in the HMO or to whom the opportunity for enrollment is offered.

(iii) The HMO must provide the description to any enrollee or person who is eligible to elect the HMO option and who requests the material from the HMO or the administrator of a health benefits plan. For purposes of this requirement, ''administrator'' (of a health benefits plan) has the meaning it is given in the Employment Retirement Income Security Act of 1974 (ERISA) at 29 U.S.C. 1002(16)(A).

(iv) If the HMO provides health services through individual practice associations (IPAs), the HMO must specify the number of member physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(v) If the HMO provides health services other than through IPAs, the HMO must specify, for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(c) *Broadly representative enrollment.* (1) Each HMO must offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area.

(2) If an HMO has a medically underserved population located in its service area, not more than 75 percent of its enrollees may be from the medically underserved population unless the area in which that population resides is a rural area.

(d) *Health status and enrollment.* (1) The HMO may not, on the basis of health status, health care needs, or age of the individual—

(i) Expel or refuse to reenroll any enrollee; or

(ii) Refuse to enroll individual members of a group.

(2) For purposes of this paragraph, a ''group'' is composed of individuals who enroll in the HMO under a contract or other arrangement that covers two or more subscribers. Examples of groups are employees who enroll under a contract between their employer and the HMO, or members of an organization that arranges coverage for its membership.

(3) Nothing in this subpart prohibits an HMO from requiring that, as a condition for continued eligibility for enrollment, enrolled dependent children, upon reaching a specified age, convert to individual enrollment, consistent with paragraph (e) of this section.

(e) *Conversion of enrollment.* (1) Each HMO must offer individual enrollment to the following:

(i) Each enrollee (and his or her enrolled dependents) leaving a group.

(ii) Each enrollee who would otherwise cease to be eligible for HMO enrollment because of his or her age, or the death or divorce of an enrollee.

(2) The individual enrollment offered must meet the conditions of subpart B of this part and this subpart C.

(3) The HMO is not required to offer individual enrollment except to the enrollees specified in this paragraph.

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

(f) [Reserved]

(g) *Grievance procedures.* Each HMO must have and use meaningful procedures for hearing and resolving grievances between the HMO's enrollees and the HMO, including the HMO staff and medical groups and IPAs that furnish services. These procedures must ensure that:

(1) Grievances and complaints are transmitted in a timely manner to appropriate HMO decisionmaking levels that have authority to take corrective action; and

(2) Appropriate action is taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Certification of institutional providers.* Each HMO must ensure that its affiliated institutional providers meet one of the following conditions:

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by CMS in accordance with section 353 of the PHS Act and part 493 of this chapter:

(i) Registration certificate.

(ii) Certificate.

(iii) Certificate of waiver.

(iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

§417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the HMO has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each HMO must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *''Significant business transaction'' defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

(i) Sale, exchange or lease of property.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(i) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds

$25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

Subpart D—Application for Federal Qualification

§ 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) Qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that CMS follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

§ 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.

(2) CMS determines whether the entity is an HMO on the basis of the entity's application and any additional information and investigation (including site visits) that CMS may require.

(3) CMS may determine that an entity is any of the following:

(i) An operational qualified HMO.

(ii) A preoperational qualified HMO.

(iii) A transitional qualified HMO.

(b) *Operational qualified HMO.* CMS determines that an entity is an operational qualified HMO if—

(1) CMS finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of CMS's determination, provides written assurances, satisfactory to CMS, that it—

(i) Provides and will provide basic health services (and any supplemental health services included in any contract) to its enrollees;

(ii) Provides and will provide these services in the manner prescribed in sections 1301(b) and 1301(c) of the PHS Act and subpart B of this part;

(iii) Is organized and operated and will continue to be organized and operated in the manner prescribed in section 1301(c) of the PHS Act and subpart C of this part;

(iv) Under arrangements that safeguard the confidentiality of patient information and records, will provide access to CMS and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operation as an HMO, and to any facilities that it operates; and

(v) Will continue to comply with any other assurances that it has given to CMS.

(c) *Preoperational qualified HMO.* (1) CMS may determine that an entity is a

preoperational qualified HMO if it provides, within 30 days of CMS's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of subparts B and C of this part.

(2) Within 30 days after receiving notice that the entity has begun operation, CMS determines whether it is an operational qualified HMO. In the absence of this determination, the entity is not an operational qualified HMO even though it becomes operational.

(d) *Transitional qualified HMO: General rules*—(1) *Basic requirements.* CMS may determine that an entity is a transitional qualified HMO if the entity—

(i) Meets the requirements of paragraph (d)(2) through (d)(4) of this section; and

(ii) Provides the assurances specified in paragraphs (d)(5) through (d)(7) of this section within 30 days of CMS's determination.

(2) *Organization and operation.* The entity is organized and operated in accordance with subpart C of this part, except that it need not—

(i) Assume full financial risk for the provision of basic health services as required by § 417.120(b); or

(ii) Comply with the limitations that are imposed on insurance by § 417.120(b)(1).

(3) *Range of services.* The entity is currently providing the following services on a prepaid basis:

(i) Physician services.

(ii) Outpatient services and inpatient hospital services. (The entity need not provide or pay for hospital inpatient or outpatient services that it can show are being provided directly, through insurance, or under arrangements, by other entities.)

(iii) Medically necessary emergency services.

(iv) Diagnostic laboratory services and diagnostic and therapeutic radiologic services.

These services must meet the requirement of § 417.101, but may be limited in time and cost without regard to the constraints imposed by § 417.101(a).

(4) *Payment for services*—(i) *General rule.* The entity pays for basic health services in accordance with § 417.104, except that it need not comply with the copayments limitations imposed by § 417.104(a)(4).

(ii) *Determination of payment rates.* In determining payment rates, the entity need not comply with the community rating requirements of §§ 417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of CMS's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of CMS's determination, and which are renewed or renegotiated during the period approved by CMS under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to CMS that—

(A) May not extend for more than 3 years from the date of CMS's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of CMS's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of CMS's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If CMS determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, CMS gives the entity written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

[59 FR 49836, Sept. 30, 1994]

§417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.* (1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by CMS.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the PHS Act and in subparts B and C of this part, this subpart D, and 417.168 and 417.169 of subpart F.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, CMS determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) $18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, CMS determines that there is no need for a site visit, $8,000 will be returned to the applicant.

(2) $6,900 for an HMO seeking expansion of its service area.

(3) $3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* CMS refunds an application fee only if the entity withdraws its application within

10 working days after receipt by CMS. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If CMS determines that a change in the amount of a fee is appropriate, CMS issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under this subpart for the same type of determination for four full months after the date of the notice in which CMS denied the application.

(h) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993]

§ 417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that CMS obtains through onsite visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the entity meets the applicable requirements of §§ 417.142 and 417.143.

(b) *Notice of determination.* CMS notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny.* (1) If CMS finds that the entity does not appear to meet the requirements for qualification and appears to be able to meet those requirements within 60 days, CMS gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding, and may revise its application to remedy any defects identified by CMS.

(d) *Denial and reconsideration of denial.* (1) If CMS denies an application for qualification under this subpart, CMS gives the entity written notice of the denial and an opportunity to request reconsideration of that determination.

(2) A request for reconsideration must—

(i) Be submitted in writing, within 60 days following the date of the notice of denial;

(ii) Be addressed to the CMS officer or employee who denied the application; and

(iii) Set forth the grounds upon which the entity requests reconsideration, specifying the material issues of fact and of law upon which the entity relies.

(3) CMS bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to CMS.

(4) CMS gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs*—(1) FEDERAL REGISTER *notices.* In quarterly FEDERAL REGISTER notices, CMS gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings.* A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, room 4360,

Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

[59 FR 49837, Sept. 30, 1994]

Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.150 Definitions.

As used in this subpart, unless the context indicates otherwise—

Agreement means a collective bargaining agreement.

Bargaining representative means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

Carrier means a voluntary association, corporation, partnership, or other organization that is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, enrollment or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

Collective bargaining agreement means an agreement entered into between an employing entity and the bargaining representative of its employees.

Contract means an employer-employee or public entity-employee contract, or a contract for health benefits.

Designee means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of enrollment in a qualified health maintenance organization to their eligible employees.

Eligible employee means an employee who meets the employer's requirements for participation in the health benefits plan.

Employee means any individual employed by an employer or public entity on a full-time or part-time basis.

Employer has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

Employing entity means an employer or public entity.

Employing entity-employee contract means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

Group enrollment period means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

Health benefits contract means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment

for, health benefits to eligible employees or to eligible employees and their eligible dependents.

Health benefits plan means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

Public entity means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

Qualified HMO means an HMO that has in effect a determination, made under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

To offer a health benefits plan means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through payments on any basis into a health and welfare trust fund.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993; 59 FR 49837, 49843, Sept. 30, 1994]

§ 417.151 Applicability.

(a) *Basic rule.* Effective October 24, 1995,[1] this subpart applies to any employing entity that offers a health benefits plan to its employees, meets the conditions specified in paragraphs (b) through (e) of this section, and elects to include one or more qualified HMOs in the health plan alternatives it offers its employees.

(b) *Number of employees.* During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage.* During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act.* The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Employees in HMO's service area.* At least 25 of the employing entity's employees reside within the HMO's service area.

[59 FR 49838, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

§ 417.153 Offer of HMO alternative.

(a) *Basic rule.* An employing entity that is subject to this subpart and that elects to include one or more qualified HMOs must offer the HMO alternative in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option.* (1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO—

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

[59 FR 49839, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

[1] Before October 24, 1995, an employing entity that met the conditions specified in § 417.151 was required to include one or more qualified HMOs, if it received from at least one qualified HMO a written request for inclusion and that request met the timing, content, and procedural requirements specified in § 417.152.

§417.155 How the HMO option must be included in the health benefits plan.

(a) *HMO access to employees*—(1) *Purpose and timing*—(i) *Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in §417.153(b), so that the HMO can explain its program in accordance with §417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of §417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* (1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage*—(1) *Prohibition of restrictions.* If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for ''free-standing'' health benefits*—(1) *Basic requirement.* At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *''Free-standing'' defined.* For purposes of this paragraph, the term ''free-standing'' refers to a benefit that—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be

made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection*—(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

(i) Are required to be offered under State law.

(ii) Are included uniformly by the HMO in its prepaid benefit package.

(iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

[59 FR 49840, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.156 When the HMO must be offered to employees.

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

(i) When a new agreement is negotiated;

(ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or

(iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the contract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

(i) At the time each contract or arrangement is renewed or reissued; or

(ii) The benefits provided under the contract or arrangement are offered to employees.

[59 FR 49841, Sept. 30, 1994]

§417.157 Contributions for the HMO alternative.

(a) *General principles*—(1) *Nondiscrimination.* The employer contribution to an HMO must be in an amount that does not discriminate financially against an employee who enrolls in an HMO. A contribution does not discriminate financially if the method of determining the contribution is reasonable and is designed to ensure that employees have a fair choice among health benefits plan alternatives.

(2) *Effect of agreements or contracts.* The employing entity or designee is not required to pay more for health benefits as a result of offering the HMO alternative than it would otherwise be required to pay under a collective bargaining agreement or contract that provides for health benefits and is in effect at the time the HMO alternative is included.

(3) *Examples of acceptable employer contributions.* The following are methods that are considered nondiscriminatory:

(i) The employer contribution to the HMO is the same, per employee, as the contribution to non-HMO alternatives.

(ii) The employer contribution reflects the composition of the HMO's enrollment in terms of enrollee attributes that can reasonably be used to predict utilization, experience, costs, or risk. For each enrollee in a given class established on the basis of those attributes, the employer contributes an equal amount, regardless of the health benefits plan chosen by the employee.

(iii) The employer contribution is a fixed percentage of the premium for each of the alternatives offered.

(iv) The employer contribution is determined under a mutually acceptable arrangement negotiated by the HMO and the employer. In negotiating the arrangement, the employer may not insist on terms that would cause the HMO to violate any of the requirements of this part.

(4) *Adjustment of employer contribution.* An employer contribution determined by an acceptable method may in some cases be adjusted if it would result in a nominal payment or no payment at all by HMO enrollees (because the HMO premium is lower than the

premiums for the other alternatives offered). If, for example the employer has a policy of requiring all employees to contribute to their health benefits plan, the employer may require HMO enrollees who would otherwise pay little or nothing at all, to make a payment that does not exceed 50 percent of the employee contribution to the principal non-HMO alternative. The principal non-HMO alternative is the one that covers the largest number of enrollees from the particular employer.

(b) *Administrative expenses.* (1) In determining the amount of its contribution to the HMO, the employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan.

(2) However, if the employing entity or designee has special requirements for other than standard solicitation brochures and enrollment literature, it must, in the case of the HMO alternative, determine and distribute any administrative costs attributable to those requirements in a manner consistent with its method of determining and distributing those costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or the designee's cost for the HMO alternative, the employing entity or designee may exclude those portions of the contribution allocable to benefits (such as life insurance or insurance for supplemental health benefits)—

(1) For which eligible employees and their eligible dependents are covered notwithstanding selection of the HMO alternative; and

(2) That are not offered on a prepayment basis by the HMO to the employing entity's employees.

(d) *Contributions determined by agreements or contracts or by law.* If the specific amount of the employing entity's contribution for health benefits is fixed by an agreement or contract, or by law, that amount constitutes the employing entity's obligation for contribution toward the HMO premiums.

(e) *Allocation of portion of a contribution determined by an agreement.* In some cases, the employing entity's contribution for health benefits is determined by an agreement that also provides for benefits other than health benefits. In that case, the employing entity must determine, or instruct its designee to determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to CMS upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *CMS review of data.* (1) CMS may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of CMS's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request CMS to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

§ 417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway

Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§417.160 Applicability.

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

§417.161 Compliance with assurances.

Any entity subject to this subpart must comply with the assurances that it provided to CMS, unless compliance is waived under §417.166.

[58 FR 38071, July 15, 1993]

§417.162 Reporting requirements.

Entities subject to this subpart must submit:

(a) The reports that may be required by CMS under §417.126, and

(b) Any additional reports CMS may reasonably require.

[58 FR 38071, July 15, 1993]

§417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with CMS a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) CMS may initiate investigations when, based on a report, a complaint, or any other information, CMS has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When CMS initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) CMS obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that CMS considers appropriate in seeking this information.

(c) *Determination and notice by CMS*—(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by CMS in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for CMS's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If CMS determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—

(1) CMS revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, CMS provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day

after the day of the notice unless CMS receives a request for reconsideration by that date.

(4) If after reconsideration CMS again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) CMS publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in § 417.164.

(e) *Notice by the HMO.* Within 15 days after the date CMS issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed.* (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§ 417.104 and 417.105. The additional rules applicable to Medicare enrollees are in § 415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability.* This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action.* If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§ 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under § 417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§ 417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under § 417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§ 417.166 Waiver of assurances.

(a) *General rule.* CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subparts G–I [Reserved]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

§417.401 Definitions.

As used in this subpart and subparts K through R of this part, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by CMS in advance of an HMO's or CMP's contract period that represents what the average per capita cost to the Medicare program would be for each class of the HMO's or CMP's Medicare enrollees if they had received covered services other than through the HMO or CMP in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk HMO or CMP would charge Medicare enrollees independently of Medicare payments if the HMO or CMP used the same rates it charges non-Medicare enrollees for a benefit package limited to covered Medicare services.

Arrangement means a written agreement between an HMO or CMP and another entity, under which—

(1) The other entity agrees to furnish specified services to the HMO's or CMP's Medicare enrollees;

(2) The HMO or CMP retains responsibility for the services; and

(3) Medicare payment to the HMO or CMP discharges the beneficiary's obligation to pay for the services.

Benefit stabilization fund means a fund established by CMS, at the request of a risk HMO or CMP, to withhold a portion of the per capita payments available to the HMO or CMP and pay that portion in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits the HMO or CMP provides to its Medicare enrollees.

Cost contract means a Medicare contract under which CMS pays the HMO or CMP on a reasonable cost basis.

Cost HMO or CMP means an HMO or CMP that has in effect a cost contract

with CMS under section 1876 of the Act and subpart L of this part.

Demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source other than the HMO or CMP and that meet the following conditions:

(1) Are needed immediately because of an injury or sudden illness.

(2) Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance and the nature of the medical condition.

Geographic area means the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means a Medicare beneficiary who has been identified on CMS records as an enrollee of an HMO or CMP that has a contract with CMS under section 1876 of the Act and subpart L of this part.

New Medicare enrollee means a Medicare beneficiary who—

(1) Enrolls with an HMO or CMP after the date on which the HMO or CMP first enters into a risk contract under subpart L of this part; and

(2) Was not enrolled with the HMO or CMP at the time he or she became entitled to benefits under Part A or eligible to enroll in Part B of Medicare.

Risk contract means a Medicare contract under which CMS pays the HMO or CMP on a risk basis for Medicare covered services.

Risk HMO or CMP means an HMO or CMP that has in effect a risk contract with CMS under section 1876 of the Act and subpart L of this part.

Urgently needed services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that—

(1) Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

(2) Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 51986, Oct. 17, 1991; 58 FR 38072, July 15, 1993; 60 FR 45675, Sept. 1, 1995]

§ 417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2013, where—

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000.

[63 FR 35066, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4713, Jan. 28, 2005; 73 FR 54248, Sept. 18, 2008; 76 FR 21560, Apr. 15, 2011; 76 FR 54633, Sept. 1, 2011]

§417.404 General requirements.

(a) In order to contract with CMS under the Medicare program, an entity must—

(1) Be determined by CMS to be an HMO or CMP (in accordance with §§117.142 and 417.407, respectively); and

(2) Comply with the contract requirements set forth in subpart L of this part.

(b) CMS enters into or renews a contract only if it determines that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

[60 FR 45675, Sept. 1, 1995]

§417.406 Application and determination.

(a) *Responsibility for making determinations.* CMS is responsible for determining whether an entity meets the requirements to be an HMO or CMP.

(b) *Application requirements.* (1) The application requirements for HMOs are set forth in §417.143.

(2) The requirements of §417.143 also apply to CMPs except that there are no application fees.

(c) *Determination.* CMS uses the procedures set forth in §417.144(a) through (d) to determine whether an entity is an HMO or CMP.

(d) *Oversight of continuing compliance.* (1) CMS oversees an entity's continued compliance with the requirements for an HMO as defined in §417.1 or for a CMP as set forth in §417.407.

(2) If an entity no longer meets those requirements, CMS terminates the contract of that entity in accordance with §417.494.

[60 FR 45675, Sept. 1, 1995]

§417.407 Requirements for a Competitive Medical Plan (CMP).

(a) *General rule.* To qualify as a CMP, an entity must be organized under the laws of a State and must meet the requirements of paragraphs (b) through (f) of this section.

(b) *Required services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, the entity furnishes to its enrollees at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, x-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) Exception for Medicaid prepayment risk contracts. An entity that had, before 1970, a Medicaid prepayment risk contract that did not include provision of inpatient hospital services is not required to provide those services.

(c) *Compensation for services.* The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrollees on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any enrollee.

(d) *Source of physicians' services.* The entity provides physicians' services primarily through—

(1) Physicians who are employees or partners of the entity; or

(2) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(e) *Assumption of financial risk.* The rules set forth in §417.120(b) for HMOs

apply also to CMPs except that reference to ''basic services'' must be read as reference to the required services listed in paragraph (b) of this section.

(f) *Protection of enrollees.* The entity provides adequately against the risk of insolvency by meeting the requirements of §§ 417.120(a) and 417.122 for protection of enrollees against loss of benefits and liability for payment of any fees that are the legal responsibility of the entity.

[60 FR 45675, Sept. 1, 1995]

§ 417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by CMS. (2) Whenever feasible, CMS exempts the HMO or CMP from resubmittal of information it has already submitted to CMS in connection with a determination made under the provisions of § 417.406.

(b) *Approval of application.* (1) If CMS approves the application, it gives written notice to the HMO or CMP, indicating that it meets the requirements for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the HMO or CMP is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in subpart R of this part.

(c) *Denial of application.* If CMS denies the application, it gives written notice to the HMO or CMP indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the HMO or CMP does not meet the contract requirements; and

(3) The HMO's or CMP's right to request reconsideration in accordance with the procedures specified in subpart R of this part.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.410 Qualifying conditions: General rules.

(a) *Basic requirement.* In order to qualify for a contract with CMS under this subpart, an HMO or CMP must demonstrate its ability to enroll Medicare beneficiaries and other individuals and groups and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) *Other qualifying conditions.* An HMO or CMP must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

(c) *Standards.* Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an HMO or CMP to determine its qualifications for a Medicare contract.

(d) *Application of standards.* Application of the standards enables the surveyor to determine—

(1) The HMO's or CMP's activities;

(2) The extent to which the HMO or CMP complies with each condition;

(3) The nature and extent of any deficiencies; and

(4) The need for improvement if CMS should enter into a contract with the HMO or CMP.

(e) *Requirements for a risk contract.* An HMO or CMP may enter into a risk contract with CMS if it—

(1) Meets all the applicable requirements in the statute and regulations;

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in § 417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies CMS that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost sontract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

(1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

(a) Has sufficient administrative capability to carry out the requirements of the contract; and

(b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid beneficiaries constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid beneficiaries in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or ''accreted'' to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section. CMS may decline to renew an HMO's or CMP's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if

compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid beneficiaries (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be ''substantially nonrepresentative'' if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in §417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs*—(1) *Basic requirement.* Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.* (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in §417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision.* The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement.* The following services may be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in §491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in §410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a clinical social worker (as defined at §410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a clinical social worker (as defined in §410.73 of this chapter). Services incident to the professional services of a clinical social worker furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity.* (1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The HMO or CMP must maintain a health (including medical) record-keeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

(3) The HMO or CMP must meet network adequacy standards specified in §422.116 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 20130, Apr. 23, 1998; 85 FR 33901, June 2, 2020]

§ 417.418 Qualifying condition: Quality assurance program.

(a) *Condition.* The HMO or CMP must make arrangements for a quality assurance program that meets the requirements of this section.

(b) *Standard.* An HMO or CMP must have an ongoing quality assurance program that meets the requirements set forth in §417.106(a).

[58 FR 38072, July 15, 1993]

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.420 Basic rules on enrollment and entitlement.

(a) *Enrollment.* Eligible individuals who are entitled to benefits under both Part A and Part B of Medicare or only

Part B may elect to receive those benefits through an HMO or CMP that has in effect a contract with CMS under subpart L of this part.

(b) *Entitlement.* If a Medicare beneficiary enrolls with an HMO or CMP, CMS pays the HMO or CMP on his or her behalf for the services to which he or she is entitled.

(c) *Beneficiary liability.* (1) The HMO or CMP may require payment, in the form of premiums or otherwise, from individuals for services not covered under Medicare, as well as deductible and coinsurance amounts attributable to Medicare covered services.

(2) As described in §417.448, Medicare enrollees of risk HMOs or CMPs are liable for services that they obtain from sources other than the HMO or CMP, unless the services are—

(i) Emergency or urgently needed; or

(ii) Determined, on appeal under subpart Q of this part, to be services that should have been furnished by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 80 FR 7958, Feb. 12, 2015]

§417.422 Eligibility to enroll in an HMO or CMP.

Except as specified in §§417.423 and 417.424, an HMO or CMP must enroll, either for an indefinite period or for a specified period of at least 12 months, any individual who meets all of the following:

(a) Is entitled to Medicare benefits under Parts A and B or under Part B only.

(b) Lives within the geographic area served by the HMO or CMP.

(c) Is not enrolled in any other HMO or CMP that has entered into a contract under subpart L of this part.

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment.

(e) Agrees to abide by the HMO's or CMP's rules after they are disclosed to him or her in connection with the enrollment process.

(f) Is not denied enrollment by the HMO or CMP under a selection policy, if any, that has been approved by CMS under §417.424(b).

(g) Is not denied enrollment by the HMO or CMP on the basis of any of the administrative criteria concerning denial of enrollment in §417.424(a).

(h) Is a United States citizen or an individual who is lawfully present in the United States as determined in 8 CFR 1.3.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012; 80 FR 7958, Feb. 12, 2015]

§417.423 Special rules: ESRD and hospice patients.

(a) *ESRD patients.* (1) A Medicare beneficiary who has been medically determined to have end-stage renal disease is not eligible to enroll in an HMO or CMP.

(2) However, if a beneficiary is already enrolled in an HMO or CMP when he or she is determined to have end-stage renal disease, the HMO or CMP—

(i) Must reenroll the beneficiary as required by §417.434; and

(ii) May not disenroll the beneficiary except as provided in §417.460.

(b) *Hospice patients.* A Medicare beneficiary who elects hospice care under §418.24 of this chapter is not eligible to enroll in an HMO or CMP as long as the hospice election remains in effect.

[60 FR 45677, Sept. 1, 1995]

§417.424 Denial of enrollment.

(a) *Basis for denial.* An HMO or CMP may deny enrollment to an individual who meets the criteria of §417.422 if acceptance would—

(1) Cause the number of enrollees who are Medicare or Medicaid beneficiaries to exceed 50 percent of the HMO's or CMP's total enrollment;

(2) Prevent the HMO or CMP from complying with any of the other contract qualifying conditions set forth in subpart J of this part;

(3) Require the HMO or CMP to exceed its enrollment capacity; or

(4) Cause the enrollment to become substantially nonrepresentative of the general population in the HMO's or CMP's geographic area.

(b) *Selection policies.* (1) Denial under paragraph (a)(4) of this section must be in accordance with written selection

policies approved by CMS. (2) Enrollment of individuals will not be considered to make the enrollment of the HMO or CMP substantially nonrepresentative of the general population in the HMO's or CMP's geographic area unless, as a result of the enrollment, the proportion of the subgroup of enrollees to which the enrollee belongs as compared to the HMO's or CMP's total enrollment exceeds by at least ten percent the subgroup's proportion of the general population in the geographic area of the HMO or CMP. (A subgroup is a class of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.)

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* (1) HMOs or CMPs must provide open enrollment for Medicare beneficiaries for at least 30 consecutive days during each contract year.

(2) During open enrollment, the HMO or CMP must enroll eligible Medicare beneficiaries in the order in which their applications are received and until its enrollment capacity is reached.

(3) The HMO or CMP may accept applications from Medicare beneficiaries after it has reached capacity if it places those individuals on a waiting list and enrolls them in chronological order as vacancies occur.

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

(b) *Capacity to accept new enrollees.* (1) If an HMO or CMP chooses to limit enrollments because of its capacity, it must notify CMS at least 90 days before the beginning of its open enrollment period and, at that time, provide CMS with its reasons for limiting enrollment.

(2) CMS evaluates the HMO's or CMP's submittal under paragraph (b)(1) of this section.

(3) The HMO or CMP must promptly notify CMS if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* (1) Subject to CMS's approval, an HMO or CMP may set aside a reasonable number of vacancies for an anticipated new group contract or for anticipated new enrollees under an existing group contract that will have its enrollment period after the Medicare open enrollment period during the contract year.

(2) Any set aside vacancies that are not filled within a reasonable time after the beginning of the group contract enrollment period must be made available to Medicare beneficiaries and other nongroup applicants under the requirements of this subpart.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§ 417.427 Extending MA and Part D program disclosure requirements to section 1876 cost contract plans.

(a) The procedures and requirements relating to disclosure in § 422.111 and § 423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of §§ 422.111 and 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

[77 FR 22166, Apr. 12, 2012]

§ 417.428 Marketing activities.

(a) With the exception of § 422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

[75 FR 19802, Apr. 15, 2010]

§ 417.430 Application procedures.

(a) *Application forms and other enrollment mechanisms.* (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS as described in

§422.2262 of this chapter. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between HHS and its designees and the HMO or CMP.

(2) The HMO or CMP must file and retain application forms for the period specified in CMS instructions.

(b) *Handling of applications.* An HMO or CMP must have an effective system for receiving, controlling, and processing applications from Medicare beneficiaries. The system must meet the following conditions and requirements:

(1) Each application is dated as of the day it is received.

(2) Applications are processed in chronological order by date of receipt.

(3) The HMO or CMP gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) The notice of acceptance. If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) The notice of denial explains the reason for denial.

(6) The HMO or CMP transmits the information necessary for CMS to add the beneficiary to its records of the HMO's or CMP's Medicare enrollees—

(i) Within 30 days from the date of application or from the date a vacancy occurs for an applicant who was accepted (for future enrollment) while there were no vacancies; or

(ii) Within an additional period of time approved by CMS on a showing by the HMO or CMP that it needs more time.

(7) The HMO or CMP promptly notifies the beneficiary of the effective month of his or her enrollment as a Medicare enrollee, when it receives that information from CMS.

(8) If the HMO or CMP accepts applications while it is enrolled to capacity, its procedures ensure that vacancies are filled in chronological order by date of application of beneficiaries who are still eligible to enroll, unless that would result in failure to comply with any of the qualifying conditions set forth in §417.413.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 76 FR 21560, Apr. 15, 2011; 83 FR 16721, Apr. 16, 2018]

§417.432 Conversion of enrollment.

(a) *Basic rule.* An HMO or CMP must accept as a Medicare enrollee any individual who is enrolled in the HMO or CMP for the month immediately before the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(b) *Effective date of conversion.* Unless the individual chooses to disenroll from the HMO or CMP the individual's conversion to a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(c) *Prohibition against disenrollment.* An HMO or CMP may not disenroll an individual who is converting under the provisions of paragraph (a) of this section unless one of the conditions specified in §417.460 is met.

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in §417.430(a).

(e) *Expedited submittal of information to CMS.* The HMO or CMP must notify CMS, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for CMS to include the enrollee in its records as a Medicare enrollee of the HMO or CMP:

(1) At least 30, but no earlier than 90, days before the enrollee—

(i) Attains age 65; or

(ii) Reaches his or her 25th month of entitlement to social security disability benefits under title II of the Act or railroad retirement disability benefits under section 7(d) of the Railroad Retirement Act of 1974.

(2) Within 30 days after the enrollee initiates a course of renal dialysis, or on or before the day he or she enters a

hospital in anticipation of a kidney transplant.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 77 FR 22166, Apr. 12, 2012]

§ 417.434 Reenrollment.

If an HMO or CMP requires periodic reenrollment, it must reenroll Medicare enrollees unless there is a basis for disenrollment as set forth in § 417.460.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.436 Rules for enrollees.

(a) *Maintaining rules.* An HMO or CMP must maintain written rules that deal with, but need not be limited to the following:

(1) All benefits provided under the contract, as described in § 417.440.

(2) How and where to obtain services from or through the HMO or CMP.

(3) The restrictions on coverage for services furnished from sources outside a risk HMO or CMP, other than emergency services and urgently needed services (as defined in § 417.401).

(4) The obligation of the HMO or CMP to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services as required by § 417.414(c).

(5) Any services other than the emergency or urgently needed services that the HMO or CMP chooses to provide as permitted by this part, from sources outside the HMO or CMP. A cost HMO or CMP must disclose that the enrollee may receive services through any Medicare providers and suppliers.

(6) Premium information, including the amount (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable.

(7) Grievance and appeal procedures.

(8) Disenrollment rights.

(9) The obligation of an enrollee who is leaving the HMO's or CMP's geographic area for more than 90 days to notify the HMO or CMP of the move or extended absence and the HMO's or CMP's policies concerning retention of enrollees who leave the geographic area for more than 90 days, as described in § 417.460(a)(2).

(10) The expiration date of the Medicare contract with CMS and notice that both CMS and the HMO or CMP are authorized by law to terminate or refuse to renew the contract, and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the HMO or CMP.

(11) Advance directives as specified in paragraph (d) of this section.

(12) Any other matters that CMS may prescribe.

(b) *Availability of rules.* The HMO or CMP must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter.

(c) *Changes in rules.* If an HMO or CMP changes its rules, it must submit the changes to CMS in accordance with § 417.428(a)(3), and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

(d) *Advance directives.* (1) An HMO or CMP must maintain written policies and procedures concerning advance directives, as defined in § 489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of

those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

(*1*) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(*2*) Identify the state legal authority permitting such objection; and

(*3*) Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency.

[58 FR 38072, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994; 60 FR 33292, June 27, 1995]

§417.440 Entitlement to health care services from an HMO or CMP.

(a) *Basic rules.* (1) Subject to the conditions and limitations set forth in this subpart, a Medicare enrollee of an HMO or CMP is entitled to receive health care services and supplies directly from, or through arrangements made by, the HMO or CMP as specified in this section and §§417.442–417.446.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services are—

(i) Emergency services or urgently needed services as defined §417.401;

(ii) Services denied by the HMO or CMP and found (upon appeal under subpart Q of this part) to be services the

enrollee was entitled to have furnished by the HMO or CMP.

(b) *Scope of services*—(1) *Part A and Part B services.* Except as specified in paragraphs (c), (d), and (e) of this section, a Medicare enrollee is entitled to receive from an HMO or CMP all the Medicare-covered services that are available to individuals residing in the HMO's or CMP's geographic area, as follows:

(i) Medicare Part A and Part B services if the enrollee is entitled to benefits under both programs.

(ii) Medicare Part B services if the enrollee is entitled only under that program.

(2) *Supplemental services elected by an enrollee.* (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

(3) *Supplemental services imposed by a risk HMO or CMP.* (i) Subject to CMS's approval, a risk HMO or CMP may require Medicare enrollees to accept and pay for services in addition to those covered by Medicare. (ii) If the HMO or CMP elects this option, it must impose the requirement on all Medicare enrollees, without regard to health status. (iii) CMS approves supplemental benefits of this type if CMS determines that imposition of the requirements will not discourage other Medicare beneficiaries from enrolling in the risk HMO or CMP.

(4) *Additional benefits from risk HMOs or CMPs required by statute.* Subject to the conditions stated in § 417.442, a new Medicare enrollee or a current nonrisk Medicare enrollee who converts to risk reimbursement under § 417.444 is eligible to receive, in addition to the covered Part A and Part B benefits for which he or she is eligible, benefits consisting of one or both of the following:

(i) A reduction in the HMO's or CMP's premium rate or in other charges for services furnished to Medicare enrollees.

(ii) Provision of health benefits or services beyond the required Part A and Part B coverage.

(5) *Special supplemental benefits.* Under conditions described in § 417.444(c), current nonrisk Medicare enrollees who are not converted to the risk portion of the contract, may enroll in a special supplemental plan, if offered by the HMO or CMP, for some or all of the additional benefits described in paragraph (b)(4) of this section.

(c) *Limitation on hospice care*—(1) *Extent of limitation*—(i) *Basic rule.* Except as provided in paragraph (c)(1)(ii) of this section, a Medicare enrollee who elects to receive hospice care under § 418.24 of this chapter waives the right to receive from the HMO or CMP any Medicare services (including services equivalent to hospice care) that are related to the terminal condition for which the enrollee elected hospice care, or to a related condition.

(ii) *Exception.* An enrollee who elects hospice care retains the right to services furnished by his or her attending physician if that physician—

(A) Is an employee or contractor of the HMO or CMP; and

(B) Is not an employee of the designated hospice and does not receive compensation from the hospice for those services.

(2) *Effective date of limitation.* The limitation in paragraph (c)(1) of this section begins on the effective date of the beneficiary's election of hospice care and remains in effect until the earlier of the following:

(i) The effective date of the enrollee's revocation of the election of hospice care as described in § 418.28 of this chapter.

(ii) The date the enrollee exhausts his or her hospice benefits.

(3) *Payment to HMO or CMP.* For the period that the Medicare enrollee's election of hospice care is in effect, CMS pays a cost HMO or CMP only as described in § 417.585.

(d) *Limitation on provision of inpatient hospital services.* If a beneficiary's effective date of coverage, as specified in §417.450, in a risk HMO or CMP occurs during an inpatient stay in a hospital paid for under part 412 of this chapter, the HMO or CMP—

(1) Is not responsible for the provision of any of the inpatient hospital services under Part A during the stay and is not required to pay for those services;

(2) Must assume responsibility for payment for or provision of inpatient hospital services under Part A on the day after the day of discharge from the inpatient stay; and

(3) Is responsible for the full scope of services under paragraph (b) of this section, other than inpatient hospital services under Part A, beginning on the effective date of enrollment.

(e) *Extension of provision of inpatient hospital services.* If an enrollee's effective date of disenrollment, as defined by §417.460, occurs during an inpatient stay in a hospital paid for under part 412 of this chapter and the stay is provided or arranged for by the HMO or CMP, or the HMO or CMP is financially responsible for the hospitalization under paragraph (a)(2) of this section, the HMO or CMP—

(1) Is financially responsible for payment of the inpatient services under Part A through the date the beneficiary is discharged from the inpatient stay; and

(2) Is not responsible for the provision of services, furnished on or after the effective date of disenrollment, other than inpatient hospital services under Part A.

(f) *Notice of noncoverage of inpatient hospital care.* (1) If an enrollee is an inpatient of a hospital, entitlement to inpatient hospital care continues until he or she receives notice of noncoverage of that care.

(2) Before giving notice of noncoverage, the HMO or CMP must obtain the concurrence of its affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP.

(3) The HMO or CMP must give the enrollee written notice that includes the following:

(i) The reason why inpatient hospital care is no longer needed.

(ii) The effective date of the enrollee's liability for continued inpatient care.

(iii) The enrollee's appeal rights.

(4) If the HMO or CMP delegates to the hospital the determination of noncoverage of inpatient care, the hospital obtains the concurrence of the HMO- or CMP-affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP, and sends notice, following the procedures set forth in §412.42(c)(3) of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 70 FR 4525, Jan. 28, 2005]

§417.442 Risk HMO's and CMP's: Conditions for provision of additional benefits.

(a) *General rule.* Except as provided in paragraph (b) of this section, a risk HMO or CMP must, during any contract period, provide to its Medicare enrollees the additional benefits described in §417.440(b)(4) if its ACRs (calculated in accordance with §417.594) are less than the average per capita rates that CMS pays for the Medicare enrollees during the contract period.

(b) *Exceptions*—(1) *Reduced payment election.* An HMO or CMP is not obligated to furnish additional services under paragraph (a) of this section if it has requested a reduction in its monthly payment from CMS under §417.592(e), and it—

(i) Elects to receive reduced payment so that there is no difference between the average of its per capita rates of payment and its ACR; or

(ii) Elects to receive partially reduced payment and furnish Medicare enrollees with additional benefits described in §417.440 (b)(4) so that the combined value of benefits and reduced payment is equivalent to the difference between the average of its per capita rates of payment and its ACR.

(2) *Benefit stabilization fund.* An HMO or CMP may elect to have a part of the value of the additional benefits it must

provide under paragraph (a) of this section withheld in a benefit stabilization fund as described in § 417.596.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.444 Special rules for certain enrollees of risk HMOs and CMPs.

(a) *Applicability.* This section applies to any Medicare enrollee of a risk HMO or CMP who meets the following conditions:

(1) On February 1, 1985, was enrolled—

(i) In an HMO or CMP that had in effect a cost contract entered into under section 1876 of the Act in accordance with regulations in effect before February 1, 1985; or

(ii) In an HCPP that was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act.

(2) Has continued enrollment in the same entity without interruption or disenrolled after February 1, 1985, and later reenrolled in the same entity.

(b) *Retention of nonrisk status*—(1) A ''nonrisk'' enrollee is a Medicare beneficiary who meets the conditions of paragraph (a) of this section and is enrolled in an entity that enters into a risk contract as an HMO or CMP. A ''nonrisk'' enrollee may retain nonrisk status indefinitely unless CMS determines under paragraph (c)(1) of this section, that the enrollee's status must be changed, or the enrollee requests the change, as provided in paragraph (c)(2) of this section.

(2) A nonrisk enrollee of a risk HMO or CMP is not entitled to additional benefits under § 417.442.

(c) *Conversion to risk status*—(1) *Conversion based on CMS determination.* If CMS determines that, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the HMO or CMP, all of its nonrisk Medicare enrollees must be covered under the risk provisions of the contract, the conversion process is as follows:

(i) CMS notifies each affected enrollee of the decision at least 90 days prior to the effective date.

(ii) The nonrisk Medicare enrollees complete and sign forms stating that they understand and accept the new rules and benefits that will be applicable to them.

(iii) The HMO or CMP notifies each affected enrollee, in writing, at least 30 days in advance, of the date upon which his or her coverage under the risk portion of the contract takes effect.

(2) *Conversion based on enrollee's request.* A nonrisk Medicare enrollee requests, using a form identical or similar to the form described in paragraph (c)(1) of this section, that he or she be covered under the risk portion of the contract.

(d) *Notification.* An HMO or CMP converting from a cost contract to a risk contract must, within 60 days of signing the risk contract, inform nonrisk enrollees of their right to remain nonrisk Medicare enrollees or to convert to risk enrollment at any time in accordance with paragraph (c)(2) of this section.

[58 FR 38073, July 15, 1993]

§ 417.446 [Reserved]

§ 417.448 Restriction on payments for services received by Medicare enrollees of risk HMOs or CMPs.

(a) *Basic rule.* Except for emergency and urgently needed services as defined in § 417.401, risk HMOs or CMPs are not required to make payments to or on behalf of certain Medicare enrollees, for any services received by the enrollees that are not provided—

(1) Directly by the HMO or CMP; or

(2) Through arrangements made by the HMO or CMP.

(b) *Application.* The restriction on payments for services imposed by paragraph (a) of this section applies to services received by—

(1) New Medicare enrollees;

(2) Nonrisk Medicare enrollees who convert to risk reimbursement; and

(3) Nonrisk Medicare enrollees who elect special supplemental benefit plans.

(c) *End of restriction.* The restriction of payments imposed by paragraph (a) of this section ends when a Medicare enrollee leaves the HMO's or CMP's geographic area for an extended period as defined in § 471.460(a)(2) and the HMO or

CMP and the enrollee make arrangements for enrollment to continue as provided in §417.460(a)(2)(iv).

(d) *Timing.* The effective date for the end of the restriction on payments, as discussed in paragraph (c) of this section is the first day of the first month following the month in which the enrollee notifies the HMO or CMP as required in §417.436(a)(9), that he or she has left the HMO's or CMP's geographic area for an extended period.

[51 FR 28573, Aug. 8, 1986, as amended at 56 FR 46571, Sept. 13, 1991; 58 FR 38079, July 15, 1993]

§417.450 Effective date of coverage.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, and notwithstanding the provisions of §417.440(d).

(1) CMS's liability for payments to an HMO or CMP on behalf of a Medicare beneficiary begins on the first day of the month in which he or she is—

(i) Entitled to Medicare benefits; and

(ii) Enrolled in an HMO or CMP; and

(2) The effective month of coverage may not be earlier than the first month after, nor later than the third month after the month in which CMS receives the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in CMS records.

(b) *Exceptions.* (1) CMS may approve a later month if it is requested by the HMO or CMP and the beneficiary.

(2) If an individual becomes an HMO or CMP enrollee before becoming entitled to Medicare Part B benefits, the effective month of coverage is the first month for which he or she becomes entitled to Medicare Part B benefits.

(c) *Notice of effective date of coverage.* For each beneficiary added to CMS's records as an enrollee of an HMO or CMP, CMS gives the HMO or CMP prompt written notice of the month with which CMS's liability begins.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance.* (1) A Medicare enrollee of an HMO or CMP is responsible for applicable Medicare deductible and coinsurance amounts, unless the HMO's or CMP's charges for these amounts are reduced under the additional benefits provision of §417.442.

(2) The deductible and coinsurance amounts may be paid by or on behalf of the enrollee in the form of a premium, membership fee, charge per unit, or other similar charge.

(3) The sum of the amounts the HMO or CMP charges its Medicare enrollees for Medicare deductibles and coinsurance may not exceed, on the average, the actuarial value of the deductible and coinsurance the Medicare enrollees otherwise would have been liable for had they not enrolled in the HMO or CMP or in another HMO or CMP.

(b) *Services not covered under Medicare.* Unless the services are provided as additional benefits under §417.442, a Medicare enrollee of an HMO or CMP is liable for payment for—

(1) All services that are not covered under Medicare Part A or Part B; or

(2) If entitled only to Medicare Part B benefits, all services that are not covered under Medicare Part B.

(c) *Services for which Medicare is not primary payer.* A Medicare enrollee of an HMO or CMP is liable for payments made to the enrollee for all covered services for which Medicare is not the primary payer as provided in §417.528.

(d) *Optional supplemental benefits plan.* (1) The HMO or CMP may offer its Medicare enrollees a supplemental benefit plan to cover deductible and coinsurance amounts, or services not covered under Medicare, or both.

(2) If a supplemental benefit plan premium includes charges for both noncovered services and the deductible and coinsurance amounts applicable to covered services, the portion of the premium that is for deductibles and coinsurance must be computed separately and must be disclosed to the beneficiary during the enrollment process and before he or she elects coverage options.

(3) The sum of the amounts an HMO or CMP charges its Medicare enrollees for services that are not covered under Part A or Part B may not exceed the ACR for these services.

(e) *Coverage of Part A services for Part B-only Medicare enrollees.* If an HMO or

CMP furnishes coverage of Medicare Part A services to a Medicare enrollee entitled to Part B only, the HMO's or CMP's premium (or other payment method) for these services may not exceed the ACR for these services. In addition, if a risk HMO or CMP furnishes these services and supplemental services, which are the same as the additional benefits furnished Medicare enrollees of the HMO or CMP who are entitled to benefits under both Parts A and B, the HMO's or CMP's combined premium for both these groups of services that the Part B enrollee must pay may not exceed 95 percent of the weighted average AAPCC for Part A services (or the Medicare payment for Part A services, if it is less) for the Medicare enrollee of the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.454 Charges to Medicare enrollees.

(a) *Limits on charges.* The HMO or CMP must agree to charge its Medicare enrollees only for the—

(1) Deductible and coinsurance amounts applicable to furnished covered services;

(2) Charges for noncovered services or services for which the enrollee is liable as described in § 417.452; and

(3) Services for which Medicare is not the primary payor as provided in § 417.528.

(b) *Limit on charges for inpatient hospital care.* If a Medicare enrollee who is an inpatient of a hospital requests immediate QIO review (as provided in § 417.605) of any determination by the hospital furnishing services or the HMO or CMP that the inpatient hospital services will no longer be covered, the HMO or CMP may not charge the enrollee for any inpatient care costs incured before noon of the first working day after the QIO issues its review decision.

(c) *Reporting requirements.* A risk HMO or CMP must report, within 90 days after the end of the contract period, all premiums, enrollment fees, and other charges collected from its Medicare enrollees during that period.

(d) *Limit on charges for specified preventive services.* An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which HMOs' cost sharing may not exceed that required under original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(4) A COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 76 FR 21561, Apr. 15, 2011; 85 FR 71197, Nov. 6, 2020; 88 FR 22328, Apr. 12, 2023]

§ 417.456 Refunds to Medicare enrollees.

(a) *Definitions.* As used in this section—

Amounts incorrectly collected means amounts collected that are in excess of those specified in § 417.452. It includes amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined to have been entitled to Medicare benefits and CMS is liable for payments as specified in § 417.450.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the HMO or CMP if they were—

(1) Emergency services;

(2) Urgently needed services for which the HMO or CMP has assumed financial responsibility; or

(3) On appeal under subpart Q of this part, found to be services the enrollee

was entitled to have furnished by the HMO or CMP.

(b) *Basic commitment.* An HMO or CMP must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and any other amounts due the enrollees or others on their behalf.

(c) *Refund by lump sum payment.* An HMO or CMP must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

(1) Incorrectly collected amounts that were not collected as premiums.

(2) Other amounts due.

(3) All amounts due, if the HMO or CMP is going out of business.

(d) *Refund by premium adjustment or lump sum payment or both.* An HMO or CMP may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for amounts that were incorrectly collected in the form of premiums or through a combination of premium payments and other charges.

(e) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort by the HMO or CMP, the HMO or CMP must make the refund in accordance with State law.

(f) *Reduction by CMS.* If the HMO or CMP does not make refund in accordance with paragraphs (b) through (d) of this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces its payment to the HMO or CMP by the amounts incorrectly collected or otherwise due, and arranges for those amounts to be paid to the Medicare enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.458 Recoupment of uncollected deductible and coinsurance amounts.

An HMO or CMP agrees not to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period except in the following circumstances:

(a) The HMO or CMP failed to collect the deductible and coinsurance amounts during the contract period in which they were due because of—

(1) Underestimation of the actuarial value of the deductible and coinsurance amounts; or

(2) A billing error.

(b) The HMO or CMP has identified the amounts and obtained advance CMS approval of the recoupment and the method and timing of recoupment.

(c) The HMO or CMP collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.460 Disenrollment of beneficiaries by an HMO or CMP.

(a) *General rule.* Except as provided in paragraphs (b) through (i) of this section, an HMO or CMP may not—

(1) Disenroll a Medicare beneficiary; or

(2) Orally or in writing, or by any action or inaction, request or encourage a Medicare enrollee to disenroll.

(b) *Bases for disenrollment: Overview*—(1) *Optional disenrollment.* Generally, an HMO or CMP may disenroll a Medicare enrollee if he or she—

(i) Fails to pay the required premiums or other charges;

(ii) Commits fraud or permits abuse of his or her enrollment card; or

(iii) Behaves in a manner that seriously impairs the HMO's or CMP's ability to furnish health care services to the particular enrollee or to other enrollees.

(2) *Required disenrollment.* Generally, an HMO or CMP must disenroll a Medicare enrollee if he or she—

(i) Moves out of the HMO's or CMP's geographic service area or is incarcerated;

(ii) Fails to convert to the risk provisions of the HMO's or CMP's Medicare contract;

(iii) Loses entitlement to Medicare Part B benefits;

(iv) Is not lawfully present in the United States; or

(v) Dies.

(3) *Related provisions.* Specific requirements, limitations, and exceptions are set forth in paragraphs (c) through (j) of this section.

(c) *Failure to pay premiums or other charges*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, an HMO or CMP may disenroll a Medicare enrollee who fails to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, if the HMO or CMP—

(i) Can demonstrate to CMS that it made reasonable efforts to collect the unpaid amount;

(ii) Gives the enrollee written notice of disenrollment, including an explanation of the enrollee's right to a hearing under the HMO's or CMP's grievance procedures; and

(iii) Sends the notice of disenrollment to the enrollee before it notifies CMS.

(2) *Exception.* If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and other charges, the HMO or CMP may discontinue the optional benefits but may not disenroll the beneficiary.

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual does all of the following:

(i) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(ii) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(iii) Shows good cause for failure to pay.

(iv) Pays all overdue premiums or other charges within 3 calendar months after the disenrollment date.

(v) Establishes by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums or other charges.

(d) *Enrollee commits fraud or permits abuse of the enrollment card*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare beneficiary if the beneficiary—

(i) Knowingly provides, on the application form, fraudulent information that materially affects the beneficiary's eligibility to enroll in the HMO or CMP; or

(ii) Intentionally permits others to use his or her enrollment card to obtain services from the HMO or CMP.

(2) *Notice requirement.* If disenrollment is for either of the reasons specified in paragraph (d)(1) of this section, the HMO or CMP must give the beneficiary a written notice of termination of enrollment.

(i) The notice must be mailed to the enrollee before submission of the disenrollment notice to CMS.

(ii) The notice must include an explanation of the enrollee's right to have the disenrollment heard under the grievance procedures established in accordance with § 417.436.

(3) *Report to the Inspector General.* The HMO or CMP must report to the Office of the Inspector General of the Department any disenrollment based on fraud or abuse by the enrollee.

(e) *Disenrollment for cause*—(1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare enrollee for cause if the enrollee's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continuing enrollment in the HMO or CMP seriously impairs the HMO's or CMP's ability to furnish services to either the particular enrollee or other enrollees.

(2) *Effort to resolve the problem.* (i) The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures, and including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities.

(ii) The HMO or CMP must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (e)(7) of this section.

(3) *Consideration of extenuating circumstances.* The HMO or CMP must ascertain that the enrollee's behavior is not related to the use of medical services or to mental illness.

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (3) of this section. Dated copies of the notices required in paragraph (d)(2)(iv) of this section must also be submitted to CMS.

(5) *CMS review of an HMO's or CMP's proposed disenrollment for cause.* (i) CMS decides on the basis of review of the documentation submitted by the HMO or CMP, whether disenrollment requirements have been met.

(ii) CMS makes this decision within 20 working days after receipt of the documentation material, and notifies the HMO or CMP within 5 working days after making its decision.

(6) *Effective date of disenrollment.* If CMS permits an HMO or CMP to disenroll an enrollee for cause, the disenrollment takes effect on the first day of the calendar month after the month in which the HMO or CMP gives the enrollee a written notice of disenrollment that meets the requirements set forth in paragraphs (d)(2)(i) and (d)(2)(ii) of this section.

(7) *Other required notices.* The HMO or CMP must provide the individual two notices before submitting the request for disenrollment to CMS.

(i) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(A) If the disruptive behavior ceases after the enrollee receives the advance notice and then later resumes, the HMO or CMP must begin the process again.

(B) The HMO or CMP must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-days period the individual has to provide an opportunity for the individual to cease their behavior.

(ii) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP requests CMS permission to involuntarily disenroll the enrollee. This notice must be provided before submission of the request to CMS.

(f) *Enrollee moves out of the HMO's or CMP's geographic area*—(1) *Basic rules*—(i) *Disenrollment.* Except as provided in paragraph (f)(2) of this section, an HMO or CMP must disenroll a Medicare enrollee who moves out of its geographic area if the HMO or CMP establishes, on the basis of a written statement from the enrollee, or other evidence acceptable to CMS, that the enrollee has permanently moved out of its geographic area.

(A) *Incarceration.* The HMO or CMP must disenroll an individual if the HMO or CMP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the geographic service area of the HMO or CMP per §417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to the individual being incarcerated and not residing in the geographic service area of the HMO or CMP, as per §417.1, the disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(C) *Exception.* The exception in paragraph (f)(2) of this section does not apply to individuals who are incarcerated.

(ii) *Notice requirement.* The HMO or CMP must comply with the notice requirements set forth in paragraph (d)(2) of this section.

(iii) *Effect on geographic area.* Failure to disenroll an enrollee who has moved out of the HMO's or CMP's geographic area does not expand that area to encompass the location of the enrollee's new residence.

(2) *Exception.* An HMO or CMP may retain a Medicare enrollee who is absent from its geographic area for an extended period, but who remains within the United States as defined in § 400.200 of this chapter if the enrollee agrees. For purposes of this exception, the following provisions apply:

(i) An absence for an extended period means an uninterrupted absence from the HMO's or CMP's geographic area for more than 90 days but less than 1 year.

(ii) The HMO or CMP and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee is absent for an extended period from the HMO's or CMP's geographic area. However, restrictions may not be imposed on the scope of services described in § 417.440.

(iii) HMOs and CMPs that choose to exercise this exception must make the option available to all Medicare enrollees who are absent for an extended period from their geographic areas. However, HMOs and CMPs may limit this option to enrollees who go to a geographic area served by an affiliated HMO or CMP.

(iv) As used in this paragraph, ''affiliated HMO or CMP'' means an HMO or CMP that—

(A) Is under common ownership or control of the HMO or CMP that seeks to retain the absent enrollees; or

(B) Has in effect an agreement to furnish services to enrollees who are on an extended absence from the geographic area of the HMO or CMP that seeks to retain them.

(v) When the enrollee returns to the HMO's or CMP's geographic area (even temporarily), the restrictions of § 417.448(a) (which limit payment for services not provided or arranged for by the HMO or CMP) apply again immediately.

(vi) If the enrollee fails to return to the HMO's or CMP's geographic area within 1 year from the date he or she left that area, the HMO or CMP must disenroll the beneficiary on the first day of the month following the anniversary of the date the enrollee left that area in accordance with paragraph (f)(1) of this section.

(g) *Failure to convert to risk provisions of Medicare contract*—(1) *Basis for disenrollment.* A risk HMO or CMP must disenroll a nonrisk Medicare enrollee who refuses to convert to the risk provisions of the Medicare contract after CMS determines that all of the HMO's or CMP's nonrisk Medicare enrollees must convert.

(2) *Advance notice requirement.* At least 30 days before it gives CMS notice of disenrollment, the HMO or CMP must give the enrollee written notice of the fact that failure to convert will result in disenrollment.

(h) *Loss of entitlement to Medicare benefits*—(1) *Loss of entitlement to Part A benefits.* If an enrollee loses entitlement to benefits under Part A of Medicare but remains entitled to benefits under Part B, the enrollee automatically continues as a Medicare enrollee of the HMO or CMP and is entitled to receive and have payment made for Part B services, beginning with the month immediately following the last month of his or her entitlement to Part A benefits.

(2) *Loss of entitlement to Part B benefits.* If a Medicare enrollee loses entitlement to Part B benefits, the HMO or CMP must disenroll him or her as a Medicare enrollee effective with the month following the last month of entitlement to Part B benefits. However, the HMO or CMP may continue to enroll the individual under its regular plan if the individual so chooses.

(i) *Death of the enrollee.* Disenrollment is effective with the month following the month of death.

(j) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h).

[60 FR 45678, Sept. 1, 1995, as amended at 77 FR 22166, Apr. 12, 2012; 79 FR 29955, May 23, 2014; 80 FR 7958, Feb. 12, 2015; 89 FR 30812, Apr. 23, 2024]

§ 417.461 Disenrollment by the enrollee.

(a) *Request for disenrollment.* (1) A Medicare enrollee who wishes to disenroll may at any time give the HMO or CMP a signed, dated request in the form and manner prescribed by CMS.

(2) The enrollee may request a certain disenrollment date but it may be no earlier than the first day of the month following the month in which the HMO or CMP receives the request.

(b) *Responsibilities of the HMO or CMP.* The HMO or CMP must—

(1) Submit a disenrollment notice to CMS promptly;

(2) Provide the enrollee with a copy of the request for disenrollment; and

(3) In the case of a risk HMO or CMP, also provide the enrollee with a statement explaining that he or she—

(i) Remains enrolled until the effective date of disenrollment; and

(ii) Until that date, is subject to the restrictions of § 417.448(a) under which neither the HMO or CMP nor CMS pays for services not provided or arranged for by the HMO or CMP.

(c) *Effect of failure to submit disenrollment notice to CMS promptly.* If the HMO or CMP fails to submit timely the correct and complete notice required in paragraph (b)(1) of this section, the HMO or CMP must reimburse CMS for any capitation payments received after the month in which payments would have ceased if the requirement had been met timely.

[60 FR 45679, Sept. 1, 1995]

§ 417.464 End of CMS's liability for payment: Disenrollment of beneficiaries and termination or default of contract.

(a) *Effect of disenrollment: General rule.* (1) CMS's liability for monthly capitation payments to the HMO or CMP generally ends as of the first day of the month following the month in which disenrollment is effective, as shown on CMS's records.

(2) Disenrollment is effective no earlier than the month immediately after, and no later than the third month after, the month in which CMS receives the disenrollment notice in acceptable form.

(b) *Effect of disenrollment: Special rules*—(1) *Fraud or abuse by the enrollee.* If disenrollment is on the basis of fraud committed or abuse permitted by the enrollee, CMS's liability ends as of the first day of the month in which disenrollment is effective.

(2) *Loss of entitlement to Part B benefits.* If disenrollment is on the basis of loss of entitlement to Part B benefits, CMS's liability ends as of the first day of the month following the last month of Part B entitlement.

(3) *Death of enrollee.* If the enrollee dies, CMS's liability ends as of the first day of the month following the month of death.

(4) *Disenrollment at enrollee's request.* If disenrollment is in response to the enrollee's request, CMS's liability ends as of the first day of the month following the month of termination requested by the enrollee.

(c) *Effect of termination or default of contract*—(1) *Termination of contract.* If the contract between CMS and the HMO or CMP is terminated by mutual consent or by unilateral action of either party, CMS's liability for payments ends as of the first day of the month after the last month for which the contract is in effect.

(2) *Default of contract.* If the HMO or CMP defaults on the contract before the end of the contract year because of bankruptcy or other reasons, CMS—

(i) Determines the month in which its liability for payments ends; and

(ii) Notifies the HMO or CMP and all affected Medicare enrollees as soon as practicable.

[60 FR 45680, Sept. 1, 1995]

Subpart L—Medicare Contract Requirements

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.470 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1857(e)(2) of the Act pertaining to cost sharing in enrollment-related costs and section 1876(c), (g), (h), and (i) of the Act that pertain to the contract between CMS and an HMO or CMP for participation in the Medicare program.

(b) *Scope.* This subpart sets forth—

(1) Specific contract requirements; and

(2) Procedures for renewal, nonrenewal, or termination of a contract.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 62 FR 63673, Dec. 2, 1997]

§ 417.472 Basic contract requirements.

(a) *Submittal of contract.* An HMO or CMP that wishes to contract with CMS to furnish services to Medicare beneficiaries must submit a signed contract that meets the requirements of this subpart and any other requirements established by CMS.

(b) *Agreement to comply with regulations and instructions.* The contract must provide that the HMO or CMP agrees to comply with all the applicable requirements and conditions set forth in this subpart and in general instructions issued by CMS.

(c) *Other contract provisions.* In addition to the requirements set forth in §§ 417.474 through 417.488, the contract must contain any other terms and conditions that CMS requires to implement section 1876 of the Act.

(d) *Exemption from Federal procurement regulations.* The Federal Acquisition Regulations and HHS Acquisition Regulations contained in title 48 of the Code of Federal Regulations do not apply to Medicare contracts under section 1876 of the Act.

(e) *Compliance with civil rights laws.* The HMO or CMP must comply with title VI of the Civil Rights Act of 1964 (regulations at 45 CFR part 80), section 504 of the Rehabilitation Act of 1973 (regulations at 45 CFR part 84), and the Age Discrimination Act of 1975 (regulations at 45 CFR part 91).

(f) *Requirements for advance directives.* The HMO or CMP must meet all the requirements for advance directives at § 417.436(d).

(g) *Authority to waive conflicting contract requirements.* Under section 1876(i)(5) of the Act, CMS is authorized to administer the terms of this subpart without regard to provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if it determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(h) *Collection of fees from risk HMOs and CMPs.* (1) The rules set forth in § 422.10 of this chapter for M + C plans also apply to collection of fees from risk HMOs and CMPs.

(2) In applying the part 422 rules, references to ''M + C organizations'' or ''M + C plans'' must be read as references to ''risk HMOs and CMPs''.

(i) *HMOs and CMPs.* The HMO or CMP must comply with the requirements at § 422.152(b)(5) and (6) of this chapter.

(j) *Coordinated care and cost contracts.* Subject to paragraph (i) of this section, all coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(k) All cost contracts under section 1876 of the Act must agree to be rated under the quality rating system specified at subpart D of part 422, and for cost plans that provide the Part D prescription benefit, under the quality rating system specified at part 423 subpart D, of this chapter. Cost contacts are not required to submit data on or be rated on specific measures determined by CMS to be inapplicable to their contract or for which data are not available, including hospital readmission and call center measures.

(l) *Resolution of complaints in the complaints tracking module.* The HMO or CMP must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the HMO or CMP within the required timeframes. References to the MA organization or MA plan in those

regulations shall be read as references to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38079, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 63 FR 35067, June 26, 1998; 75 FR 19802, Apr. 15, 2010; 83 FR 16721, Apr. 16, 2018; 85 FR 19289, Apr. 6, 2020; 89 FR 30812, Apr. 23, 2024]

§417.474 Effective date and term of contract.

(a) *Effective date.* The contract must specify its effective date, which may not be earlier than the date it is signed by both CMS and the HMO or CMP.

(b) *Term.* The contract must specify the duration of its term as follows:

(1) For the initial term, at least 12 months, but no more than 23 months.

(2) For any subsequent term, 12 months.

[60 FR 45680, Sept. 1, 1995]

§417.476 Waived conditions.

If CMS waives any of the qualifying conditions required under subpart J of this part, the contract must specify the following information for each waived condition:

(a) The specific terms of the waiver.

(b) The expiration date of the waiver.

(c) Any other information required by CMS.

[60 FR 45680, Sept. 1, 1995]

§417.478 Requirements of other laws and regulations.

The contract must provide that the HMO or CMP agrees to comply with—

(a) The requirements for QIO review of services furnished to Medicare enrollees as set forth in subchapter D of this chapter;

(b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;

(c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect enrollees of the HMO or CMP; and

(d) The reporting requirements in §417.126(a), which pertain to the monitoring of an HMO's or CMP's continued compliance.

(e)(1) The prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list, defined in §422.2 of this chapter, apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

(2) In applying the provisions of §§422.2, 422.222, and 422.224 of this chapter under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, 38082, July 15, 1993; 80 FR 80556, Nov. 15, 2016; 83 FR 16721, Apr. 16, 2018]

§417.479 Requirements for physician incentive plans.

(a) The contract must specify that an HMO or CMP may operate a physician incentive plan only if—

(1) 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 furnished to an individual enrollee; and

(2) The stop-loss protection, enrollee survey, and disclosure requirements of this section are met.

(b) *Applicability.* The requirements in this section apply to physician incentive plans between HMOs and CMP and individual physicians or physician groups with which they contract to provide medical services to enrollees. The requirements in this section also apply to subcontracting arrangements as specified in §417.479(i). These requirements apply only to physician incentive plans that base compensation (in whole or in part) on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries.

(c) *Definitions.* For purposes of this section:

Bonus means a payment an HMO or CMP makes to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) that an organization pays a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the

physician's own services, referral services, or all medical services.

Payments means any amounts the HMO or CMP pays physicians or physician groups for services they furnish directly, plus amounts paid for administration and amounts paid (in whole or in part) based on use and costs of referral services (such as withhold amounts, bonuses based on referral levels, and any other compensation to the physician or physician group to influence the use of referral services). Bonuses and other compensation that are not based on referral levels (such as bonuses based solely on quality of care furnished, patient satisfaction, and participation on committees) are not considered payments for purposes of this section.

Physician group means a partnership, association, corporation, individual practice association, or other group that distributes income from the practice among members. An individual practice association is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement between an HMO or CMP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Medicare beneficiaries or Medicaid beneficiaries enrolled in the HMO or CMP.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk.

Withhold means a percentage of payments or set dollar amounts that an HMO or CMP deducts from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(d) *Prohibited physician payments.* No specific payment of any kind may be made directly or indirectly under the incentive plan to a physician or physician group as an inducement to reduce or limit covered medically necessary services covered under the HMO's or CMP's contract furnished to an individual enrollee. Indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(e) *General rule: Determination of substantial financial risk.* Substantial financial risk occurs when the incentive arrangements place the physician or physician group at risk for amounts beyond the risk threshold, if the risk is based on the use or costs of referral services. Amounts at risk based solely on factors other than a physician's or physician group's referral levels do not contribute to the determination of substantial financial risk. The risk threshold is 25 percent.

(f) *Arrangements that cause substantial financial risk.* For purposes of this paragraph, *potential payments* means the maximum anticipated total payments (based on the most recent year's utilization and experience and any current or anticipated factors that may affect payment amounts) that could be received if use or costs of referral services were low enough. The following physician incentive plans cause substantial financial risk if risk is based (in whole or in part) on use or costs of referral services and the patient panel size is not greater than 25,000 patients:

(1) Withholds greater than 25 percent of potential payments.

(2) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(3) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(4) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—

Withhold = 0.75 (Bonus %) + 25%.

(5) Capitation, arrangements, if—

(i) The difference between the maximum potential payments and the minimum potential payments is more than

25 percent of the maximum potential payments; or

(ii) The maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract.

(6) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(g) *Requirements for physician incentive plans that place physicians at substantial financial risk.* HMOs and CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk must do the following:

(1) Conduct enrollee surveys. These surveys must—

(i) Include either all current Medicare/Medicaid enrollees in the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees;

(ii) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(iii) Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services; and

(iv) Be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

(2) Ensure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(i) If aggregate stop-loss protection is provided, it must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(2) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

Panel size	Single combined limit	Separate institutional limit	Separate professional limit
1–1000	$6,000	$10,000	$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	none	none	none

(h) *Disclosure and other requirements for organizations with physician incentive plans*—(1) *Disclosure to CMS.* Each health maintenance organization or competitive medical plan must provide to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—

(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

(ii) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled;

(iii) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled;

(iv) The distribution of payments to physicians from the risk pool is not calculated separately by patient category; and

(v) The terms of the risk borne by the physicians or physician group are comparable for all categories of patients being pooled.

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

(i) Whether the prepaid plan uses a physician incentive plan that affects the use of referral services.

(ii) The type of incentive arrangement.

(iii) Whether stop-loss protection is provided.

(iv) If the prepaid plan was required to conduct a survey, a summary of the survey results.

(i) *Requirements related to subcontracting arrangements*—(1) *Physician groups.* An HMO or CMP that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish must do the following:

(i) Disclose to CMS any incentive plan between the physician group and its individual physicians that bases compensation to the physician on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information specified in paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) Provide adequate stop-loss protection to the individual physicians.

(iii) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(2) *Intermediate entities.* An HMO or CMP that contracts with an entity (other than a physician group) for the provision of services to Medicare beneficiaries must do the following:

(i) Disclose to CMS any incentive plan between the entity and a physician or physician group that bases compensation to the physician or physician group on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information required to be disclosed under paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) If the physician incentive plan puts a physician or physician group at substantial financial risk for the cost of services the physician or physician group does not furnish—

(A) Meet the stop-loss protection requirements of this subpart; and

(B) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(3) For purposes of paragraph (i)(2) of this section, an entity includes, but is not limited to, an individual practice association that contracts with one or more physician groups and a physician hospital organization.

(j) *Sanctions against the HMO or CMP.* CMS may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if CMS determines that an HMO or CMP fails to comply with the requirements of this section.

[61 FR 13446, Mar. 27, 1996; 61 FR 46385, Sept. 3, 1996, as amended at 61 FR 69049, Dec. 31, 1996; 68 FR 50855, Aug. 22, 2003]

§ 417.480 Maintenance of records: Cost HMOs and CMPs.

A reasonable cost contract must provide that the HMO or CMP agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, HMO or CMP, and operation of the HMO's or CMP's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

(4) Asset acquisition, lease, sale, or other action.

(5) Agreements, contracts, and subcontracts.

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the HMO's or CMP's fee-for-service patients.

(8) Matters pertaining to costs of operations.

(9) Amounts of income received by source and payment.

(10) Cash flow statements.

(11) Any financial reports filed with other Federal programs or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.481 Maintenance of records: Risk HMOs and CMPs.

A risk contract must provide that the HMO or CMP agrees to maintain

and make available to CMS upon request, books, records, documents, and other evidence of acounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§417.482 Access to facilities and records.

The contract must provide that the HMO or CMP agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the HMO or CMP when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or CMP or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract.

(d) HHS may evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three prior periods, when there is reasonable evidence of some need for that inspection.

(e) In the case of a reasonable cost HMO or CMP to make available for the purposes specified in paragraphs (a), (b), (c), and (d) of this section, its premises, physical facilities, and equipment, its records relating to its Medicare enrollees, the records specified in §417.480 and any additional relevant information that CMS may require.

(f) That the right to inspect, evaluate, and audit, will extend through three years from the date of the final settlement for any contract period unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the HMO or CMP at least 30 days before the normal disposition date;

(2) There has been a termination, dispute, fraud, or similar fault by the HMO or CMP, in which case the retention may be extended to three years from the date of any resulting final settlement; or

(3) CMS determines that there is a reasonable possibility of fraud, in which case it may reopen a final settlement at any time.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.484 Requirement applicable to related entities.

(a) *Definition.* As used in this section, *related entity* means any entity that is related to the HMO or CMP by common ownership or control and—

(1) Performs some of the HMO's or CMP's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the HMO or CMP at a cost of more than $2,500 during a contract period.

(b) *Requirement.* The contract must provide that the HMO or CMP agrees to require all related entities to agree that—

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) The right under paragraph (b)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in §417.482(f).

(3) That payments must not be made to individuals and entities included on

the preclusion list, defined in § 422.2 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 81 FR 80556, Nov. 15, 2016; 83 FR 16721, Apr. 16, 2018]

§ 417.486 Disclosure of information and confidentiality.

The contract must provide that the HMO or CMP agrees to the following:

(a) To submit to CMS—

(1) All financial information required under subpart O of this part and for final settlement;

(2) Any other information necessary for the administration or evaluation of the Medicare program; and

(3) Risk adjustment data as specified in § 422.310 of this chapter for the purposes of determining an individual's health status. In applying this paragraph (a)(3), references to Medicare Advantage (MA) organizations in § 422.310 must be read to mean HMOs and CMPs.

(b) To comply with the requirements set forth in part 420, subpart C, of this chapter pertaining to the disclosure of ownership and control information.

(c) To comply with the requirements of the Privacy Act, as implemented by 45 CFR part 5b and subpart B of part 401 of this chapter, with respect to any system of records developed in performing carrier or intermediary functions under §§ 417.532 and 417.533.

(d) To meet the confidentiality requirements of § 482.24(b)(3) of this chapter for medical records and for all other enrollee information that is—

(1) Contained in its records or obtained from CMS or other sources; and

(2) Not covered under paragraph (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 90 FR 15909, Apr. 15, 2025]

§ 417.488 Notice of termination and of available alternatives: Risk contract.

A risk contract must provide that the HMO or CMP agrees to give notice as follows if the contract is terminated:

(a) At least 60 days before the effective date of termination, to give its Medicare enrollees a written notice that—

(1) Specifies the termination date; and

(2) Describes the alternatives available for obtaining Medicare services after termination.

(b) To pay the cost of the written notices.

[60 FR 45680, Sept. 1, 1995]

§ 417.490 Renewal of contract.

A contract with an HMO or CMP is renewed automatically for the next 12-month period unless CMS or the HMO or CMP decides not to renew, in accordance with § 417.492.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.492 Nonrenewal of contract.

(a) *Nonrenewal by the HMO or CMP.* (1) If an HMO or CMP does not intend to renew its contract, it must—

(i) Give written notice to CMS at least 90 days before the end of the current contract period; and

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period.

(2) CMS may accept a nonrenewal notice submitted less than 90 days before the end of a contract period if—

(i) The HMO or CMP notifies its Medicare enrollees and the public in accordance with paragraph (a)(1) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program.

(b) *Nonrenewal by CMS*—(1) *Notice of nonrenewal.* If CMS decides not to renew a contract, it gives written notice of nonrenewal as follows:

(i) To the HMO or CMP at least 90 days before the end of the contract period.

(ii) To the HMO's or CMP's Medicare enrollees at least 60 days before the end of the contract period.

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its

right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in §417.494(b).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010; 77 FR 22166, Apr. 12, 2012]

§417.494 Modification or termination of contract.

(a) *Modification or termination by mutual consent.* (1) CMS and an HMO or CMP may modify or terminate a contract at any time by written mutual consent.

(2) If the contract is modified, the HMO or CMP must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification.

(3) If the contract is terminated, the HMO or CMP must notify its Medicare enrollees, and CMS notifies the general public, at least 30 days before the termination date.

(b) *Termination by CMS.* (1) CMS may terminate a contract for any of the following reasons:

(i) The HMO or CMP has failed substantially to carry out the terms of the contract.

(ii) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the effective and efficient implementation of section 1876 of the Act.

(iii) The HMO or CMP has failed substantially to comply with the composition of enrollment requirements specified in §417.413(d).

(iv) CMS determines that the HMO or CMP no longer meets the requirements of section 1876 of the Act and this subpart for being an HMO or CMP.

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

(3) An HMO or CMP with a risk contract must notify its Medicare enrollees of the termination as described in §417.488.

(4) CMS notifies the HMO's or CMP's Medicare enrollees and the general public of the termination at least 30 days before the effective date of termination.

(c) *Termination by the HMO or CMP.* The HMO or CMP may terminate the contract if CMS has failed substantially to carry out the terms of the contract.

(1) The HMO or CMP must notify CMS at least 90 days before the effective date of the termination and must include in its notice the reasons for the termination.

(2) The HMO or CMP must notify its Medicare enrollees of the termination at least 60 days before the termination date. Risk HMOs or CMPs must also provide a written description of alternatives available for obtaining Medicare services after termination of the contract. The HMO or CMP is responsible for the cost of these notices.

(3) The HMO or CMP must notify the general public of the termination at least 30 days before the termination date.

(4) The contract is terminated effective 60 days after the HMO or CMP mails the notice to Medicare enrollees as required in paragraph (c)(2) of this section.

(5) CMS's liability for payment ends as of the first day of the month after the last month for which the contract is in effect.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 22322, June 11, 1987; 56 FR 46571, Sept. 13, 1991; 58 FR 38079, 38082, July 15, 1993; 60 FR 45681, Sept. 1, 1995; 75 FR 19803, Apr. 15, 2010]

§417.496 Cost plan crosswalk.

(a) *General rules*—(1) *Definition.* Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition.* (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules.* The cost plan must comply with renewal and nonrenewal rules

in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal.* A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception.* (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and may permit a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

[86 FR 6093, Jan. 19, 2021]

§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422 of this chapter.

[75 FR 19803, Apr. 15, 2010]

Subpart M—Change of Ownership and Leasing of Facilities: Effect on Medicare Contract

§ 417.520 Effect on HMO and CMP contracts.

(a) The provisions set forth in subpart L of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying these provisions, references to ''M + C organizations'' must be read as references to ''HMOs and CMPs''.

(c) In § 422.550, reference to ''subpart K of this part'' must be read as reference to ''subpart L of part 417 of this chapter''.

(d) In §422.553, reference to ''subpart K of this part'' must be read as reference to ''subpart J of part 417 of this chapter''.

[63 FR 35067, June 26, 1998]

Subpart N—Medicare Payment to HMOs and CMPs: General Rules

§417.524 Payment to HMOs or CMPs: General.

(a) *Basic rule.* The payments that CMS makes to an HMO or CMP under this subpart and subparts O and P of this part for furnishing covered Medicare services are in place of any payment that CMS would otherwise make to a beneficiary or the HMO or CMP under sections 1814(b) and 1833(a) of the Act.

(b) *Basis of payment.* (1) CMS pays the HMOs or CMPs on either a reasonable cost basis or a risk basis depending on the type of contract the HMO or CMP has with CMS.

(2) In certain cases a risk HMO or CMP also receives payments on a reasonable cost basis for certain Medicare enrollees who retain nonrisk status, as provided in §417.444, after the HMO or CMP enters into a risk contract.

[60 FR 46229, Sept. 6, 1995]

§417.526 Payment for covered services.

Subpart O of this part set forth the principles that CMS follows in determining Medicare payment to an HMO or CMP that has a reasonable cost contract. Subpart P of this part describes the per capita method of Medicare payment to HMOs or CMPs that contract on a risk basis.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

§417.528 Payment when Medicare is not primary payer.

(a) *Limits on payments and charges.* (1) CMS may not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(2) The circumstances under which an HMO or CMP may charge, or authorize a provider to charge, for covered Medicare services for which Medicare is not the primary payer are stated in paragraphs (b) and (c) of this section.

(b) *Charge to other insurers or the enrollee.* If a Medicare enrollee receives from an HMO or CMP covered services that are also covered under State or Federal worker's compensation, automobile medical, or any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the HMO or CMP may charge, or authorize a provider that furnished the service to charge—

(1) The insurance carrier, employer, or other entity that is liable to pay for these services; or

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or other entity.

(c) *Charge to group health plans (GHPs) or large group health plans (LGHPs).* An HMO or CMP may charge a GHP or LGHP for covered services it furnished to a Medicare enrollee and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP for these covered services if—

(1) The Medicare enrollee is covered under the plan; and

(2) Under section 1862(b) of the Act, CMS is precluded from paying for the covered services .

(d) *Responsibilities of HMO or CMP.* An HMO or CMP must—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act;

(2) Determine the amounts payable by these payers; and

(3) Coordinate the benefits of its Medicare enrollees with these payers.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

Subpart O—Medicare Payment: Cost Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.530 Basis and scope.

This subpart sets forth the principles that CMS follows to determine the amount it pays for services furnished by a cost HMO or CMP to its Medicare enrollees. These principles are based on sections 1861(v) and 1876 of the Act and

are, for the most part, the same as those set forth—

(a) In part 412 of this chapter, for paying the costs of inpatient hospital services which, for cost HMOs and CMPs, are considered ''reasonable'' only if they do not exceed the amounts allowed under the prospective payment system; and

(b) In part 413 of this chapter, for the costs of all other covered services.

[60 FR 46230, Sept. 6, 1995]

§ 417.531 Hospice care services.

(a) If a Medicare enrollee of an HMO or CMP with a reasonable cost contract makes an election under § 418.24 of this chapter to receive hospice care services, payment for these services is made to the hospice that furnishes the services in accordance with part 418 of this chapter.

(b) While the enrollee's hospice election is in effect, CMS pays the HMO or CMP on a reasonable cost basis for only the following covered Medicare services furnished to the Medicare enrollee:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.532 General considerations.

(a) *Conditions and criteria for payment.* (1) The costs incurred by the HMO or CMP to furnish services covered by Medicare are reimbursable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients.

(2) In determining fair and equitable payment for the HMOs or CMPs, CMS generally applies the cost payment principles set forth in § 413.5 of this chapter.

(3) In judging whether costs are reasonable, CMS applies the weighted average of the AAPCCs of each class of the HMO's or CMP's Medicare enrollees (as defined in § 417.582) for the HMO's or CMP's geographic area as an absolute limitation on the total amount payable.

(b) *Method and amount of payment to the HMO or CMP.* (1) CMS makes interim per capita payments each month for each Medicare enrollee, equivalent to the interim per capita cost rate determined in accordance with § 417.570.

(2) CMS adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the HMO or CMP, CMS deducts from the reasonable cost actually incurred by the HMO or CMP for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare Part A and Part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in the HMO or CMP or another HMO or CMP.

(c) *Election by HMO or CMP.* An HMO or CMP must elect, on an individual provider basis, one of the following methods for payment for hospital and SNF services it furnishes to Medicare enrollees:

(1) Direct payment by CMS.

(2) Direct payment by the HMO or CMP.

(d) *Notice of election.* The election must be made in writing before the beginning of the contract period and is binding for that period.

(e) *Payment by HMO or CMP.* If the HMO or CMP elects to pay providers directly, as provided in paragraph (c) of this section, it must—

(1) Determine the eligibility of its Medicare enrollees to receive covered services through the HMO or CMP;

(2) Make proper coverage decisions and appropriate payments, in accordance with §§ 421.100 and 421.200 of this chapter, for the services furnished to its Medicare enrollees;

(3) Ensure that providers maintain and furnish appropriate documentation of physician certification and recertification, to the extent required under subpart B of part 424 of this chapter; and

(4) Carry out any other procedures required by CMS.

(f) *Review of HMO's or CMP's bill processing capabilities.* If the HMO or CMP elects to pay providers directly, CMS determines whether the HMO or CMP has the experience and capability to carry out the responsibilities specified in paragraph (e) of this section in an efficient and effective manner.

(g) *Direct payment by CMS.* (1) If the HMO or CMP elects to have CMS pay for provider services, CMS pays each provider on a reasonable cost basis or under the PPS system, whichever is appropriate for the particular provider under part 412 or part 413 of this chapter.

(2) In computing the Medicare payment to the HMO or CMP, CMS deducts these payments and any other payments made by the Medicare intermediary or carrier on behalf of the HMO or CMP (such as payment for emergency or urgently needed services under § 417.558).

(h) *Payment for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP.* CMS pays the HMO or CMP for services it furnishes to Medicare beneficiaries who are not its enrollees through the HMO's or CMP's Medicare intermediary or carrier, as appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.533 Part B carrier responsibilities.

In paying for Part B services furnished to its enrollees by suppliers, the HMO or CMP must—

(a) Determine the eligibility of individuals to receive those services through the HMO or CMP;

(b) Make proper coverage decisions and appropriate payment as authorized under § 421.200 of this chapter for the services for which its Medicare enrollees are eligible; and

(c) Carry out any other procedures that CMS may require.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.534 Allowable costs.

(a) *Definition—Allowable costs* means the direct and indirect costs, including normal standby costs incurred by the HMO or CMP, that are proper and necessary for efficient delivery of needed health care services. They include the costs of furnishing services to the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients, which are typical ''provider'' costs, and costs (such as marketing, enrollment, membership, and operation of the HMO or CMP) that are peculiar to health care prepayment organizations.

(b) *Basic rules.* (1) The allowability of an HMO's or CMP's costs for furnishing services is generally determined in accordance with principles applicable to provider costs, as set forth in § 417.536.

(2) The allowability of other costs is determined in accordance with principles set forth in §§ 417.538 through 417.550.

(3) Costs for covered services for which Medicare is not the primary payor, as described in § 417.528, are not allowable.

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 70 FR 4525, Jan. 28, 2005]

§ 417.536 Cost payment principles.

(a) *Applicability.* Unless otherwise specified in this subpart, the principles set forth in parts 412 and 413 of this chapter are applicable to the costs incurred by an HMO or CMP or by providers and other facilities owned or operated by the HMO or CMP or related to it by common ownership or control. The most common examples of these costs are set forth in this section.

(b) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable cost, in accordance with §§ 413.134, 413.144, and 413.149 of this chapter.

(c) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable cost, in accordance with § 413.153 of this chapter.

(d) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities of a provider or other health care facility owned or operated by an HMO or CMP is an allowable cost in accordance with § 413.85 of this chapter.

(e) *Compensation of owners.* An appropriate amount of compensation for services of owners is an allowable cost, if the services are actually performed and are necessary, as specified in § 413.102 of this chapter.

(f) *Bad debts.* (1) Bad debts attributable to Medicare deductible and coinsurance amounts are allowable only if the requirements of § 413.89 of this chapter are met, subject to the limitations described under § 413.89(h) and the exceptions for services described under § 413.89(i).

(2) If all or part of the deductible and coinsurance amounts is payable through a monthly premium or other periodic payment, the amount allowed as a bad debt may not exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent, if the periodic payment is on other than a monthly basis.

(3) Any bad debt related to a service furnished to a Medicare enrollee of the HMO or CMP, and claimed on a cost report submitted for payment by a provider or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the HMO or CMP.

(g) *Charity and courtesy allowances.* As specified in § 413.89 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

(h) *Research costs.* As specified in § 413.90 of this chapter, costs incurred for research purposes, over and above patient care, are not allowable costs.

(i) *Value of services of nonpaid workers.* The value of services of nonpaid workers of an organization is not an allowable cost, except as provided in § 413.94 of this chapter.

(j) *Purchase discounts and allowances and refund of expenses.* Discounts and allowances that an HMO or CMP receives on purchases of goods and services and refunds of previous expense payments must be deducted from the costs to which they relate, in accordance with § 413.98 of this chapter.

(k) *Cost to related entities.* (1) The costs of services, facilities, or supplies furnished to an HMO or CMP by a related entity are allowable at the cost to the related entity in accordance with § 413.17 of this chapter.

(2) An entity is not considered related to the HMO or CMP merely because—

(i) It has a risk or incentive agreement under which the HMO or CMP reimburses or compensates the entity for services it furnishes to the HMOs' or CMPs' enrollees; or

(ii) Substantially all the services the entity furnishes are furnished to the HMO's or CMP's enrollees.

(3) However, an entity described in paragraph (k)(2) of this section and an HMO or CMP are considered related if either of them is in a position to exercise significant management or ownership influence or control over the other.

(l) *Return on equity capital of proprietary providers owned by the HMO or CMP.* An allowance for a reasonable return on equity capital invested and used in providing services is allowable in addition to the reasonable cost of services furnished by a proprietary provider owned by the HMO or CMP. The amount of the allowance is determined in accordance with § 413.157 of this chapter.

(m) *Limitations on payment.* Medicare payment for covered services furnished by entities owned by or operated by, or related to, an HMO or CMP paid on a reasonable cost basis is subject to certain provisions of parts 412 and 413 of this chapter that pertain to reasonable cost and reasonable charge. Those provisions include, but are not necessarily limited to, the following:

(1) For ESRD treatment, the limitations authorized under § 413.170 of this chapter.

(2) For services of physical, occupational, and speech therapists and other therapists and nonphysician health specialists, the limitations set forth in § 413.106 of this chapter.

(3) For drugs, the allowable cost as determined under §§ 405.517 and 410.29 of this chapter.

(4) The overall cost limits established in accordance with § 413.30 of this chapter.

(5) The limitation to the lesser of reasonable cost or customary charges, as set forth in § 413.13 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995; 77 FR 67531, Nov. 9, 2012; 85 FR 59025, Sept. 18, 2020]

§ 417.538 Enrollment and marketing costs.

(a) *Principle.* Costs incurred by an HMO or CMP in performing the enrollment and marketing activities described in subpart k of this part are allowable.

(b) *Included costs.* Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the HMO's or CMP's plan to potential enrollees in accordance with this part. Those costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(c) *Application.* Enrollment and marketing costs are allowable, whether incurred directly by HMO or CMP staff or under contract with marketing specialists or other outside consultants.

(d) *Limitation on payment.* The relatively higher costs that an HMO or CMP is likely to incur in initially offering its plan to Medicare beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if those costs exceed amounts that would be paid by prudent management, the excess is not allowable.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.540 Enrollment costs.

(a) *Principle.* Enrollment costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees.

(b) *Kind of costs included.* Enrollment costs include, but are not limited to, reasonable costs incurred in connection with maintaining statistical, financial, and other data on enrollees.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.542 Reinsurance costs.

Reinsurance costs are not allowable.

§ 417.544 Physicians' services furnished directly by the HMO or CMP.

(a) *Principles.* (1) Compensation paid by an HMO or CMP to physicians is an allowable cost to the extent that it is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or a similar locality.

(2) Physician compensation may take various forms, but the aggregate compensation allowable must be reasonable in relation to the services personally furnished.

(3) If aggregate physician compensation costs exceed what is normally incurred, the excess is not a reasonable cost.

(b) *Application.* (1) In determining the allowability of the costs of physicians' services, the cost of personal services (for example, expenses attributable to salaries, wages, incentive payments, fringe benefits) must be distinguished from the cost of nonpersonal services (for example, expenses attributable to facilities, equipment, support personnel, supplies).

(2) To be allowable, compensation must be reasonable in relation to the personal services furnished.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.546 Physicians' services and other Part B supplier services furnished under arrangements.

General principle. The amount paid by an HMO or CMP for physicians' services and other Part B supplier services

furnished under arrangements is an allowable cost to the extent it is reasonable. Costs are considered reasonable if they—

(a) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(b) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45372, Aug. 31, 1995]

§ 417.548 Provider services through arrangements.

(a) *Principle.* The cost incurred by an HMO or CMP for covered services furnished under arrangement with a provider is allowable to the extent that it would be allowable and payable under parts 412 and 413 of this chapter, unless the HMO or CMP petitions CMS and demonstrates to HFCA's satisfaction that payment in excess of the amount authorized under parts 412 and 413 of this chapter is justified on the basis of advantages gained by the HMO or CMP.

(b) *Application.* An advantage gained must represent a real and tangible benefit received by the HMO or CMP for the excess cost incurred, and any excess payment is subject to other applicable requirements of parts 405, 412 and 413 of this chapter, including tests of reasonableness.

(c) *Example.* In the case of an arrangement an HMO or CMP has with a provider that is located outside the HMO's or CMP's geographic area and that is not related to the HMO or CMP by common ownership or control, payment of the provider's charges to the HMO or CMP (rather than the payment amounts determined under part 412 or part 413 of this chapter) may be justified in exchange for the advantages of not having to incur the administrative costs of determining the provider's reasonable cost and of making a more timely final settlement with the HMO or CMP. However, repayment of the provider's charges would be acceptable only if—

(1) The provider furnishes services to the HMO's or CMP's enrollees infrequently;

(2) The charges represent an insignificant portion of total Medicare reimbursement to the HMO or CMP; and

(3) The charges do not exceed the customary charges by the provider to its other patients for similar services.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.550 Special Medicare program requirements.

(a) *Principle.* CMS pays the full reasonable cost incurred by an HMO or CMP for activities that are solely for Medicare purposes and unique to Medicare contracts under section 1876 of the Act.

(b) *Application.* CMS pays the full reasonable cost of the following activities:

(1) Reporting increases and decreases in the number of Medicare enrollees.

(2) Obtaining independent certification of the HMO's or CMP's cost report to the extent that it is for Medicare purposes.

(3) Reporting special data that CMS requires solely for program planning and evaluation.

(c) *Prior approval requirement.* The costs specified in paragraph (b) of this section must be separately budgeted and approved by CMS before the contract period begins.

(d) *Limit on full payment.* Full payment is limited to the costs specified in paragraph (b) of this section. All other administrative costs must be apportioned in accordance with § 417.552.

[60 FR 46230, Sept. 6, 1995]

§ 417.552 Cost apportionment: General provisions.

(a) *Basic rule.* The HMO or CMP must apportion its total allowable direct and indirect costs among its Medicare enrollees, its other enrollees, and its nonenrolled patients—

(1) In accordance with this subpart; and

(2) Using methods approved by CMS.

(b) *Purpose of apportionment.* The purpose of apportionment is to ensure that—

(1) The cost of services furnished to Medicare enrollees is not borne by other enrollees and nonenrolled patients; and

(2) The cost of the services furnished to other enrollees and nonenrolled patients is not borne by Medicare.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.554 Apportionment: Provider services furnished directly by the HMO or CMP.

The Medicare share of the cost of covered services furnished to Medicare enrollees by providers that are owned or operated by the HMO or CMP or are related to the HMO or CMP by common ownership or control must be determined in accordance with the apportionment methods set forth in part 412, §§ 413.24, 413.55, and 415.55 of this chapter.

[51 FR 28574, Aug. 8, 1986, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995; 60 FR 63189, Dec. 8, 1995]

§ 417.556 Apportionment: Provider services furnished by the HMO or CMP through arrangements with others.

The Medicare share of the cost of covered services furnished to Medicare enrollees through arrangements with providers other than those specified in § 417.554 must be determined as follows:

(a) The Medicare share must be based on the cost the HMO or CMP pays the provider under their arrangement, to the extent that cost is reasonable and within the limits established by §§ 417.534 through 417.548.

(b) Except as specified in paragraph (c) of this section, apportionment must be on the same approved basis that is used by the provider for Medicare beneficiaries who are not Medicare enrollees of the HMO or CMP, subject to the conditions and limitations set forth in § 417.548.

(c) If, because of the special nature or terms of the HMO's or CMP's arrangement with the provider, apportionment on the basis specified in paragraph (b) of this section would result in Medicare's bearing the costs of furnishing services to individuals other than the HMO's or CMP's Medicare enrollees, apportionment must be on another basis that is approved by CMS and that will ensure that Medicare does not pay any of the cost of furnishing services to individuals who are not Medicare enrollees of the HMO or CMP.

(d) If the HMO or CMP elects to have providers reimbursed by the HMO's or CMP's Medicare intermediary, the Medicare share is the amount the intermediary paid the provider.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.558 Emergency, urgently needed, and out-of-area services for which the HMO or CMP accepts responsibility.

(a) *Source of payment.* Either CMS or the HMO or CMP may pay a provider for emergency or urgently needed services or other covered out-of-area services for which the HMO or CMP accepts responsibility.

(b) *Limits on payment.* If the HMO or CMP pays, the payment amount may not exceed the amount that is allowable under part 412 or part 413 of this chapter.

(c) *Exception to limit on payment.* Payment in excess of the limit imposed by paragraph (b) of this section is allowable only if the HMO or CMP demonstrates to CMS's satisfaction that it is justified on the basis of advantages gained by the HMO or CMP, as set forth in § 417.548.

[60 FR 46231, Sept. 6, 1995]

§ 417.560 Apportionment: Part B physician and supplier services.

(a) *Medical services furnished directly by the HMO or CMP.* The total allowable cost of Part B physician and supplier services furnished by employees or partners of the HMO or CMP or by a related entity of the HMO or CMP must be apportioned on the basis of the ratio of covered Part B services furnished to Medicare enrollees to total services furnished to all the HMO's or CMP's enrollees and nonenrolled patients. The HMO or CMP must use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(b) *Medical services furnished under arrangements made by the HMO or CMP.*

When the HMO or CMP pays for Part B physician and supplier services on some basis other than fee-for-service, the reasonable cost the HMO or CMP pays under its financial arrangement with the physician or supplier must be apportioned between Medicare enrollees and others based on the ratio of covered services furnished to Medicare enrollees to the total services furnished to all enrollees and nonenrolled patients. If apportionment on this basis would result in Medicare bearing the cost of furnishing services to individuals who are not Medicare enrollees, the Medicare share must be determined on another basis (approved by CMS) to ensure that Medicare pays only for services furnished to Medicare enrollees.

(c) *Medical services furnished under an arrangement that provides for the HMO or CMP to pay on a fee-for-service basis.* The Medicare share of the cost of Part B physician and supplier services furnished to Medicare enrollees under arrangements, and paid for by the HMO or CMP on a fee-for-service basis, is determined by multiplying the total amount for all such services by the ratio of charges for covered services furnished to Medicare enrollees to the total charges for all such services.

(d) *Emergency services, urgently needed services, and other covered medical services for which the HMO or CMP assumes financial responsibility.* The Medicare share of the cost of Part B emergency or urgently needed services or other Part B services that are not furnished by a provider and for which the HMO or CMP accepts financial responsibility is determined in accordance with paragraphs (b) and (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995]

§ 417.564 Apportionment and allocation of administrative and general costs.

(a) *Costs not directly associated with providing medical care.* Enrollment, marketing, and other administrative and general costs that benefit the total enrollment of the HMO or CMP and are not directly associated with furnishing medical care must be apportioned on the basis of a ratio of Medicare enrollees to the total HMO or CMP enrollment.

(b) *Costs significantly related to providing medical services.* (1) The following administrative and general costs, which bear a significant relationship to the services furnished, are not apportioned to Medicare directly; they must be allocated or distributed to the HMO or CMP components and then apportioned to Medicare in accordance with §§ 417.552 through 417.560:

(i) Facility costs.

(ii) Interest expense.

(iii) Medical record costs.

(iv) Centralized purchasing costs.

(v) Accounting and data processing costs.

(vi) Other administrative and general costs that are not included in paragraph (a) of this section.

(2) The allocation or distribution process must be as follows:

(i) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which can be quantitatively measured (such as centralized purchasing and data processing), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP in reasonable proportion to the benefits received by these components.

(ii) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which cannot be quantitatively measured (such as facility costs), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP on the basis of a ratio of total incurred and distributed costs per component to the total incurred and distributed costs for all components.

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

(1) Donations.
(2) Fines and penalties.
(3) Political and lobbying activities.
(4) Charity or courtesy allowances.
(5) Spousal education.
(6) Entertainment.
(7) Return on equity.

[60 FR 46231, Sept. 6, 1995, as amended at 75 FR 19803, Apr. 15, 2010]

§417.566 Other methods of allocation and apportionment.

(a) *Justification.* A method of apportionment or allocation of costs, other than the methods prescribed in this subpart may be used if it results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint.

(b) *Required approval.* (1) An HMO or CMP that desires to use an alternative method must submit a written request for CMS approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If CMS approves use of a different method, the HMO or CMP may not revert to another method without first obtaining CMS's approval.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.568 Adequate financial records, statistical data, and cost finding.

(a) *Maintenance of records.* (1) An HMO or CMP must maintain sufficient financial records and statistical data for proper determination of costs payable by CMS for covered services the HMO or CMP furnished to its Medicare enrollees either directly or under arrangements with others. These include accurate and sufficient detail of incurred costs and enrollment data.

(2) Unless otherwise provided for in this subpart, the HMO or CMP must follow standardized definitions and accounting, statistics, and reporting practices that are widely accepted in the health care industry.

(b) *Provision of data.* (1) The HMO or CMP must provide adequate cost and statistical data, based on its financial and statistical records, that can be verified by qualified auditors.

(2) The cost data must be based on an approved method of cost finding and, except as provided in paragraph (b)(3) of this section, on the accrual method of accounting.

(3) For governmental institutions that use a cash basis of accounting, cost data developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the capital asset, is allowable.

(c) *Provider services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes provider services directly, the provider is subject to the cost-finding and cost-reporting requirements set forth in parts 412 and 413 of this chapter. The provider must use an approved cost-finding method described in §413.24 of this chapter to determine the actual cost of these covered services.

(d) *Supplier services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes Part B physician and supplier services directly, it must furnish statistics that indicate the frequency and type of service provided, in the form and detail prescribed by CMS.

(e) *Part B physician and supplier services furnished through arrangement.* If the HMO or CMP furnishes Part B physician and supplier services under arrangements with others, it must furnish to CMS statistical, financial, and other information with respect to those services in the form and detail prescribed by CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§417.570 Interim per capita payments.

(a) *Principle of payment.* (1) CMS makes monthly advance payments equivalent to the HMO's or CMP's interim per capita rate for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(2) Additional lump-sum payments may be made at other times during the contract period, at CMS's discretion, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to the HMO's or CMP's Medicare enrollees, based upon the types and components of costs that are reimbursable under this part. The interim per capita rate is determined annually by CMS on the basis of the HMO's or CMP's annual operating and enrollment forecast (as set forth in § 417.572) and may be revised during the contract period as explained in paragraphs (c) and (d) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, CMS will adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the HMO or CMP in its interim estimated cost and enrollment reports or on other evidence showing that the rate based on actual costs is more or less than the current rate. Adjustments may also be made if there is—

(1) A change in the number of Medicare enrollees that affects the per capita rate;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by the HMO's or CMP's Medicare enrollees.

(d) *Reduction of interim payments.* If the HMO or CMP does not submit, on time, the reports and other data required to determine the proper amount of payment, CMS may reduce interim payments to the extent appropriate, or may take any other action authorized under this part. An interim payment reduction remains in effect until CMS can make a reasonable estimate of per capita costs.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.572 Budget and enrollment forecast and interim reports.

(a) *Annual submittal.* The HMO or CMP must submit an annual operating budget and enrollment forecast, in the form and detail required by CMS, at least 90 days before the beginning of each contract period. The forecast must be based on financial and statistical data and records that can be verified if CMS requires a detailed review of supporting records. The data and records include, but are not limited to, all ledgers, books, records, and original evidence of costs, and statistical data used in the determination of reasonable cost.

(b) *Effect of failure to submit on time.* If the HMO or CMP does not submit the budget and enrollment forecast on time, CMS may—

(1) Establish an interim per capita rate of payment on the basis of the best available data and adjust payments on the basis of that rate until the required reports are submitted and a new interim per capita rate can be established; or

(2) If there is not enough data on which to base an interim per capita rate, inform the HMO or CMP that interim payments will not be made until the required reports are submitted.

(c) *Interim cost reports.* (1) An HMO or CMP must submit interim cost reports on a quarterly basis in the form and detail prescribed by CMS. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) CMS may reduce the frequency of the reports required under paragraph (c)(1) of this section if CMS determines that, on the basis of the HMO's or CMP's reporting experience, there is good cause to do so.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.574 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the HMO's or CMP's final interim cost and enrollment reports, CMS will make an interim determination of the estimated amount payable to the HMO or CMP for the reasonable cost of covered services furnished to its Medicare enrollees during the contract period. CMS will base the determination on the interim cost report and enrollment data submitted by the HMO or CMP, and any other relevant data CMS finds appropriate. For this purpose, CMS will accept costs as reported, subject to later review or audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments

and the amount found payable on the basis of the interim determination under paragraph (a) of this section, must be paid by the HMO or CMP or will be paid by CMS, whichever is appropriate, no later than 30 days after CMS's determination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.576 Final settlement.

(a) *General rule.* Final settlement and payment of amounts due the HMO or CMP or the appropriate Medicare trust funds are made following the HMO's or CMP's submission and CMS's review of an independently certified cost report and supporting documents as described in paragraph (b) of this section.

(b) *Certified cost report as basis for final settlement*—(1) *Timing of cost report.* The HMO or CMP must submit to CMS an independently certified cost report and supporting documents, in the form and detail required by CMS, no later than 180 days after the end of each contract period, unless CMS extends the period for good cause shown by the HMO or CMP.

(2) *Content of cost report.* The cost report and supporting documents must include the following:

(i) The per capita costs incurred in furnishing covered services to its Medicare enrollees, determined in accordance with subpart O of this part and including—

(A) The costs incurred by entities related to the HMO or CMP by common ownership or control; and

(B) For reports for cost-reporting periods that begin on or after January 1, 1996, the costs of hospital and SNF services paid by Medicare's intermediaries under the option provided by §417.532(d).

(ii) The HMO's or CMP's methods of apportioning cost among Medicare enrollees, and nonenrolled patients, in accordance with the payment procedures specified in this subpart (as, applicable, in parts 412 and 413 of this chapter); and

(iii) Any other information required by CMS.

(3) *Failure to report required financial information.* If the HMO or CMP fails to submit the required cost report and supporting documents within 180 days (or an extended period approved by CMS under paragraph (b)(1) of this section), CMS may—

(i) Consider the failure to report as evidence of likely overpayment; and

(ii) Initiate recovery of amounts previously paid, or reduce interim payments, or both.

(c) *Final determination and adjustment.* (1) After receipt of acceptable reports as specified in paragraph (b) of this section, CMS determines the total payment due the HMO or CMP for furnishing covered services to its Medicare enrollees (which is subject to the audit provisions of this subpart) and makes a retroactive adjustment to bring interim payments into agreement with the payable amount due the HMO or CMP.

(2) A final settlement may be made with the HMO or CMP even though a provider that is not owned or operated by the HMO or CMP or related to the HMO or CMP by common ownership or control and that provides services to the HMO's or CMP's Medicare enrollees has not had a final settlement with CMS under parts 412 and 413 of this chapter for services furnished by the provider to Medicare beneficiaries who are not enrolled in the HMO or CMP. In this situation—

(i) CMS must be satisfied that the costs of covered services furnished to the HMO's or CMP's Medicare enrollees, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interest of the Medicare program would best be served by not delaying final settlement with the HMO or CMP until there is a final settlement with the provider for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP; and

(ii) Prompt settlement with the HMO or CMP would be in the best interest of the Medicare program if, for instance, the provider's costs represent an insignificant portion of total payment due to the HMO or CMP; or if CMS is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under parts 412 and 413 of this chapter.

(d) *Notice of amount of payment.* The notice of amount of Medicare payment—

(1) Explains CMS's determination regarding total Medicare payment due the HMO or CMP for the contract period covered by the financial information specified in paragraph (b) of this section;

(2) Relates this determination to the HMO's or CMP's claimed total payable cost for that period;

(3) Explains the amounts and reasons, by appropriate reference to law, regulations, and Medicare program policy and procedures, if the determined amounts differ from the HMO's or CMP's claim; and

(4) Informs the HMO or CMP of its right to a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter

(e) *Basis for retroactive adjustment.* (1) CMS's determination (as contained in the notice of amount of Medicare payment) constitutes the basis for making retroactive adjustments to any Medicare payment made to the HMO or CMP during the period to which the determination applies.

(2) Further payments to the HMO or CMP may be withheld or offset in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO or CMP, even if the HMO or CMP requests a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(3) Any withholding continues until the earliest of the following occurs:

(i) The overpayment is liquidated.

(ii) The HMO or CMP enters into an agreement with CMS to refund the overpaid amount.

(iii) CMS, on the basis of subsequently acquired information, determines that there was no overpayment.

(iv) The decision of a hearing specified in paragraph (d)(4) of this section is that there was no overpayment.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995; 60 FR 46231, Sept. 6, 1995; 73 FR 30267, May 23, 2008]

Subpart P—Medicare Payment: Risk Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.580 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1876 (a), (e), and (g) of the Act that pertain to the amount CMS pays an organization for its Medicare enrollees who are enrolled on a risk basis.

(b) *Scope.* This subpart sets forth—

(1) Method of payment;

(2) Procedures for determining the HMO's or CMP's payment rate; and

(3) Procedures for determining the additional benefits (and their value) the HMO or CMP must provide to its Medicare enrollees.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§ 417.582 Definitions.

As used in this subpart—

AAPCC stands for adjusted average per capita cost.

ACR stands for adjusted community rate.

Actuarial factors means factors such as the age, sex, and disability level distribution of the population and any other relevant factors that CMS determines have a significant effect on the level of utilization and cost of health services.

APCRP stands for average of per capita rates of payment.

Class of Medicare enrollees means a group of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.

Similar area means an area similar to the HMO's or CMP's geographic area but free from special characteristics that would distort the determination of the AAPCC.

U.S. per capita incurred cost means the average per capita cost, including intermediary or carrier administrative costs, incurred by Medicare, as determined on an accrual basis, for covered services furnished to Medicare beneficiaries nationwide during the most

recent period for which CMS has complete data.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.584 Payment to HMOs or CMPs with risk contracts.

Except in the circumstances specified in §417.440(d) for inpatient hospital care, and as provided in §417.585 for hospice care, CMS makes payment for covered services only to the HMO or CMP.

(a) *Principle of payment.* CMS makes monthly advance payments equivalent to the HMO's or CMP's per capita rate of payment for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(b) *Determination of rate.* (1) The annual per capita rate of payment for each class of Medicare enrollees is equal to 95 percent of the AAPCC (as determined under the provisions of §417.588) for that class of Medicare enrollees.

(2) CMS furnishes each HMO or CMP with its per capita rate of payment for each class of Medicare enrollees not later than 90 days before the beginning of the HMO's or CMP's contract period.

(c) *Adjustments to payments.* If the actual number of Medicare enrollees differs from the estimated number on which the amount of advance monthly payment was based, CMS adjusts subsequent monthly payments to take account of the difference.

(d) *Reduction of payments.* If an HMO or CMP requests a reduction in its monthly payment in accordance with §417.592(b)(2), CMS reduces the amount of payment by the appropriate amount.

(e) *Determination of rate for calendar year 1998.* For calendar year 1998, HMOs or CMPs with risk contracts will be paid in accordance with principles contained in subpart F of part 422 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995; 63 FR 35067, June 26, 1998]

§417.585 Special rules: Hospice care.

(a) No payment is made to an HMO or CMP on behalf of a Medicare enrollee who has elected hospice care under §418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in §417.592. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the enrollee resumes normal Medicare coverage.

(b) During the time the election is in effect, the HMO or CMP may bill CMS on a fee-for-service basis (subject to the usual Medicare rules of payment) but only for the following covered Medicare services:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which the enrollee elected hospice care or a condition related to the terminal condition.

(3) Services furnished after the revocation or expiration of the enrollee's hospice election until the full monthly capitation payments begin again.

(c) Payment for hospice care services furnished to Medicare enrollees of an HMO or CMP is made to the Medicare-participating hospice elected by the enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.588 Computation of adjusted average per capita cost (AAPCC).

(a) *Basic data.* In computing the AAPCC, CMS uses the U.S. per capita incurred cost and adjusts it by the factors specified in paragraph (c) of this section to establish an AAPCC for each class of Medicare enrollees.

(b) *Advance notice to the HMO or CMP.* Before the beginning of a contract period, CMS informs the HMO or CMP of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors*—(1) *Geographic.* CMS makes an adjustment to reflect the relative level of Medicare expenditures for beneficiaries who reside in the HMO's or CMP's geographic area (or a similar area). This adjustment is based

on reimbursement for Medicare covered services and uses the most accurate and timely data that pertain to the HMO's or CMP's geographic area and that is available to CMS when it makes the determination.

(2) *Enrollment.* CMS makes a further adjustment to remove the cost effect of all area Medicare beneficiaries who are enrolled in the HMO or CMP or another HMO or CMP.

(3) *Age, sex, and disability status.* CMS makes adjustments to reflect the age and sex distribution and the disability status of the HMO's or CMP's enrollees based on Medicare program experience and available data that indicate cost differences that result from those factors.

(4) *Other relevant factors.* If accurate data are available and appropriate, CMS makes adjustments to reflect welfare and institutional status and other relevant factors.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.590 Computation of the average of the per capita rates of payment.

(a) *Computation by the HMO or CMP.* As indicated in § 417.584(b), before an HMO's or CMP's contract period begins, CMS determines a per capita rate of payment for each class of the HMO's or CMP's Medicare enrollees. In order to determine the additional benefits required under § 417.592, weighted averages of those per capita rates must be computed separately for enrollees entitled to Part A and Part B, and for enrollees entitled only to Part B. Except as provided in paragraph (b) of this section, the HMO or CMP must make the computations.

(b) *Computation by CMS.* If the HMO or CMP claims to have insufficient enrollment experience to make the computations required by paragraph (a) of this section, and CMS agrees with the claim, CMS makes the computations, using the best available information, which may include the enrollment experience of other risk HMOs and CMPs.

[58 FR 38075, July 15, 1993]

§ 417.592 Additional benefits requirement.

(a) *General rules.* (1) An HMO or CMP that has an APCRP (as determined under § 417.590) greater than its ACR (as determined under § 417.594) must elect one of the options specified in paragraph (b) of this section.

(2) The dollar value of the elected option must, over the course of a contract period, be at least equal to the difference between the APCRP and the proposed ACR.

(b) *Options*—(1) *Additional benefits.* Provide its Medicare enrollees with additional benefits in accordance with paragraph (c) of this section.

(2) *Payment reduction.* Request CMS to reduce its monthly payments.

(3) *Combination of additional benefits and payment reduction.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section and request CMS to reduce the monthly payments by the remaining difference between the APCRP and the ACR.

(4) *Combination of additional benefits and withholding in a stabilization fund.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section, and request CMS to withhold in a stabilization fund (as provided in § 417.596) the remaining difference between the APCRP and the ACR.

(c) *Special rules: Additional benefits option.* (1) The HMO or CMP must determine additional benefits separately for enrollees entitled to both Part A and Part B benefits and those entitled only to Part B.

(2) The HMO or CMP may elect to provide additional benefits in any of the following forms—

(i) A reduction in the HMO's or CMP's premium or in other charges it imposes in the form of deductibles or coinsurance.

(ii) Health benefits in addition to the required Part A and Part B covered services.

(iii) A combination of reduced charges and additional benefits.

(d) *Notification to CMS.* (1) The HMO or CMP must give CMS notice of its ACR and its weighted APCRP at least 45 days before its contract period begins.

(2) An HMO or CMP that elects the option of providing additional benefits must include in its submittal—

(i) A description of the additional benefits it will provide to its Medicare enrollees; and

(ii) Supporting evidence to show that the selected benefits meet the requirements of paragraph (a)(2) of this section with respect to dollar value equivalence.

[60 FR 46232, Sept. 6, 1995]

§417.594 Computation of adjusted community rate (ACR).

(a) *Basic rule.* Each HMO or CMP must compute its basic rate as follows:

(1) Compute an initial rate in accordance with paragraph (b) of this section.

(2) Adjust and reduce the initial rate in accordance with paragraphs (c) and (d) of this section.

(b) *Computation of initial rates.* (1) The HMO or CMP must compute its initial rate using either of the following systems:

(i) A community rating system as defined in §417.104(b); or

(ii) A system, approved by CMS, under which the HMO or CMP develops an aggregate premium for all its enrollees and weights the aggregate by the size of the various enrolled groups that compose its enrollment.

(For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers that enroll in the HMO or CMP through payment of premiums.)

(2) Regardless of which method the HMO or CMP uses—

(i) The initial rate must be equal to the premium it would charge its non-Medicare enrollees for the Medicare-covered services;

(ii) The HMO or CMP must compute the rates separately for enrollees entitled to Medicare Part A and Part B and for those entitled only to Part B; and

(iii) The HMO or CMP must identify and take into account anticipated revenue from health insurance payers for those services for which Medicare is not the primary payer as provided in §417.528.

(3) Except as provided in paragraph (b)(4) of this section, the HMO or CMP must identify in its initial rate calculation, the following components whose rates must be consistent with rates used by the HMO or CMP in calculating premiums for non-Medicare enrollees:

(i) Hospital services (services covered under Medicare Part A and Part B shown separately).

(ii) Physicians' services.

(iii) Other medical services (for example, X-ray and laboratory services).

(iv) Home health services.

(v) Out-of-plan claims for emergency services.

(vi) Skilled nursing care services.

(vii) Ambulance services.

(viii) Other Medicare covered services.

(ix) General and administrative.

(x) Noncovered Medicare services (for example, eyeglasses).

(xi) Services for which Medicare is the secondary payer.

(xii) Enrollee liabilities (for example, deductibles, coinsurance, or copayments) for covered services.

(4) An HMO or CMP that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the HMO or CMP provides CMS with the documentation necessary to support any adjustments the HMO or CMP makes to the initial rate in accordance with paragraph (e) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the HMO or CMP during prior contract periods. The HMO or CMP must submit supporting documentation to assure CMS that rates do not include past losses but only premiums for the price of additional benefits and services of the upcoming contract period.

(c) *Adjustment of initial rates*—(1) *Purpose of adjustment.* The purpose of adjustment is to reflect the utilization characteristics of Medicare enrollees.

(2) *Adjustment by the HMO or CMP.* The HMO or CMP may adjust the rate for a particular service using more than one of the following factors if they do not duplicate each other:

(i) *Unit of service.* If the HMO or CMP purchases or identifies services on a unit of service basis and the unit of

service is defined the same for all enrollees, the HMO or CMP may make an adjustment in its initial rate to reflect the number of units of services furnished to its Medicare enrollees in comparison to those furnished to other enrollees.

(ii) *Complexity or intensity of services.* The HMO or CMP may make an adjustment to reflect the differences in the complexity or intensity of services furnished to its Medicare enrollees if the calculation of its initial rate includes the elements of this adjustment.

(3) *Support documentation.* All adjustments made by the HMO or CMP must be accompanied by adequate supporting data. If an HMO or CMP does not have sufficient enrollment experience to develop this data, it may, during its initial contract period, use documented statistics from a nationally recognized statistical source.

(4) *Adjustment by CMS.* If the HMO or CMP does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of its Medicare enrollees, CMS will, at the HMO's or CMP's request, adjust the initial rate. CMS adjusts the rate on the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other HMOs or CMPs; or

(ii) Medicare beneficiaries (in the HMO's or CMP's area, or State, or the United States) who are eligible to enroll in an HMO or CMP and other individuals in that same area, or State, or the United States.

(d) *Reduction of adjusted rates.* The HMO or CMP or CMS further reduces the adjusted rates by the actuarial value of applicable Medicare deductibles and coinsurance.

(e) *CMS review*—(1) *Submission of data.* The HMO or CMP must submit its ACR and the methodology used to compute it for CMS review and approval, and must include adequate supporting data.

(2) *Appeals procedures.* (i) If CMS determines that an HMO's or CMP's ACR computation is not acceptable, the HMO or CMP may, within 30 days after receipt of notice of the determination, file with CMS a request for a hearing.

(ii) The request must state why the HMO or CMP believes the determination is incorrect, and include any supporting evidence the HMO or CMP considers pertinent.

(iii) A hearing officer designated by CMS conducts the hearing in accordance with the hearing procedures set forth in §§ 405.1819 through 405.1833 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.596 Establishment of a benefit stabilization fund.

(a) *General.* If an HMO or CMP is required to provide its Medicare enrollees with additional benefits as described in § 417.592, the organization may request that CMS withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

(b) *Notification to CMS.* An HMO's or CMP's request to have monies withheld in a benefit stabilization fund must be made when the HMO or CMP notifies CMS under § 417.592(d) of its ACR and its APCRP in preparation for its next contract period.

(c) *Limitations on the amounts withheld*—(1) *Limit per contract period.* Except as provided in paragraph (c)(3) of this section, CMS does not withhold in a benefit stabilization fund more than 15 percent of the difference between an HMO's or CMP's ACR and its ACPRP for a given contract period.

(2) *Cumulative limit.* If CMS has established a benefit stabilization fund for an HMO or CMP, it does not approve a request for withholding made by that HMO or CMP for a subsequent contract period that would cause the total value of the benefit stabilization fund to exceed 25 percent of the difference between the HMO's or CMP's ACR and the average of its per capita rates of payment for that subsequent contract period.

(3) *Exception.* CMS may grant an exception to the limit described in paragraph (c)(1) of this section if an HMO or CMP can demonstrate to CMS's satisfaction that the value of the additional

benefits it provides to its Medicare enrollees fluctuates substantially in excess of 15 percent from one contract period to another.

(d) *Financial management of benefit stabilization funds.* (1) The amounts withheld by CMS to establish and maintain a benefit stabilization fund are in the custody of the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

(2) The amounts withheld in a benefit stabilization fund are accounted for by CMS in accounts in which interest does not accrue to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended by 56 FR 46571, Sept. 13, 1991; 58 FR 38083, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

§417.597 Withdrawal from a benefit stabilization fund.

(a) *Notification to CMS.* An HMO's or CMP's request to make a withdrawal from its benefit stabilization fund for use during a contract period must be made when the HMO or CMP notifies CMS of its ACR and its ACPRP for that contract period. In making its request, the HMO or CMP must—

(1) Indicate how it intends to use the withdrawn amounts;

(2) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(3) Document the HMO's or CMP's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(4) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the HMO or CMP will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(b) *Criteria for CMS approval.* CMS approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(1) The HMO's or CMP's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The HMO's or CMP's ACR for the next contract period is significantly higher than that of the previous contract period; or

(3) The HMO's or CMP's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period.

(c) *Basis for denial.* CMS does not approve a request for a withdrawal from a benefit stabilization fund if the withdrawal would allow the HMO or CMP to—

(1) Offer without charge the supplemental services it provides to its Medicare enrollees under the provisions of §417.440 (b)(2) or (b)(3); or

(2) Refinance prior contract period losses or to avoid losses in the upcoming contract period.

(d) *Form of payment.* Payment of monies withdrawn from a benefit stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the HMO or CMP under §417.584 during the period of the contract.

[58 FR 38075, July 15, 1993, as amended at 60 FR 46233, Sept. 6, 1995]

§417.598 Annual enrollment reconciliation.

CMS's payment to an HMO or CMP may be subject to an enrollment reconciliation at least annually. CMS conducts this reconciliation as necessary to ensure that the payments made do not exceed or fall short of the appropriate per capita rate of payment for each Medicare enrollee of the HMO or CMP during the contract period. The HMO or CMP must submit any information or reports required by CMS to conduct the reconciliation.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

Subpart Q—Beneficiary Appeals

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

[60 FR 46233, Sept. 6, 1995, as amended at 62 FR 23374, Apr. 30, 1997; 70 FR 4713, Jan. 28, 2005]

Subpart R—Medicare Contract Appeals

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.640 Applicability.

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

[75 FR 19803, Apr. 15, 2010]

Subparts S–T [Reserved]

Subpart U—Health Care Prepayment Plans

SOURCE: 50 FR 1375, Jan. 10, 1985, unless otherwise noted.

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions.* As used in this subpart, unless the context indicates otherwise—

Covered Part B services means physicians' services, diagnostic X-ray tests, laboratory, other diagnostic tests, and any additional medical and other health services, that the HCPP furnishes to its Medicare enrollees.

Health care prepayment plan (HCPP) means an organization that meets the following conditions:

(1) Effective January 1, 1999, (or on the effective date of the HCPP agreement in the case of a 1998 applicant) either—

(A) Is union or employer sponsored; or

(B) Does not provide, or arrange for the provision of, any inpatient hospital services.

(2) Is responsible for the organization, financing, and delivery of covered Part B services to a defined population on a prepayment basis.

(3) Meets the conditions specified in paragraph (b) of this section.

(4) Elects to be reimbursed on a reasonable cost basis.

Medicare enrollee means a beneficiary under Part B of Medicare who has been identified on CMS records as an enrollee of the HCPP. *Reporting period* means the period specified by CMS for which an HCPP must report its costs and utilization.

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with CMS as specified in § 417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of title XVIII of the Social Security Act and section 353 of the PHS Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would not otherwise meet the conditions specified in paragraph (b)(1) of this section, may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with CMS as required by §417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, CMS pays an HCPP on the basis of the reasonable cost it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(2) *Payment for Part B services: Basic rules*—(i) *Cost basis payment.* Except as provided in paragraph (d) of this section, CMS pays an HCPP on the basis of the reasonable costs it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(ii) *Deductions.* In determining the amount due an HCPP for covered Part B services furnished to its Medicare enrollees, CMS deducts, from the reasonable cost actually incurred by the HCPP, the following:

(A) The actuarial value of the Part B deductible.

(B) An amount equal to 20 percent of the cost incurred for any service that is subject to the Medicare coinsurance.

(d) *Covered services not reimbursed to an HCPP.* (1) Services reimbursed under Part A are not reimbursable to an HCPP. CMS makes payment for these services directly to the hospital, or other provider of services, on a reasonable cost basis through the provider's Medicare fiscal intermediary (for more details, see parts 412 and 413 of this chapter).

(2) Covered Part B services furnished by a provider of services to an HCPP's Medicare enrollees are not payable to the HCPP. CMS makes payment for these services to the provider on behalf of the Medicare enrollee through the provider's Medicare fiscal intermediary. This requirement does not affect Medicare payment to the HCPP for physicians' services furnished to its Medicare enrollees for which the physicians are compensated by the HCPP.

(e) *Payment for services to nonenrollees.* CMS makes payment to an HCPP for covered Part B services furnished by the HCPP to a Medicare beneficiary who is not enrolled in the HCPP if the beneficiary assigns his rights to payment in accordance with §424.55 of this chapter. Payment is made on a reasonable charge basis through the HCPP's Medicare carrier.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 7135, Feb. 28, 1992; 58 FR 38081, July 15, 1993; 60 FR 34888, July 5, 1995; 63 FR 35067, June 26, 1998; 63 FR 52611, Oct. 1, 1998]

§417.801 Agreements between CMS and health care prepayment plans.

(a) *General requirement.* (1) In order to participate and receive payment under the Medicare program as an HCPP as defined in §417.800, an organization must enter into a written agreement with CMS.

(2) An existing group practice prepayment plan (GPPP) that continues as an HCPP under this subpart U must have entered into a written agreement with CMS within 60 days of January 31, 1983.

(b) *Terms.* The agreement must provide that the HCPP agrees to—

(1) Maintain compliance with the requirements for participation and reimbursement on a reasonable cost basis of HCPPs as specified in §417.800;

(2) Not charge the Medicare enrollee or any other person for items or services for which that enrollee is entitled to have payment made under the provisions of this part, except for any deductible or coinsurance amounts for which the enrollee is liable;

(3) Refund, as promptly as possible, any money incorrectly collected as charges or premiums, or in any other way from Medicare enrollees in the HCPP in accordance with the requirements specified in §417.456;

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Meet the advance directives requirements specified in § 417.436(d) of this part;

(6) Establish administrative review procedures in accordance with §§ 417.830 through 417.840 for Medicare enrollees who are dissatisfied with denied services or claims; and

(7) Consider any additional requirements that CMS finds necessary or desirable for efficient and effective program administration.

(c) *Duration of agreement.* Except for the term of the initial agreement, the agreement is for a term of one year and may be renewed annually by mutual consent. The term of the initial agreement is set by CMS.

(d) *Termination or nonrenewal of agreement by CMS.* (1) CMS may terminate or not renew an agreement if it determines that—

(i) The HCPP no longer meets the requirements for participation and reimbursement as an HCPP as specified in § 417.800;

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law. This includes, but is not limited to, the following:

(A) Failure to provide for and document adequate access to providers.

(B) Failure to comply with CMS requirements concerning provision of data and maintenance of records.

(C) Failure to comply with financial requirements specified at § 417.806; or

(iii) The HCPP undergoes a change in ownership as specified in subpart M of this part.

(2) CMS will give notice of termination or nonrenewal to the HCPP at least 90 days before the effective date stated in the notice.

(e) *Termination or nonrenewal of agreement by HCPP.* (1) If an HCPP does not wish to renew its agreement at the end of the term, it must give written notice to CMS at least 90 days before the end of the term of the agreement. If an HCPP wishes to terminate its agreement before the end of the term, it must file a written notice with CMS stating the intended effective date of termination.

(2) CMS may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. CMS makes this decision based on a finding that termination on a specific date would not—

(i) Unduly disrupt the furnishing of services to the community serviced by the HCPP; or

(ii) Otherwise interfere with the efficient administration of the Medicare program.

[50 FR 1375, Jan. 10, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38081, July 15, 1993; 59 FR 49843, Sept. 30, 1994; 59 FR 59943, Nov. 21, 1994; 77 FR 22166, Apr. 12, 2012]

§ 417.802 Allowable costs.

(a) *General rule.* The costs that are considered allowable for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs specified in subpart O of this part, except those in §§ 417.531, 417.532 (a)(3) and (c) through (g), 417.536 (l) and (m), 417.546, 417.548, and 417.550(b)(2).

(b) *Physicians' services and other Part B supplier services furnished under arrangements*—(1) *Principle.* The amount paid by an HCPP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable.

(2) *Application: Payment on other than a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the HCPP may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the HCPP makes payment compensates its physicians on a fee-for-service basis, the HCPP's payment to the group may not exceed the reasonable charges for those services, as defined in subpart E of part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(2)(ii)(A) of this section is allowable if the group has procedures under which members

of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

(3) *Application: Payment on a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(3)(ii) of this section, the costs incurred by the HCPP are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in subpart E of part 405 of this chapter; and

(B) The amount that CMS would pay for those services if they were furnished to beneficiaries who are not enrolled in the HCPP and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the paragraph (b)(3)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In these cases, the amount paid by an HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.804 Cost apportionment.

(a) The HCPP follows the cost apportionment principles specified in §§ 417.552 through 417.566, except for provisions on provider costs and provisions on departmental apportionment.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

§ 417.806 Financial records, statistical data, and cost finding.

(a) The principles specified in § 417.568 apply to HCPPs, except those in paragraph (c) of that section.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(c) An HCPP must permit the Department and the Comptroller General to audit or inspect any books and records of the HCPP and of any related organization that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees. For purposes of this requirement, the principles specified in § 417.486 apply to HCPPs.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.808 Interim per capita payments.

The HCPP follows the principles specified in §§ 417.570 and 417.572 on interim per capita payments, except for the following:

(a) When applying these principles to HCPPs, the term ''reporting period'' should be used instead of the term ''contract period'' contained in that section.

(b) An HCPP must submit to CMS an annual operating budget and enrollment forecast, in the form and detail specified by CMS, at least 60 days before the beginning of each reporting period. A reporting period must be 12 consecutive months, except that the HCPP's initial reporting period for participating in Medicare may be as short as 6 months or as long as 18 months.

(c) An HCPP must submit to CMS an interim cost report and enrollment data applicable to the first 6-month period of the HCPP's reporting period in the form and detail specified by CMS. The interim cost report must be submitted not later than 45 days after the close of the first 6-month period of the HCPP's reporting period.

(d) In lieu of an interim payment based on the actual monthly enrollment in an HCPP, CMS and the HCPP

may agree to a uniform monthly interim reimbursement rate for a reporting period. This interim rate is based on the HCPP's budget and enrollment forecast, if CMS is satisfied that the rate is consistent with efficiency and economy, and will not result in excessive adjustment at the end of the reporting period.

§ 417.810 Final settlement.

(a) *General requirement.* CMS and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to CMS, following the submission and review of the HCPP's annual cost report and the supporting documents specified in paragraph (b) of this section.

(b) *Annual cost report as basis for final settlement*—(1) *Form and due date.* An HCPP must submit to CMS a cost report and supporting documents in the form and detail specified by CMS, no later than 120 days following the close of a reporting period.

(2) *Contents.* The report must include—

(i) The HCPP's per capita incurred costs of providing covered Part B services to its Medicare enrollees during the reporting period, including any costs incurred by another organization related to the HCPP by common ownership or control;

(ii) The HCPP's methods of apportioning costs among its Medicare enrollees, enrollees who are not Medicare beneficiaries, and other nonenrollees, including Medicare beneficiaries receiving health care services on a fee-for-service or other basis; and

(iii) Information on enrollment and other data as specified by CMS.

(3) *Extension of time to submit cost report.* CMS may grant an HCPP an extension of time to submit a cost report for good cause shown.

(4) *Failure to report required financial information.* If an HCPP does not submit the required cost report and supporting documents within the time specified in paragraph (b)(1) of this section, and has not requested and received an extension of time for good cause shown, CMS may—

(i) Regard the failure to report this information as evidence of likely overpayment and reduce or suspend interim payments to the HCPP; and

(ii) Determine that amounts previously paid are overpayments, and make appropriate recovery.

(c) *Determination of final settlement.* Following the HCPP's submission of the reports specified in paragraph (b) of this section in acceptable form, CMS makes a determination of the total reimbursement due the HCPP for the reporting period and the difference, if any, between this amount and the total interim payments made to the HCPP. CMS sends to the HCPP a notice of the amount of reimbursement by the Medicare program. This notice—

(1) Explains CMS's determination of total reimbursement due the HCPP for the reporting period; and

(2) Informs the HCPP of its right to have the determination reviewed at a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(d) *Payment of amounts due.* (1) Within 30 days of CMS's determination, CMS or the HCPP, as appropriate, will make payment of any difference between the total amount due and the total interim payments made to the HCPP by CMS.

(2) If the HCPP does not pay CMS within 30 days of CMS's determination of any amounts the HCPP owes CMS, CMS may offset further payments to the HCPP to recover, or to aid in the recovery of, any overpayment identified in its determination.

(3) Any offset of payments CMS makes under paragraph (d)(2) of this section will remain in effect even if the HCPP has requested a hearing in accordance with the requirements specified in § 405.1801(b)(2) of this chapter.

(e) *Tentative settlement.* (1) If a final settlement cannot be made within 90 days after the HCPP submits the report specified in paragraph (b) of this section, CMS will make an interim settlement by estimating the amount payable to the HCPP.

(2) CMS or the HCPP will make payment within 30 days of CMS's determination under the tentative settlement of any estimated amounts due.

(3) The tentative settlement is subject to adjustment at the time of a final settlement.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993; 73 FR 30267, May 23, 2008]

§417.830 Scope of regulations on beneficiary appeals.

Sections 417.832 through 417.840 establish procedures for the presentation and resolution of organization determinations, reconsiderations, hearings, Departmental Appeals Board review, court reviews, and finality of decisions that are applicable to Medicare enrollees of an HCPP.

[59 FR 59943, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

§417.832 Applicability of requirements and procedures.

(a) The administrative review rights and procedures specified in §§417.834 through 417.840 pertain to disputes involving an organization determination, as defined in §417.838, with which the enrollee is dissatisfied.

(b) Physicians and other individuals who furnish items or services under arrangements with an HCPP have no right of administrative review under §§417.834 through 417.840.

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

[59 FR 59943, Nov. 21, 1994, as amended at 70 FR 4713, Jan. 28, 2005]

§417.834 Responsibility for establishing administrative review procedures.

The HCPP is responsible for establishing and maintaining the administrative review procedures that are specified in §§417.830 through 417.840.

[59 FR 59943, Nov. 21, 1994]

§417.836 Written description of administrative review procedures.

Each HCPP is responsible for ensuring that all Medicare enrollees are informed in writing of the administrative review procedures that are available to them.

[59 FR 59943, Nov. 21, 1994]

§417.838 Organization determinations.

(a) *Actions that are organization determinations.* For purposes of §§417.830 through 417.840, an organization determination is a refusal to furnish or arrange for services, or reimburse the party for services provided to the beneficiary, on the grounds that the services are not covered by Medicare.

(b) *Actions that are not organization determinations.* The following are not organization determinations for purposes of §§417.830 through 417.840:

(1) A determination regarding services that were furnished by the HCPP, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding services that are not covered under the HCPP's agreement with CMS.

[59 FR 59943, Nov. 21, 1994]

§417.840 Administrative review procedures.

The HCPP must apply §422.568 through §422.626 of this chapter to—

(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and

(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

[75 FR 19803, Apr. 15, 2010]

Subpart V—Administration of Outstanding Loans and Loan Guarantees

§417.910 Applicability.

The regulations in this subpart apply, as appropriate, to public and private entities that have loans or loan guarantees that—

(a) Were awarded to them before October 1986 under section 1304 or section 1305 of the PHS Act; and

(b) Are still outstanding.

[59 FR 49842, Sept. 30, 1994]

§ 417.911 Definitions.

As used in this subpart—

Any 12-month period means the 12-month period beginning on the first day of any month.

Expansion of services means—

(1) The addition of any health service not previously provided by or through the HMO, that requires an increase in the facilities, equipment, or health professionals of the HMO; or

(2) The improvement or upgrading of existing facilities or equipment, or an increase in the number of categories of health professionals, of the HMO so that the HMO could provide directly services that it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

First 60 months of operation or expansion means the 60-month period beginning on the first day of the month during which the HMO first provided services to enrollees, or in the case of significant expansion, first provided services in accordance with its expansion plan.

Health system agency means an entity that has been designated in accordance with section 1515 of the PHS Act; and the term *State health planning and development agency* means an agency that has been designated in accordance with section 1521 of the PHS Act.

Initial costs of operation means any cost incurred in the first 60 months of an operation or expansion that met any of the following requirements:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority, was not a capital cost.

(2) Was required by State regulatory authority to meet reserves or tangible net equity requirements.

(3) Was for a payment made to reduce balance sheet liabilities existing at the beginning of the 60-month period, but only if—

(i) The payment had been approved in writing by the Secretary; and

(ii) The total of these payments did not exceed 20 percent of the amount of the loan.

(4) Was for a small capital expenditure, but only if—

(i) The cost had been approved in writing by the Secretary; and

(ii) The total of these costs did not exceed $200,000 in any 12-month period, and $400,000 during the first 60 months of operation or expansion.

Nonprofit as applied to a private entity, means a private agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Significant expansion means—

(1) A planned substantial increase in the enrollment of the HMO, that requires an increase in the number of health professionals serving enrollees of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or

(2) A planned expansion of the service area beyond the current service area, that would be made possible by the addition of health service delivery facilities and health professionals to serve enrollees at a new site or sites in areas previously without service sites.

Small capital expenditure means expenditures for—

(1) Equipment as defined in 2 CFR 200.1; or

(2) Alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

[58 FR 38076, July 15, 1993, as amended at 59 FR 49842, Sept. 30, 1994; 81 FR 3011, Jan. 20, 2016; 89 FR 80069, Oct. 2, 2024]

§ 417.920 Planning and initial development.

(a) Under section 1304 of the PHS Act, grants and loan guarantees were awarded for projects for planning and initial development of HMOs.

(b) Planning projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(c) Initial development projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(3) Expansion of the range or amount of services furnished by the HMO.

[58 FR 38076, July 15, 1993]

§ 417.930 Initial costs of operation.

Under section 1305 of the PHS, loans and loan guarantees were awarded for initial costs of operation of HMOs.

[58 FR 38077, July 15, 1993]

§ 417.931 [Reserved]

§ 417.934 Reserve requirement.

(a) *Timing.* Unless the Secretary approved a longer period, an entity that received a loan or loan guarantee under section 1305 of the PHS Act was required to establish a restricted reserve account on the earlier of the following:

(1) When the HMO's revenues and costs of operation reached the breakeven point.

(2) At the end of the 60-month period following the Secretary's endorsement of the loan or loan guarantee.

(b) *Purpose and amount of reserve.* The reserve had to be constituted so as to accumulate, no later than 12 years after endorsement of the loan or loan guarantee, an amount equal to 1 year's principal and interest.

[59 FR 49842, Sept. 30, 1994]

§ 417.937 Loan and loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart was disbursed to the entity in accordance with an agreement entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, is repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary could approve a shorter repayment period if he or she determined that a repayment period of less than 22 years is more appropriate to an entity's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon is repayable in accordance with a repayment schedule that is agreed upon by the parties to the loan or loan guarantee and approved by the Secretary before or at the time of endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary is repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient in amount to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation could be deferred with payment of interest only during that period. The Secretary could set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date of disbursement for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[59 FR 49842, Sept. 30, 1994]

§ 417.940 Civil action to enforce compliance with assurances.

The provisions of § 417.163(g) apply to entities that have outstanding loans or loan guarantees administered under this subpart.

[59 FR 49843, Sept. 30, 1994]

PART 418—HOSPICE CARE

Subpart A—General Provision and Definitions

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