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Part

CHAPTER IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services 414

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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SUBCHAPTER A—GENERAL PROVISIONS

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

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AUTHORITY: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

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Subpart A—General Provisions

§ 414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l)—Establishment of a fee schedule for ambulance services.

1834(m)—Rules for Medicare reimbursement for telehealth services.

1842(o)—Rules for payment of certain drugs and biologicals.

1847(a) and (b)—Competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

1848—Fee schedule for physician services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

[67 FR 9132, Feb. 27, 2002, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 48409, Aug. 18, 2006]

§ 414.2 Definitions.

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

AA stands for anesthesiologist assistant.

AHPB stands for adjusted historical payment basis.

CF stands for conversion factor.

CRNA stands for certified registered nurse anesthetist.

CY stands for calendar year.

FY stands for fiscal year.

GAF stands for geographic adjustment factor.

GPCI stands for geographic practice cost index.

HCPCS stands for CMS Common Procedure Coding System.

Physician services means the following services to the extent that they are covered by Medicare:

(1) Professional services of doctors of medicine and osteopathy (including osteopathic practitioners), doctors of optometry, doctors of podiatry, doctors

of dental surgery and dental medicine, and chiropractors.

(2) Supplies and services covered ''incident to'' physician services (excluding drugs as specified in § 414.36).

(3) Outpatient physical and occupational therapy services if furnished by a person or an entity that is not a Medicare provider of services as defined in § 400.202 of this chapter.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding diagnostic laboratory tests paid under the fee schedule established under section 1833(h) of the Act).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens, as described in section 1861(s)(2)(G) of the Act.

(7) Bone mass measurement.

RVU stands for relative value unit.

(8) Screening mammography services.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994; 60 FR 63177, Dec. 8, 1995; 63 FR 34328, June 24, 1998; 66 FR 55322, Nov. 1, 2001]

§ 414.4 Fee schedule areas.

(a) *General*. CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes*. CMS announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

Subpart B—Physicians and Other Practitioners

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

§ 414.20 Formula for computing fee schedule amounts.

(a) *Participating supplier*. The fee schedule amount for a participating supplier for a physician service as defined in § 414.2 is computed as the product of the following amounts:

(1) The RVUs for the service.

(2) The GAF for the fee schedule area.

(3) The CF.

(b) *Nonparticipating supplier*. The fee schedule amount for a nonparticipating supplier for a physician service as defined in § 414.2 is 95 percent of the fee schedule amount as calculated in paragraph (a) of this section.

[62 FR 59101, Oct. 31, 1997]

§ 414.21 Medicare payment basis.

Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.

[62 FR 59101, Oct. 31, 1997]

§ 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

(a) *Physician work RVUs*—(1) *General rule*. Physician work RVUs are established using a relative value scale in which the value of physician work for a particular service is rated relative to the value of work for other physician services.

(2) *Special RVUs for anesthesia and radiology services)*—(i) *Anesthesia services*. The rules for determining RVUs for anesthesia services are set forth in § 414.46.

(ii) *Radiology services*. CMS bases the RVUs for all radiology services on the relative value scale developed under section 1834(b)(1)(A) of the Act, with appropriate modifications to ensure that the RVUs established for radiology services that are similar or related to other physician services are consistent with the RVUs established for those similar or related services.

(b) *Practice expense RVUs*. (1) Practice expense RVUs are computed for each service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average practice expense percentage for a service or class of services is computed as follows:

(i) Multiply the average practice expense percentage for each specialty by the proportion of a particular service or class of service performed by that specialty.

(ii) Add the products for all specialties.

(3) For services furnished beginning calendar year (CY) 1994, for which 1994 practice expense RVUs exceed 1994 work RVUs and that are performed in office settings less than 75 percent of the time, the 1994, 1995, and 1996 practice expense RVUs are reduced by 25 percent of the amount by which they exceed the number of 1994 work RVUs. Practice expense RVUs are not reduced to less than 128 percent of 1994 work RVUs.

(4) For services furnished beginning January 1, 1998, practice expense RVUs for certain services are reduced to 110 percent of the work RVUs for those services. The following two categories of services are excluded from this limitation:

(i) The service is provided more than 75 percent of the time in an office setting; or

(ii) The service is one described in section 1848(c)(2)(G)(v) of the Act, codified at 42 U.S.C. 1395w–4(c)(2)(G). Section 1848(c)(2)(G)(v) of the Act refers to the 1998 proposed resource-based practice expense RVUs (as specified in the June 18, 1997 physician fee schedule proposed rule (62 FR 33158)) for the specific site, either in-office or out-of-office, increased from its 1997 practice expense RVUs.)

(5) For services furnished beginning January 1, 1999, the practice expense RVUs are based on 75 percent of the practice expense RVUs applicable to services furnished in 1998 and 25 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2000, the practice expense RVUs are based on 50 percent of the practice expense RVUs applicable to services furnished in 1998 and 50 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2001, the practice expense RVUs are based on 25 percent of the practice expense RVUs applicable to services furnished in 1998 and 75 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs.* The lower facility practice expense RVUs apply to services furnished to patients in the hospital, skilled nursing facility, community mental health center, or in an ambulatory surgical center when the physician performs procedures on the ASC approved procedures list. (The facility practice expense RVUs for a particular code may not be greater than the non-facility RVUs for the code.)

(B) *Non-facility practice expense RVUs.* The higher non-facility practice expense RVUs apply to services performed in a physician's office, a patient's home, an ASC if the physician is performing a procedure not on the ASC approved procedures list, a nursing facility, or a facility or institution other than a hospital or skilled nursing facility, community mental health center, or ASC performing an ASC approved procedure.

(C) *Outpatient therapy services.* Outpatient therapy services billed under the physician fee schedule are paid using the non-facility practice expense RVU component.

(ii) Only one practice expense RVU per code can be applied for each of the following services: services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits, that are furnished exclusively in one setting; and major surgical services.

(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by March 1, 2004 to determine CY 2005 practice expense RVUs and by March 1, 2005 to determine CY 2006 practice expense RVUs.

(c) *Malpractice insurance RVUs.* (1) Malpractice insurance RVUs are computed for each service or class of services by applying average malpractice insurance historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average historical malpractice insurance percentage for a service or class of services is computed as follows:

(i) Multiply the average malpractice insurance percentage for each specialty by the proportion of a particular service or class of services performed by that specialty.

(ii) Add all the products for all the specialties.

(3) For services furnished in the year 2000 and subsequent years, the malpractice RVUs are based on the relative malpractice insurance resources.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 62 FR 59102, Oct. 31, 1997; 63 FR 58910, Nov. 2, 1998; 64 FR 59441, Nov. 2, 1999; 65 FR 25668, May 3, 2000; 65 FR 65440, Nov. 1, 2000; 67 43558, June 28, 2002; 68 FR 63261, Nov. 7, 2003]

§ 414.24 Review, revision, and addition of RVUs for physician services.

(a) *Interim values for new and revised HCPCS level 1 and level 2 codes.* (1) CMS establishes interim RVUs for new services and for codes for which definitions have changed.

(2) CMS publishes a notice in the FEDERAL REGISTER to announce interim RVUs and seek public comment on them. The RVUs are effective prospectively for services furnished beginning on the effective date specified in the notice.

(3) After considering public comments, CMS revises, if necessary, the interim RVUs and announces those revisions in a final notice published in the FEDERAL REGISTER. Any revisions in the RVUs are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(b) *Revision of RVUs for established HCPCS level 1 and level 2 codes.* (1) CMS publishes a proposed notice in the FEDERAL REGISTER to announce changes in RVUs for established codes and provides an opportunity for public comment no less often than every 5 years.

(2) After considering public comments, CMS publishes a final notice in the FEDERAL REGISTER to announce revisions to RVUs.

(3) The RVU revisions are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(c) *Values for local codes (HCPCS Level 3).* (1) Carriers establish relative values for local codes for services not included in HCPCS levels 1 or 2.

(2) Carriers must obtain prior approval from CMS to establish local codes for services that meet the definition of ''physician services'' in § 414.2.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992]

§ 414.26 Determining the GAF.

CMS establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* CMS uses the following indices to establish the GAF:

(1) An index that reflects one-fourth of the difference between the relative value of physicians' work effort in each of the different fee schedule areas as determined under § 414.22(a) and the national average of that work effort.

(2) An index that reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in each of the different fee schedule areas as determined under § 414.22(b) compared to the national average of those costs.

(3) An index that reflects the relative costs of malpractice expenses in each of the different fee schedule areas as determined under § 414.22(c) compared to the national average of those costs.

(b) *Class-specific practice cost indices.* If the application of a single index to different classes of services would be substantially inequitable because of differences in the mix of goods and services comprising practice expenses for the different classes of services, more than one index may be established under paragraph (a)(2) of this section.

(c) *Computation of GAF.* The GAF for each fee schedule area is the sum of the physicians' work adjustment factor,

the practice expense adjustment factor, and the malpractice cost adjustment factor, as defined in this section:

(1) The geographic physicians' work adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the work component and the geographic physicians' work index value established under paragraph (a)(1) of this section.

(2) The geographic practice expense adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the practice expense component, multiplied by the geographic practice cost index (GPCI) value established under paragraph (a)(2) of this section.

(3) The geographic malpractice adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the malpractice component, multiplied by the GPCI value established under paragraph (a)(3) of this section.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992]

§ 414.28 Conversion factors.

CMS establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* CMS established the CF for 1992 so that had section 1848 of the Act applied during 1991, it would have resulted in the same aggregate amount of payments for physician services as the estimated aggregate amount of these payments in 1991, adjusted by the update for 1992 computed as specified in § 414.30.

(b) *Subsequent CFs.* For calendar years 1993 through 1995, the CF for each year is equal to the CF for the previous year, adjusted in accordance with § 414.30. Beginning January 1, 1996, the CF for each calendar year may be further adjusted so that adjustments to the fee schedule in accordance with section 1848(c)(2)(B)(ii) of the Act do not cause total expenditures under the fee schedule to differ by more than $20 million from the amount that would have been spent if these adjustments had not been made.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 53877, Oct. 18, 1995; 60 FR 63177, Dec. 8, 1995]

§ 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

(a) *General rule.* The CF update for a CY equals the Medicare Economic Index increased or decreased by the number of percentage points by which the percentage increase in expenditures for physician services (or for a particular category of physician services, such as surgical services) in the second preceding FY over the third preceding FY exceeds the performance standard rate of increase established for the second preceding FY.

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

(1) For CYs 1992 and 1993, 2 percentage points.

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points.

[55 FR 23441, June 8, 1990, as amended at 60 FR 63177, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§ 414.32 Determining payments for certain physicians' services furnished in facility settings.

(a) *Definition.* As used in this section, *facility settings* include the following facilities:

(1) Hospital outpatient departments, including clinics and emergency rooms.

(2) Hospital inpatient departments.

(3) Comprehensive outpatient rehabilitation facilities.

(4) Comprehensive inpatient rehabilitation facilities.

(5) Inpatient psychiatric facilities.

(6) Skilled nursing facilities.

(b) *General rule.* If physicians' services of the type routinely furnished in physicians' offices are furnished in facility settings before January 1, 1999, the physician fee schedule amount for those services is determined by reducing the practice expense RVUs for the services by 50 percent. For services furnished on or after January 1, 1999, the practice expense RVUs are determined in accordance with § 414.22(b)(5).

(c) *Services covered by the reduction.* CMS establishes a list of services routinely furnished in physicians' offices nationally. Services furnished at least 50 percent of the time in physicians' offices are subject to this reduction.

(d) *Services excluded from the reduction.* The reduction established under this section does not apply to the following:

(1) Rural health clinic services.

(2) Surgical services not on the ambulatory surgical center covered list of procedures published under § 416.65(c) of this chapter when furnished in an ambulatory surgical center.

(3) Anesthesiology services and diagnostic and therapeutic radiology services.

[58 FR 63687, Dec. 2, 1993, as amended at 60 FR 63177, Dec. 8, 1995; 62 FR 59102, Oct. 31, 1997; 63 FR 58911, Nov. 2, 1998; 64 FR 25457, May 12, 1999]

§ 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense, and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnished in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service if the following requirements are met:

(i) It is a procedure that can safely be furnished in the office setting in appropriate circumstances.

(ii) It requires specialized supplies that are not routinely available in physicians' offices and that are generally disposable.

(iii) It is furnished before January 1, 1999.

(3) For the purpose of paragraph (a)(2) of this section, provider settings include only the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(4) For the purpose of paragraph (a)(2) of this section, ''routinely furnished in provider settings'' means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) CMS establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.* Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.36 Payment for drugs incident to a physician's service.

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

(b) *Exception.* Separate payment is made under the following conditions for physician care plan oversight services furnished to beneficiaries who receive HHA and hospice services that are covered by Medicare:

(1) The care plan oversight services require recurrent physician supervision of therapy involving 30 or more minutes of the physician's time per month.

(2) Payment is made to only one physician per patient for services furnished during a calendar month period. The physician must have furnished a service requiring a face-to-face encounter with the patient at least once during the 6-month period before the month for which care plan oversight payment is first billed. The physician may not

have a significant ownership interest in, or financial or contractual relationship with, the HHA in accordance with § 424.22(d) of this chapter. The physician may not be the medical director or employee of the hospice and may not furnish services under an arrangement with the hospice.

(3) If a physician furnishes care plan oversight services during a post-operative period, payment for care plan oversight services is made if the services are documented in the patient's medical record as unrelated to the surgery.

(c) *Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.* (1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) only if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either—

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995 as amended at 69 FR 66423, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 414.40 Coding and ancillary policies.

(a) *General rule.* CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* CMS establishes uniform national ancillary policies necessary to implement the fee schedule for physician services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery, bilateral surgery, split surgical global services, team surgery, and unusual services).

§ 414.42 Adjustment for first 4 years of practice.

(a) *General rule.* For services furnished during CYs 1992 and 1993, except as specified in paragraph (b) of this section, the fee schedule payment amount or prevailing charge must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), occupational therapists (OTs), and all other health care practitioners who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services or to services furnished in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The ''first year of practice'' is the first full CY during the first 6 months of which the physician, PT, OT, or other health care practitioner furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 6 months test.

(2) The ''second, third, and fourth years of practice'' are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment*. The fee schedule payment for the service of a new physician, PT, OT, or other health care practitioner is limited to the following percentages for each of the indicated years:

(1) First year—80 percent
(2) Second year—85 percent
(3) Third year—90 percent
(4) Fourth year—95 percent

[57 FR 42493, Sept. 15, 1992, as amended at 58 FR 63687, Dec. 2, 1993]

§ 414.44 Transition rules.

(a) *Adjusted historical payment basis*—(1) *All services other than radiology and nuclear medicine services*. For all physician services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by CMS without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services*. For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services*. For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101–239 and section 4102(g) of Public Law 101–508, adjusted by the update established for CY 1992.

(4) *Transition adjustment*. CMS adjusts the AHPB for all services by 5.5 percent to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physician services other than radiology services*. For physician services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(c) *Adjustment of 1992 payments for radiology services*. For radiology services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 109 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 109 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 9 percent of the fee schedule amount is substituted for the fee schedule amount.

(d) *Computation of payments for CY 1993*. For physician services subject to the transition rules in CY 1992 and furnished during CY 1993, the fee schedule is equal to 75 percent of the amount that would have been paid in the fee schedule area under the 1992 transition rules, adjusted by the amount of the 1993 update, plus 25 percent of the 1993 fee schedule amount.

(e) *Computation of payments for CY 1994*. For physician services subject to the transition rules in CY 1993, and furnished during CY 1994, the fee schedule

is equal to 67 percent of the amount that would have been paid in the fee schedule area under the 1993 transition rules, adjusted by the amount of the 1994 update, plus 33 percent of the 1994 fee schedule amount.

(f) *Computation of payments for CY 1995.* For physician services subject to the transition rules in CY 1994 and furnished during CY 1995, the fee schedule is equal to 50 percent of the amount that would have been paid in the fee schedule area under the 1994 transition rules, adjusted by the amount of the 1995 update, plus 50 percent of the 1995 fee schedule amount.

§ 414.46 Additional rules for payment of anesthesia services.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Base unit* means the value for each anesthesia code that reflects all activities other than anesthesia time. These activities include usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services.

(2) *Anesthesia practitioner*, for the purpose of anesthesia time, means a physician who performs the anesthesia service alone, a CRNA who is not medically directed who performs the anesthesia service alone, or a medically directed CRNA.

(3) *Anesthesia time* means the time during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

(b) *Determinations of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, CMS pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The carrier bases the fee schedule amount for an anesthesia service on the product of the sum of allowable base and time units and an anesthesia-specific CF. The carrier calculates the time units from the anesthesia time reported by the anesthesia practitioner for the anesthesia procedure. The physician who fulfills the conditions for medical direction in § 415.110 (Conditions for payment: Anesthesiology services) reports the same anesthesia time as the medically-directed CRNA.

(2) CMS furnishes the carrier with the base units for each anesthesia procedure code. The base units are derived from the 1988 American Society of Anesthesiologists' Relative Value Guide except that the number of base units recognized for anesthesia services furnished during cataract or iridectomy surgery is four units.

(3) Modifier units are not allowed. Modifier units include additional units charged by a physician or a CRNA for patient health status, risk, age, or unusual circumstances.

(c) *Physician personally performs the anesthesia procedure.* (1) CMS considers an anesthesia service to be personally performed under any of the following circumstances:

(i) The physician performs the entire anesthesia service alone.

(ii) The physician establishes an attending physician relationship in one or two concurrent cases involving an intern or resident and the service was furnished before January 1, 1994.

(iii) The physician establishes an attending physician relationship in one case involving an intern or resident and the service was furnished on or after January 1, 1994 but prior to January 1, 1996. For services on or after January 1, 1996, the physician must be the teaching physician as defined in §§ 415.170 through 415.184 of this chapter.

(iv) The physician and the CRNA or AA are involved in a single case and

the services of each are found to be medically necessary.

(v) The physician is continuously involved in a single case involving a student nurse anesthetist.

(vi) The physician is continuously involved in a single case involving a CRNA or AA and the service was furnished prior to January 1, 1998.

(2) CMS determines the fee schedule amount for an anesthesia service personally performed by a physician on the basis of an anesthesia-specific fee schedule CF and unreduced base units and anesthesia time units. One anesthesia time unit is equivalent to 15 minutes of anesthesia time, and fractions of a 15-minute period are recognized as fractions of an anesthesia time unit.

(d) *Anesthesia services medically directed by a physician.* (1) CMS considers an anesthesia service to be medically directed by a physician if:

(i) The physician performs the activities described in § 415.110 of this chapter.

(ii) The physician directs qualified individuals involved in two, three, or four concurrent cases.

(iii) Medical direction can occur for a single case furnished on or after January 1, 1998 if the physician performs the activities described in § 415.110 of this chapter and medically directs a single CRNA or AA.

(2) The rules for medical direction differ for certain time periods depending on the nature of the qualified individual who is directed by the physician. If more than two procedures are directed on or after January 1, 1994, the qualified individuals could be AAs, CRNAs, interns, or residents. The medical direction rules apply to student nurse anesthetists only if the physician directs two concurrent cases, each of which involves a student nurse anesthetist or the physician directs one case involving a student nurse anesthetist and the other involving a CRNA, AA, intern, or resident.

(3) Payment for medical direction is based on a specific percentage of the payment allowance recognized for the anesthesia service personally performed by a physician alone. The following percentages apply for the years specified:

(i) CY 1994—60 percent of the payment allowance for personally performed procedures.

(ii) CY 1995—57.5 percent of the payment allowance for personally performed services.

(iii) CY 1996—55 percent of the payment allowance for personally performed services.

(iv) CY 1997—52.5 percent of the payment allowance for personally performed services.

(v) CY 1998 and thereafter—50 percent of the payment allowance for personally performed services.

(e) *Physicians involved with two concurrent cases with residents.* The physician can bill base units and time units based on the amount of time the physician is actually present with the resident during each of two concurrent cases furnished on or after January 1, 2004.

(1) To bill the base units, the physician must be present with the resident during the pre- and post-anesthesia care included in the base units.

(2) If the physician is not present with the resident during pre- and post-anesthesia care, then the physician may bill the case as a medically directed case in accordance with paragraph (d) of this section.

(f) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, CMS bases the fee schedule amount on an anesthesia-specific CF and three base units. This represents payment for the physician's involvement in the pre-surgical anesthesia services.

(g) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) CMS allows separate payment under the fee schedule for certain reasonable and medically necessary medical or surgical services furnished by a physician while furnishing anesthesia services to the patient. CMS makes payment for these services in accordance with the general physician fee schedule rules in § 414.20. These services are described in program operating instructions.

(2) CMS makes no separate payment for other medical or surgical services, such as the pre-anesthetic examination of the patient, pre- or post-operative

visits, or usual monitoring functions, that are ordinarily included in the anesthesia service.

(h) *Physician involved in multiple anesthesia services.* If the physician is involved in multiple anesthesia services for the same patient during the same operative session, the carrier makes payment according to the base unit associated with the anesthesia service having the highest base unit value and anesthesia time that encompasses the multiple services. The carrier makes payment for add-on anesthesia codes according to program operating instructions.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 60 FR 63177, Dec. 8, 1995; 64 FR 59441, Nov. 2, 1999; 67 FR 80041, Dec. 31, 2002; 68 FR 63261, Nov. 7, 2003]

§ 414.48 Limits on actual charges of nonparticipating suppliers.

(a) *General rule.* A supplier, as defined in § 400.202 of this chapter, who is nonparticipating and does not accept assignment may charge a beneficiary an amount up to the limiting charge described in paragraph (b) of this section.

(b) *Specific limits.* For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the fee schedule amount for nonparticipating suppliers. For items or services CMS excludes from payment under the physician fee schedule (in accordance with section 1848 (j)(3) of the Act), the limiting charge is 115 percent of 95 percent of the payment basis applicable to participating suppliers as calculated in § 414.20(b).

[58 FR 63687, Dec. 2, 1993, as amended at 62 FR 59102, Oct. 31, 1997]

§ 414.50 Physician billing for purchased diagnostic tests.

(a) *General rule.* For services covered under section 1861(s)(3) of the Act and paid for under this part 414 subpart A, if a physician bills for a diagnostic test performed by an outside supplier, the payment to the physician less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

(1) The supplier's net charge to the physician.

(2) The physician's actual charge.

(3) The fee schedule amount for the test that would be allowed if the supplier billed directly.

(b) *Restriction on payment.* The physician must identify the supplier and indicate the supplier's net charge for the test. If the physician fails to provide this information, CMS makes no payment to the physician and the physician may not bill the beneficiary.

(1) Physicians who accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(2) Physicians who do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 34328, June 24, 1998]

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

(a) For assistant-at-surgery services, 65 percent of the amount that would be allowed under the physician fee schedule if the assistant-at-surgery service was furnished by a physician.

(b) For services (other than assistant-at-surgery services) furnished in a hospital, 75 percent of the physician fee schedule amount for the service.

(c) For all other services, 85 percent of the physician fee schedule amount for the service.

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the

assistant-at-surgery service were furnished by a physician.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.54 Payment for certified nurse-midwives' services.

For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65 percent of the physician fee schedule amount for the service.

§ 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[63 FR 58911, Nov. 2, 1998]

§ 414.58 Payment of charges for physician services to patients in providers.

(a) *Payment under the physician fee schedule.* In addition to the special conditions for payment in §§ 415.100 through 415.130, and § 415.190 of this chapter, CMS establishes payment for physician services to patients in providers under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *Teaching hospitals.* Services furnished by physicians in teaching hospitals may be made on a reasonable cost basis set forth in § 415.162 of this chapter if the hospital exercises the election described in § 415.160 of this chapter.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 63189, Dec. 8, 1995]

§ 414.60 Payment for the services of CRNAs.

(a) *Basis for payment.* The allowance for the anesthesia service furnished by a CRNA, medically directed or not medically directed, is based on allowable base and time units as defined in § 414.46(a). Beginning with CY 1994—

(1) The allowance for an anesthesia service furnished by a medically directed CRNA is based on a fixed percentage of the allowance recognized for the anesthesia service personally performed by the physician alone, as specified in § 414.46(d)(3); and

(2) The CF for an anesthesia service furnished by a CRNA not directed by a physician may not exceed the CF for a service personally performed by a physician.

(b) *To whom payment may be made.* Payment for an anesthesia service furnished by a CRNA may be made to the CRNA or to any individual or entity (such as a hospital, critical access hospital, physician, group practice, or ambulatory surgical center) with which the CRNA has an employment or contract relationship that provides for payment to be made to the individual or entity.

(c) *Condition for payment.* Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person

presenting a claim or request for payment for the service.

[60 FR 63178, Dec. 8, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 59441, Nov. 2, 1999]

§ 414.62 Fee schedule for clinical psychologist services.

The fee schedule for clinical psychologist services is set at 100 percent of the amount determined for corresponding services under the physician fee schedule.

[62 FR 59102, Oct. 31, 1997]

§ 414.63 Payment for outpatient diabetes self-management training.

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by CMS to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

(c) Limitation on payment. Payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

(2) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(3) Is not receiving services as an outpatient in an RHC or FQHC.

[65 FR 83153, Dec. 29, 2000]

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to non-physician professionals, as specified in paragraph (b) of this section, is the lesser of the actual charges or 80 percent of 85 percent of the physician fee schedule amount.

(b) *To whom payment may be made.* Payment may be made to a registered dietician or nutrition professional qualified to furnish medical nutrition therapy in accordance with part 410, subpart G of this chapter.

(c) *Effective date of payment.* Medicare pays suppliers of medical nutrition therapy on or after the effective date of enrollment of the supplier at the carrier.

(d) *Limitation on payment.* Payment is made only for documented nutritional therapy sessions actually attended by the beneficiary.

(e) *Other conditions for fee-for-service payment.* Payment is made only if the beneficiary:

(1) Is not an inpatient of a hospital, SNF, nursing home, or hospice.

(2) Is not receiving services in an RHC, FQHC or ESRD dialysis facility.

[66 FR 55332, Nov. 1, 2001]

§ 414.65 Payment for telehealth services.

(a) *Professional service.* Medicare payment for the professional service via an interactive telecommunications system is made according to the following limitations:

(1) The Medicare payment amount for office or other outpatient visits, consultation, individual psychotherapy, psychiatric diagnostic interview examination, pharmacologic management, end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site), and individual medical nutrition therapy furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(2) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(3) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) *Originating site facility fee.* For telehealth services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(c) *Deductible and coinsurance apply.* The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) *Assignment required for physicians, practitioners, and originating sites.* Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) *Sanctions.* A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2003; 69 FR 66424, Nov. 15, 2004; 70 FR 70332, Nov. 21, 2005]

§ 414.66 Incentive payments for physician scarcity areas.

(a) *Definition.* As used in this section, the following definitions apply.

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

[69 FR 66424, Nov. 15, 2004]

§ 414.67 Incentive payments for Health Professional Shortage Areas.

(a) Physicians' services furnished to a beneficiary in a geographic-based Health Professional Shortage Area (HPSA) are eligible for a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(b) Physicians furnishing services in a geographic-based primary medical care HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(c) Psychiatrists furnishing services in a mental health HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule. (The only physicians eligible to receive the 10 percent incentive payment in mental health HPSAs that do not overlap with primary care HPSAs are psychiatrists.)

[69 FR 66424, Nov. 15, 2004]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§ 414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104.

(b) Payment classification. (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

§ 414.104 PEN Items and Services.

(a) Payment Rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) Fee schedule amount. The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

[57 FR 57689, Dec. 7, 1992]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home. (See § 410.38 of this chapter for a description of when an institution qualifies as a home.)

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

Region means those carrier service areas administered by CMS regional offices.

[57 FR 57689, Dec. 7, 1992]

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232.

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in § 413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§ 414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in § 405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of purchased equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made, as needed, in a lump sum based on the carrier's consideration of the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for other durable medical equipment, as described in § 414.229(e).

(2) *Exception.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not purchased in accordance with § 414.229(d); and

(iii) Oxygen equipment, as defined in § 414.226.

(f) *Replacement of equipment.* Except as provided in § 414.229(g), if a purchased item of DME or a prosthetic or

orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

[57 FR 57689, Dec. 7, 1992]

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions*. (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories*. Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules*. (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990*. The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990*. For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990*. For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount*. The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent

of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a backup rate, previously referred to as ''intermittent assist devices with continuous airway pressure devices'').

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of §414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-

month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995; 71 FR 4525, Jan. 27, 2006]

§ 414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§ 414.226 Oxygen and oxygen equipment.

(a) *Payment rules.* (1) Payment for rental of oxygen equipment and purchase of oxygen contents is made based on a monthly fee schedule amount.

(2) Monthly fee schedule payments continue until medical necessity ends.

(b) *Monthly fee schedule amount.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For years after 1990, the fee schedule amounts are determined using the methodology contained in § 414.220 (d), (e), and (f).

(c) *Application of monthly fee schedule amounts.* (1) The fee schedule amount for items described in paragraph (b)(1)(i) of this section is paid when the beneficiary rents a stationary oxygen system.

(2) Subject to the limitation set forth in paragraph (d)(2) of this section, the fee schedule amount for items described in paragraph (b)(1)(ii) of this section is paid when the beneficiary rents a portable oxygen system.

(3) The fee schedule amount for items described in paragraph (b)(1)(iii) of this section is paid when the beneficiary

owns a stationary gaseous or liquid oxygen system.

(4) The fee schedule amount for items described in paragraph (b)(1)(iv) of this section is paid when the beneficiary owns or rents a portable gaseous or portable liquid oxygen system and uses either a stationary oxygen concentrator or no stationary oxygen system.

(d) *Volume adjustments:* (1) The fee schedule amount for an item described in paragraph (b)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (d)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (b)(1)(i) and (ii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (d)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

[57 FR 57690, Dec. 7, 1992]

§414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Subject to the limitation set forth in paragraph (b) of this section, payment is made on a rental or purchase option basis for other durable medical equipment that is not subject to the payment provisions set forth in §§ 414.220 through 414.228.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For *1991.* (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in § 414.220(f).

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in § 414.229(c).

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month

from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Transition to the fee schedules.* For purposes of computing the 10-month or 15-month period of continuous use for other durable medical equipment, as described in §414.230, the carrier counts the first month that the beneficiary continuously rented the equipment without regard to whether that month occurred before January 1, 1989 or after. If a beneficiary's 15-month rental period ends prior to January 1, 1989, no further purchase or rental payments are to be made except for maintenance and servicing of equipment as described in paragraph (e) of this section.

(g) *Replacement of equipment.* If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a rental or purchase basis in accordance with paragraph (a) of this section or on a lump-sum purchase basis if a purchase agreement had been entered into in accordance with paragraph (d) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts lnnger than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992]

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. The payment amount for TENS computed under § 414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§ 414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in §414.314.

(2) *Applicability*. These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under §413.170 of this chapter.

(c) *Definitions*. For purposes of this section, the following definitions apply:

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of ''supervision of staff'' of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

Routine professional services include all physicians' services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) *Types of routine professional services*. Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses' notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient's medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) *Payment for routine professional services*. Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the ''initial method'' of payment described in §414.313, (if all of the physicians at the facility elect the initial method) or under the ''physician MCP method'' described in §414.314. Physician services furnished after July 31, 1983 and before August 6, 1990, are payable only under the MCP method described in §414.314.

§414.313 Initial method of payment.

(a) *Basic rule*. Under this method, the intermediary pays the facility for routine professional services furnished by

physicians. Payment is in the form of an add-on to the facility's composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) *Services for which payment is not included in the add-on payment.* (1) Physician administrative services are considered to be facility services and are paid for as part of the facility's composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:

(i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.

(ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.

(iv) Administration of hepatitis B vaccine.

(c) *Physician election of the initial method.* (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) *Termination of the initial method.* (1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—

(i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the termination notice is received by the carrier(s) and intermediary; or

(ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) *Determination of payment amount.* The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) *Publication of payment amount.* Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[55 FR 23441, June 8, 1990, as amended at 62 FR 43674, Aug. 15, 1997]

§ 414.314 Monthly capitation payment method.

(a) *Basic rules.* (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, either to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of time, and the capitation amounts are consistent with physicians' charging patterns in their localities.

(4) Payment of the capitation amount for any particular month is contingent upon the physician furnishing to the patient all physician services required by the patient during

the month, except those listed in paragraph (b) of this section.

(5) Payment for physician administrative services (§414.310) is made to the dialysis facility as part of the facility's composite rate (part 413, subpart H of this subchapter) and not to the physician under the MCP.

(b) *Services not included in the MCP.* (1) Services that are not included in the MCP and which may be paid in accordance with the reasonable charge rules set forth in subpart E of part 405 of this chapter are limited to the following:

(i) Administration of hepatitis B vaccine.

(ii) Covered physician services furnished by another physician when the patient is not available to receive, or the attending physician is not available to furnish, the outpatient services as usual (see paragraph (b)(3) of this section).

(iii) Covered physician services furnished to hospital inpatients, including services related to inpatient dialysis, by a physician who elects not to continue to receive the MCP during the period of inpatient stay.

(iv) Surgical services, including declotting of shunts, other than the insertion of catheters for patients on maintenance peritoneal dialysis who do not have indwelling catheters.

(v) Needed physician services that are—

(A) Furnished by the physician furnishing renal care or by another physician;

(B) Not related to the treatment of the patient's renal condition; and

(C) Not furnished during a dialysis session or an office visit required because of the patient's renal condition.

(2) For the services described in paragraph (b)(1)(v) of this section, the following rules apply:

(i) The physician must provide documentation to show that the services are not related to the treatment of the patient's renal condition and that additional visits are required.

(ii) The carrier's medical staff, acting on the basis of the documentation and appropriate medical consultation obtained by the carrier, determines whether additional payment for the additional services is warranted.

(3) The MCP is reduced in proportion to the number of days the patient is—

(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery

performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in § 405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments*. Payments for covered medical services furnished to the transplant recipient by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in § 405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule*. Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at § 413.170.

(2) *Exception*. If the conditions in subparagraphs (a)(2) (i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See subpart U of part 405 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with subpart U (Conditions for Coverage of Suppliers of ESRD Services) of this chapter. (§ 410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§ 410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at § 413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim

for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at §413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in subpart U (Conditions for Coverage of Suppliers of ESRD Services) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(b) *Support services*—(1) *Basic rule*. Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in §413.170 of this chapter.

(2) *Exceptions*. If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) *Payment limits*—(1) *Support services*. The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies*. Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in §413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits*. Updated data are incorporated into the payment limits when the prospective payment rates established at §413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992]

§414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies.

(b) Payment is made in accordance with the rules set forth in § 413.170 of this chapter.

[56 FR 43710, Sept. 4, 1991]

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400–§ 414.404 [Reserved]

§ 414.406 Implementation of programs.

(a) *Implementation contractor*. CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b)–(d) [Reserved]

(e) *Claims processing*. The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006]

§ 414.408–§ 414.426 [Reserved]

Subpart G [Reserved]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.

(2) Endotracheal intubation.

(3) Central venous line.

(4) Cardiac pacing.

(5) Chest decompression.

(6) Surgical airway.

(7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a

limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-Basic). These laws may vary from State to State. For example, only in some States is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line.

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Goldsmith modification means the recognition of rural areas within certain Standard Metropolitan Statistical Areas wherein a census tract is deemed to be rural when located within a large metropolitan county of at least 1,225 square miles, but is so isolated from the metropolitan core of that county by distance or physical features as to be more rural than urban in character.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in §410.40(c) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside a Metropolitan Statistical Area (MSA), or, in New England, a New England County Metropolitan Area (NECMA), or an area within an MSA or NECMA that is identified as rural by the Goldsmith modification.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003]

§414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or

the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in § 413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in § 414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is one percent higher than otherwise is applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is two percent higher than otherwise is applicable under this section. The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is based on loaded miles. Payment for air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* (i) For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the

rural adjustment factor applies to the sum of the base rate and the mileage rate.

(ii) For services furnished during the period July 1, 2004 through December 31, 2009, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

(6) *Multiple patients.* The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(7) *Payment rate for mileage greater than 50 miles.* For services furnished during the period July 1, 2004 through December 31, 2008, each loaded ambulance mile greater than 50 (that is, miles 51 and greater) for ambulance transports originating in either urban areas or in rural areas are paid based on a rate that is 25 percent higher than otherwise is applicable under this section.

(d) *Payment.* Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year.

(g) *Adjustments.* The Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates. The CF and air ambulance rates will not be adjusted solely because of changes in the total number of ambulance transports.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 69 FR 40292, July 1, 2004]

§414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in §414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment.* For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the

reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment*. For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment*. For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment*. For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment*. For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates*. The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in § 414.610(f).

(g) *Exception*. There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§ 414.617 Transition from regional to national ambulance fee schedule.

For services furnished during the period July 1, 2004 through December 31, 2009, the amount for the ground ambulance base rate is subject to a floor amount determined by establishing nine fee schedules based on each of the nine census divisions using the same methodology as used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount

that is less than or equal to the national ground base rate, then it is not used, and the national FS amount applies. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the FS portion of the base rate for that census division is equal to a blend of the national rate and the regional rate in accordance with the following schedule:

Time period	Regional percent	National percent
7/1/04–12/31/04	80	20
CY 2005	60	40
CY 2006	40	60
CY 2007–CY 2009	20	80
CY 2010 and thereafter	0	100

[69 FR 40292, July 1, 2004]

§414.620 Publication of the ambulance fee schedule.

Changes in payment rates resulting from incorporation of the annual inflation factor described in §414.610(f) will be announced by notice in the FEDERAL REGISTER without opportunity for prior comment. CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than the inflation factor.

§414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§414.701 Purpose.

This subpart implements section 1842(o) of the Social Security Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the ''program'') that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal and hepatitis vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs.

§414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal and influenza vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting

hepatitis B (as determined by the Secretary).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA	87
LEUPROLIDE ACETATE	81
GOSERELIN ACETATE	80
RITUXIMAB	81
PACLITAXEL	81
DOCETAXEL	80
CARBOPLATIN	81
IRINOTECAN	80
GEMCITABINE HCL	80
PAMIDRONATE DISODIUM	85
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (*See* § 402 of this chapter).

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§ 414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§ 414.802 Definitions.

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

Drug means both drugs and biologicals.

Manufacturer means any entity that is engaged in the following (This term

does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug Code. During the first 3 years of the CAP (as defined in § 414.902), the method of counting units excludes units of CAP drugs (as defined in § 414.902) sold to an approved CAP vendor (as defined in § 414.902) for use under the CAP (as defined in § 414.902).

[70 FR 69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006]

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.* (1) The manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after deducting the types of items and transactions listed in paragraph (a)(2) of this section and excluding sales referenced in paragraph (a)(4) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales referenced in paragraph (a)(4) of this section).

(2) In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items:

(i) Volume discounts.

(ii) Prompt pay discounts.

(iii) Cash discounts.

(iv) Free goods that are contingent on any purchase requirement.

(v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in paragraphs (a)(3)(i) through (a)(3)(iv) of this section.

(i) For each such National Drug Code, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(ii) The manufacturer then multiplies the percentage described in paragraph (a)(3)(i) of this section by the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted.

(iii) The manufacturer then uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter as the denominator to calculate the manufacturer's average sales price for the National Drug Code in the quarter being submitted.

(iv) *Example.* The total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with direct sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000. The total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = .33333. The total in dollars for the direct sales subject to the average sales price reporting requirement for the quarter being reported equals $50,000 for 10,000 units sold. Assuming no non-

lagged price concessions apply, the manufacturer's average sales price calculation for this National Drug Code for this quarter is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33 (average sales price).

(4) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005]

§ 414.806 Penalties associated with the failure to submit timely and accurate ASP data.

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal and Hepatitis B vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

§ 414.902 Definitions.

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

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of §414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

§414.904 Average sales price as the basis for payment.

(a) *Method of payment*. Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(b) *Multiple source drugs*—(1) *Average sales prices*. The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price*. The average sales price is determined by—

(i) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(c) *Single source drugs*—(1) *Average sales price*. The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price*. The average sales price is determined by computing—

(i) The sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a single source drug*. The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient*. (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in 2006, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is 106 percent of the average sales price.

(3) *Widely available market price and average manufacturer price*. If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2006, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) *Exceptions to the average sales price*—(1) *Vaccines*. The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment*. The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2006.

(3) *Blood and blood products*. In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable*. In the case of

a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 70332, Nov. 21, 2005]

§414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under §414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in §414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* (1) Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted, as a result of the bidding process as described in §414.910. Based on these bids, a single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the payment year. This single payment amount is then updated on an annual basis based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS, based, in part, on information disclosed to CMS and limited by the weighted payment amount established under section 1847A of the Act across all drugs for which a composite bid is required in the category, and limited by the payment amount established under section 1847A of the Act for each other drug for which the approved CAP vendor submits a bid in accordance with §414.910. Adjustment to the payment amounts may be made more often than annually, but no more often than quarterly, in any of the following cases:

(i) Introduction of new drugs.

(ii) Expiration of a drug patent or availability of a generic drug.

(iii) Material shortage that results in a significant price increase for the drug.

(iv) Withdrawal of a drug from the market.

(2) The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments*. There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory*. A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in § 414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in § 414.902.

(f) *Substitution or addition of drugs on an approved CAP vendor's CAP drug list*—(1) *Short-term substitution of a CAP drug*. On an occasional basis (for a period of time less than 2 weeks), an approved CAP vendor may agree to furnish a substitute NDC within a HCPCS code on the approved CAP vendor's CAP drug list if the approved CAP vendor—

(i) Is willing to accept the payment amount that was established for the HCPCS code under this section; and

(ii) Obtains the participating CAP physician's prior approval.

(2) *Long-term substitution or addition of a CAP drug*. An approved CAP vendor may submit a request, as specified in paragraph (f)(3) of this section, for approval to substitute an NDC supplied by the approved CAP vendor for another NDC within the same HCPCS code or to add an NDC to the approved CAP vendor's drug list, if at least one of the following criteria is met:

(i) Proposed substitution of an NDC for a period of 2 weeks or longer.

(ii) Proposed addition of one or more NDCs within a HCPCS code included in the CAP drug category specified by CMS or on the approved CAP vendor's approved CAP drug list.

(iii) Proposed addition of—

(A) One or more newly issued HCPCS codes; or

(B) One of the following single indication orphan drug J codes or their updates: J0205, J0256, J9300, J1785, J2355, J3240, J7513, J9010, J9015, J9017, J9160, J9216.

(iv) Beginning January 1, 2007, the proposed addition of a drug(s) that has not yet been assigned a HCPCS code, but for which a HCPCS code must be established.

(3) *Requesting the addition or substitution of CAP drug*. An approved CAP vendor that meets the one of the criteria specified in paragraph (f)(2) must submit a written request to CMS or its designee. The request must—

(i) Specify the NDC(s) and the respective HCPCS code that is to be added or substituted.

(ii) Address the rationale for the substitution or addition of the NDC(s) or the addition of the HCPCS code(s) as applicable; and

(iii) Address the impact of the substitution of the NDC(s) or the addition of the NDC(s) or HCPCS code(s), or both on—

(A) Patient and drug safety;

(B) Drug waste; and

(C) The potential for cost savings.

(4) *Approval of a request(s)*. CMS or its designee notifies the approved CAP vendor of its decision.

(i) Except as specified in paragraph (f)(4)(ii) of this section, an approved request is effective at the beginning of the next calendar quarter.

(ii) Approved substitutions for request based on a drug shortage or other exigent circumstance may become effective immediately provided that—

(A) CMS approves the immediate substitution; and

(B) The approved CAP vendor's notifies its CAP participating physicians of the substitution immediately following CMS approval.

(5) *Payment for an approved drug change(s)*. The payment for—

(i) Substituted or added CAP drugs that are within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is the

single payment for that HCPCS code, as determined and updated in accordance with paragraph (c)(1) of this section; or

(ii) Added CAP drugs that are not within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is specified under paragraph (c)(2) of this section.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 71 FR 9460, Feb. 24, 2006]

§414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor*. (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in §414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) For other exigent circumstances defined by CMS.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in §414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in §414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9–CM (if necessary).

(vi) Agrees to accept the particular National Drug Codes (NDCs) supplied by the approved CAP vendor for the duration of the participating CAP physician's enrollment with the approved CAP vendor, subject to paragraphs (a)(3)(vii) and (a)(3)(xiv) of this section. By electing to participate with an approved CAP vendor, the participating CAP physician also agrees to accept the changes to the approved CAP vendor's CAP drug list that have been approved in accordance with §414.906(f).

(vii) Agrees to place routine orders for CAP drugs at the HCPCs level, except when medical necessity requires a particular formulation on the approved CAP vendor's CAP drug list. Medical necessity must be documented. When the conditions of this paragraph are met, the participating CAP physician may submit a prescription order to the

approved CAP vendor that specifies the NDC.

(viii) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(ix) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(x) Agrees to file the Medicare claim within 14 calendar days of the date of drug administration;

(xi) Agrees to submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment if the participating CAP physician's drug administration claim for a CAP drug is denied;

(xii) Agrees not to transport CAP drugs from one practice location (place of service) to another location;

(xiii) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xiv) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(5) *Additional opt out provision*. In addition to the circumstances listed in paragraph (a)(2) of this section, if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) were met, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor.

(b) *Program requirements*. (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations*. CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005]

§414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§414.912 Conflicts of interest

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at §414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of § 414.914(h) are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in § 414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in §1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of final payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) If a balance remains, after the supplemental insurer pays their share of the bill, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (h) delivery means postmark date, or the date the coinsurance bill or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (h)(5)(ii), if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (h)(6), (h)(7), or (h)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in §414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and § 414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with § 414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005]

§ 414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in § 414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of § 414.908(a)(3).

(c) *Reconsideration*—(1) *Right to reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under

section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing

officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005]

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with § 414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract.

(c) *Reconsideration*—(1) *Right to reconsideration.* An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within

30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

[70 FR 39098, July 6, 2005]

§ 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

§ 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

Subpart L—Supplying and Dispensing Fees

§ 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§ 414.1001 Basis of payment.

(a) *Supplying fees*. Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following the first prescription (as specified in paragraph (a)(1) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(3) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *Supplying fees following transplant*. Beginning CY 2006—(1) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(2) A supplying fee of $16 is paid to a pharmacy for each prescription following an initial prescription after a transplant (as specified in paragraph (b)(1) of this section) of drugs and biologicals describe in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(c) *30-day dispensing fees*. Beginning CY 2006—(1) A dispensing fee of $57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (c)(1) of this section, a dispensing fee of $33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) *90-day dispensing fee*. Beginning CY 2006, a dispensing fee of $66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005]

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

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415.208 Services of moonlighting residents.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 60 FR 63178, Dec. 8, 1995, unless otherwise noted.

Subpart A—General Provisions

§415.1 Basis and scope.

(a) *Basis.* This part is based on the provisions of the following sections of the Act: Section 1848 establishes a fee schedule for payment for physician services. Section 1861(q) specifies what is included in the term ''physician services'' covered under Medicare. Section 1862(a)(14) sets forth the exclusion of nonphysician services furnished to hospital patients under Part B of Medicare. Section 1886(d)(5)(B) provides for a payment adjustment under the prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983, to account for the indirect costs of medical education. Section 1886(h) establishes the methodology for Medicare payment of the cost of direct GME activities.

(b) *Scope.* This part sets forth rules for fiscal intermediary payments to providers for physician services, Part B carrier payments for physician services to beneficiaries in providers, physician services in teaching settings, and services of residents.

Subpart B—Fiscal Intermediary Payments to Providers for Physician Services

§415.50 Scope.

This subpart sets forth rules for payment by fiscal intermediaries to providers for services furnished by physicians. Payment for covered services is

made either under the prospective payment system (PPS) to PPS-participating providers in accordance with part 412 of this chapter or under the reasonable cost method to non-PPS participating providers in accordance with part 413 of this chapter.

§ 415.55 General payment rules.

(a) *Allowable costs.* Except as specified otherwise in §§ 413.102 of this chapter (concerning compensation of owners), 415.60 (concerning allocation of physician compensation costs), and 415.162 (concerning payment for physician services furnished to beneficiaries in teaching hospitals), costs a provider incurs for services of physicians are allowable only if the following conditions are met:

(1) The services do not meet the conditions in § 415.102(a) regarding fee schedule payment for services of physicians to a beneficiary in a provider.

(2) The services include a surgeon's supervision of services of a qualified anesthetist, but do not include physician availability services, except for reasonable availability services furnished for emergency rooms and the services of standby surgical team physicians.

(3) The provider has incurred a cost for salary or other compensation it furnished the physician for the services.

(4) The costs incurred by the provider for the services meet the requirements in § 413.9 of this chapter regarding costs related to patient care.

(5) The costs do not include supervision of interns and residents unless the provider elects reasonable cost payment as specified in § 415.160, or any other costs incurred in connection with an approved GME program that are payable under §§ 413.75 through 413.83 of this chapter.

(b) *Allocation of allowable costs.* The provider must follow the rules in § 415.60 regarding allocation of physician compensation costs to determine its costs of services.

(c) *Limits on allowable costs.* The intermediary must apply the limits on compensation set forth in § 415.70 to determine its payments to a provider for the costs of services.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.60 Allocation of physician compensation costs.

(a) *Definition.* For purposes of this subpart, *physician compensation costs* means monetary payments, fringe benefits, deferred compensation, and any other items of value (excluding office space or billing and collection services) that a provider or other organization furnishes a physician in return for the physician services. Other organizations are entities related to the provider within the meaning of § 413.17 of this chapter or entities that furnish services for the provider under arrangements within the meaning of the Act.

(b) *General rule.* Except as provided in paragraph (d) of this section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

(1) Physician services to the provider (as described in § 415.55);

(2) Physician services to patients (as described in § 415.102); and

(3) Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

(c) *Allowable physician compensation costs.* Only costs allocated to payable physician services to the provider (as described in § 415.55) are allowable costs to the provider under this subpart.

(d) *Allocation of all compensation to services to the provider.* Generally, the total physician compensation received by a physician is allocated among all services furnished by the physician, unless—

(1) The provider certifies that the compensation is attributable solely to the physician services furnished to the provider; and

(2) The physician bills all patients for the physician services he or she furnishes to them and personally receives the payment from or on behalf of the patients. If returned directly or indirectly to the provider or an organization related to the provider within the meaning of § 413.17 of this chapter, these payments are not compensation for physician services furnished to the provider.

(e) *Assumed allocation of all compensation to beneficiary services.* If the provider and physician agree to accept the assumed allocation of all the physician services to direct services to beneficiaries as described under § 415.102(a), CMS does not require a written allocation agreement between the physician and the provider.

(f) *Determination and payment of allowable physician compensation costs.* (1) Except as provided under paragraph (e) of this section, the intermediary pays the provider for these costs only if—

(i) The provider submits to the intermediary a written allocation agreement between the provider and the physician that specifies the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not payable under either Part A or Part B of Medicare; and

(ii) The compensation is reasonable in terms of the time devoted to these services.

(2) In the absence of a written allocation agreement, the intermediary assumes, for purposes of determining reasonable costs of the provider, that 100 percent of the physician compensation cost is allocated to services to beneficiaries as specified in paragraph (b)(2) of this section.

(g) *Recordkeeping requirements.* Except for services furnished in accordance with the assumed allocation under paragraph (e) of this section, each provider that claims payment for services of physicians under this subpart must meet all of the following requirements:

(1) Maintain the time records or other information it used to allocate physician compensation in a form that permits the information to be validated by the intermediary or the carrier.

(2) Report the information on which the physician compensation allocation is based to the intermediary or the carrier on an annual basis and promptly notify the intermediary or carrier of any revisions to the compensation allocation.

(3) Retain each physician compensation allocation, and the information on which it is based, for at least 4 years after the end of each cost reporting period to which the allocation applies.

§ 415.70 Limits on compensation for physician services in providers.

(a) *Principle and scope.* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section, CMS establishes reasonable compensation equivalency limits on the amount of compensation paid to physicians by providers. These limits are applied to a provider's costs incurred in compensating physicians for services to the provider, as described in § 415.55(a).

(2) Limits established under this section do not apply to costs of physician compensation attributable to furnishing inpatient hospital services that are paid for under the prospective payment system implemented under part 412 of this chapter or to costs of physician compensation attributable to approved GME programs that are payable under §§ 413.75 through 413.83 of this chapter.

(3) Compensation that a physician receives for activities that may not be paid for under either Part A or Part B of Medicare is not considered in applying these limits.

(b) *Methodology for establishing limits.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty and type of location using the best available data.

(c) *Application of limits.* If the level of compensation exceeds the limits established under paragraph (b) of this section, Medicare payment is based on the level established by the limits.

(d) *Adjustment of the limits.* The intermediary may adjust limits established under paragraph (b) of this section to account for costs incurred by the physician or the provider related to malpractice insurance, professional memberships, and continuing medical education.

(1) For the costs of membership in professional societies and continuing medical education, the intermediary may adjust the limit by the lesser of—

(i) The actual cost incurred by the provider or the physician for these activities; or

(ii) Five percent of the appropriate limit.

(2) For the cost of malpractice expenses incurred by either the provider or the physician, the intermediary may adjust the reasonable compensation equivalency limit by the cost of the malpractice insurance expense related to the physician service furnished to patients in providers.

(e) *Exception to limits.* An intermediary may grant a provider an exception to the limits established under paragraph (b) of this section only if the provider can demonstrate to the intermediary that it is unable to recruit or maintain an adequate number of physicians at a compensation level within these limits.

(f) *Notification of changes in methodologies and payment limits.* (1) Before the start of a cost reporting period to which limits established under this section will be applied, CMS publishes a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how it calculated the limits.

(2) If CMS proposes to revise the methodology for establishing payment limits under this section, CMS publishes a notice, with opportunity for public comment, in the FEDERAL REGISTER. The notice explains the proposed basis and methodology for setting limits, specifies the limits that would result, and states the date of implementation of the limits.

(3) If CMS updates limits by applying the most recent economic index data without revising the limit methodology, CMS publishes the revised limits in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

§ 415.100 Scope.

This subpart implements section 1887(a)(1)(A) of the Act by providing general conditions that must be met in order for services furnished by physicians to beneficiaries in providers to be paid for on the basis of the physician fee schedule under part 414 of this chapter. Section 415.102 sets forth the conditions for fee schedule payment for physician services to beneficiaries in providers. Section 415.105 sets forth general requirements for determining the amounts of payment for services that meet the conditions of this section. Sections 415.120 and 415.130 set forth additional conditions for payment for physician services in the specialties of radiology and pathology (laboratory services).

§ 415.102 Conditions for fee schedule payment for physician services to beneficiaries in providers.

(a) *General rule.* If the physician furnishes services to beneficiaries in providers, the carrier pays on a fee schedule basis provided the following requirements are met:

(1) The services are personally furnished for an individual beneficiary by a physician.

(2) The services contribute directly to the diagnosis or treatment of an individual beneficiary.

(3) The services ordinarily require performance by a physician.

(4) In the case of radiology or laboratory services, the additional requirements in § 415.120 or § 415.130, respectively, are met.

(b) *Exception.* If a physician furnishes services in a provider that do not meet the requirements in paragraph (a) of this section, but are related to beneficiary care furnished by the provider, the intermediary pays for those services, if otherwise covered. The intermediary follows the rules in §§ 415.55 and 415.60 for payment on the basis of reasonable cost or PPS, as appropriate.

(c) *Effect of billing charges for physician services to a provider.* (1) If a physician furnishes services that may be paid under the reasonable cost rules in § 415.55 or § 415.60, and paid by the intermediary, or would be paid under those rules except for the PPS rules in part 412 of this chapter, and under the payment rules for GME established by §§ 413.75 through 413.83 of this chapter, neither the provider nor the physician may seek payment from the carrier, beneficiary, or another insurer.

(2) If a physician furnishes services to an individual beneficiary that do not

meet the applicable conditions in §§415.120 (concerning conditions for payment for radiology services) and 415.130 (concerning conditions for payment for physician pathology services), the carrier does not pay on a fee schedule basis.

(3) If the physician, the provider, or another entity bills the carrier or the beneficiary or another insurer for physician services furnished to the provider, as described in §415.55(a), CMS considers the provider to which the services are furnished to have violated its provider participation agreement, and may terminate that agreement. See part 489 of this chapter for rules governing provider agreements.

(d) *Effect of physician assumption of operating costs.* If a physician or other entity enters into an agreement (such as a lease or concession) with a provider, and the physician (or entity) assumes some or all of the operating costs of the provider department in which the physician furnishes physician services, the following rules apply:

(1) If the conditions set forth in paragraph (a) of this section are met, the carrier pays for the physician services under the physician fee schedule in part 414 of this chapter.

(2) To the extent the provider incurs a cost payable on a reasonable cost basis under part 413 of this chapter, the intermediary pays the provider on a reasonable cost basis for the costs associated with producing these services, including overhead, supplies, equipment costs, and services furnished by nonphysician personnel.

(3) The physician (or other entity) is treated as being related to the provider within the meaning of §413.17 of this chapter (concerning cost to related organizations).

(4) The physician (or other entity) must make its books and records available to the provider and the intermediary as necessary to verify the nature and extent of the costs of the services furnished by the physician (or other entity).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.105 Amounts of payment for physician services to beneficiaries in providers.

(a) *General rule.* The carrier determines amounts of payment for physician services to beneficiaries in providers in accordance with the general rules governing the physician fee schedule payment in part 414 of this chapter, except as provided in paragraph (b) of this section.

(b) *Application in certain settings*—(1) *Teaching hospitals.* The carrier applies the rules in subpart D of this part (concerning physician services in teaching settings), in addition to those in this section, in determining whether fee schedule payment should be made for physician services to individual beneficiaries in a teaching hospital.

(2) *Hospital-based ESRD facilities.* The carrier applies §§414.310 through 414.314 of this chapter, which set forth determination of reasonable charges under the ESRD program, to determine the amount of payment for physician services furnished to individual beneficiaries in a hospital-based ESRD facility approved under part 405 subpart U.

§415.110 Conditions for payment: Medically directed anesthesia services.

(a) *General payment rule.* Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in §415.102(a) and the following additional conditions:

(1) For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in § 414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) *Medical documentation*. The physician alone inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

[63 FR 58912, Nov. 2, 1998]

§ 415.120 Conditions for payment: Radiology services.

(a) *Services to beneficiaries*. The carrier pays for radiology services furnished by a physician to a beneficiary on a fee schedule basis only if the services meet the conditions for fee schedule payment in § 415.102(a) and are identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of x-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures. The carrier pays for interpretations only if there is a written report prepared for inclusion in the patient's medical record maintained by the hospital.

(b) *Services to providers*. The carrier does not pay on a fee schedule basis for physician services to the provider (for example, administrative or supervisory services) or for provider services needed to produce the x-ray films or other items that are interpreted by the radiologist. However, the intermediary pays the provider for these services in accordance with § 415.55 for provider costs; § 415.102(d)(2) for costs incurred by a physician, such as under a lease or concession agreement; or part 412 of this chapter for payment under PPS.

§ 415.130 Conditions for payment: Physician pathology services.

(a) *Definitions*. The following definitions are used in this section.

(1) *Covered hospital* means, with respect to an inpatient or an outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for this technical component directly to a Medicare carrier.

(2) *Fee-for-service Medicare beneficiaries* means those beneficiaries who are entitled to benefits under Part A or are enrolled under Part B of Title XVIII of the Act or both and are not enrolled in any of the following:

(i) A Medicare+Choice plan under Part C of Title XVIII of the Act.

(ii) A plan offered by an eligible organization under section 1876 of the Act;

(iii) A program of all-inclusive care for the elderly (PACE) under 1894 of the Act; or

(iv) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987.

(b) *Physician pathology services*. The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in § 415.102(a) and are one of the following services:

(1) Surgical pathology services.

(2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.

(3) Clinical consultation services that meet the requirements in paragraph (c) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of

paragraphs (c)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

(c) *Clinical consultation services.* For purposes of this section, clinical consultation services must meet the following requirements:

(1) Be requested by the beneficiary's attending physician.

(2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.

(3) Result in a written narrative report included in the beneficiary's medical record.

(4) Require the exercise of medical judgment by the consultant physician.

(d) *Physician pathology services furnished by an independent laboratory.* The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient before January 1, 2001 may be paid to the laboratory on a fee schedule basis. After December 31, 2000 but before January 1, 2003, if an independent laboratory furnishes the technical component of a physician pathology service to a fee-for-service Medicare beneficiary who is an inpatient or outpatient of a covered hospital, the carrier will treat the technical component as a service for which payment will be made to the laboratory under the physician fee schedule. For these two years the service will not be treated as an inpatient hospital service for which payment is made to the hospital under section 1886(d) of the Act or as an outpatient hospital service for which payment is made to the hospital under section 1833(t) of the Act. After December 31, 2002, the technical component for physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient is paid only to the hospital.

[60 FR 63178, Dec. 8, 1995, as amended at 64 FR 59442, Nov. 2, 1999; 66 FR 55332, Nov. 1, 2001]

Subpart D—Physician Services in Teaching Settings

§415.150 Scope.

This subpart sets forth the rules governing payment for the services of physicians in teaching settings and the criteria for determining whether the payments are made as one of the following:

(a) Services to the hospital under the reasonable cost election in §§415.160 through 415.164.

(b) Provider services through the direct GME payment mechanism in §§413.75 through 413.83 of this chapter.

(c) Physician services to beneficiaries under the physician fee schedule as set forth in part 414 of this chapter.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.152 Definitions.

As used in this subpart—

Approved graduate medical education (GME) program means one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medicine Education of the American Podiatric Medical Association.

(2) A program otherwise recognized as an ''approved medical residency program'' under §413.75(b) of this chapter.

Direct medical and surgical services means services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital making the cost election described in §§415.160 through 415.162.

Nonprovider setting means a setting other than a hospital, skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility in which residents furnish services. These include, but are not limited to, family practice or multispecialty clinics and physician offices.

Resident means one of the following:

(1) An individual who participates in an approved GME program, including programs in osteopathy, dentistry, and podiatry.

(2) A physician who is not in an approved GME program, but who is authorized to practice only in a hospital, for example, individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. For purposes of this subpart, the term *resident* is synonymous with the terms *intern* and *fellow*.

Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.

Teaching physician means a physician (other than another resident) who involves residents in the care of his or her patients.

Teaching setting means any provider, hospital-based provider, or nonprovider settings in which Medicare payment for the services of residents is made under the direct GME payment provisions of §§ 413.75 through 413.83, or on a reasonable-cost basis under the provisions of § 409.26 or § 409.40(f) for resident services furnished in skilled nursing facilities or home health agencies, respectively.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 63 FR 26359, May 12, 1998; 70 FR 47490, Aug. 12, 2005]

§ 415.160 Election of reasonable cost payment for direct medical and surgical services of physicians in teaching hospitals: General provisions.

(a) *Scope*. A teaching hospital may elect to receive payment on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of fee schedule payments that might otherwise be made for these services.

(b) *Conditions*. A teaching hospital may elect to receive these payments only if—

(1) The hospital notifies its intermediary in writing of the election and meets the conditions of either paragraph (b)(2) or paragraph (b)(3) of this section;

(2) All physicians who furnish services to Medicare beneficiaries in the hospital agree not to bill charges for these services; or

(3) All physicians who furnish services to Medicare beneficiaries in the hospital are employees of the hospital and, as a condition of employment, are precluded from billing for these services.

(c) *Effect of election*. If a teaching hospital elects to receive reasonable cost payment for physician direct medical and surgical services furnished to beneficiaries—

(1) Those services and the supervision of interns and residents furnishing care to individual beneficiaries are covered as hospital services, and

(2) The intermediary pays the hospital for those services on a reasonable cost basis under the rules in § 415.162. (Payment for other physician compensation costs related to approved GME programs is made as described in § 413.78 of this chapter.)

(d) *Election declined*. If the teaching hospital does not make this election, payment is made—

(1) For physician services furnished to beneficiaries on a fee schedule basis as described in part 414 subject to the rules in this subpart, and

(2) For the supervision of interns and residents as described in §§ 413.75 through 413.83.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.162 Determining payment for physician services furnished to beneficiaries in teaching hospitals.

(a) *General rule*. Payments for direct medical and surgical services of physicians furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries is made by Medicare on the basis of reasonable cost if the hospital exercises the election as provided for in § 415.160. If this election is made, the following occurs:

(1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries are paid on a reasonable-cost basis, as provided for in paragraph (b) of this section.

(2) Payment for certain medical school costs may be made as provided for in paragraph (c) of this section.

(3) Payments for services donated by volunteer physicians to beneficiaries are made to a fund designated by the organized medical staff of the teaching hospital or medical school as provided for in paragraph (d) of this section.

(b) *Reasonable cost of physician services and supervision of interns and residents.* (1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries in a teaching hospital are payable as provider services on a reasonable-cost basis.

(2) For purposes of this paragraph, *reasonable cost* is defined as the direct salary paid to these physicians, plus applicable fringe benefits.

(3) The costs must be allocated to the services as provided by paragraph (j) of this section and apportioned to program beneficiaries as provided by paragraph (g) of this section.

(4) Other allowable costs incurred by the provider related to the services described in this paragraph are payable subject to the requirements applicable to all other provider services.

(c) *Reasonable costs for the services furnished by a medical school or related organization in a hospital.* An amount is payable to the hospital by CMS under the Medicare program provided that the costs would be payable if incurred directly by the hospital rather than under the arrangement. The amount must not be in excess of the reasonable costs (as defined in paragraphs (c)(1) and (c)(2) of this section) incurred by a teaching hospital for services furnished by a medical school or organization as described in §413.17 of this chapter for certain costs to the medical school (or a related organization) in furnishing services in the hospital.

(1) *Reasonable costs of physician services.* (i) *When the medical school and the hospital are related organizations.* If the medical school (or organization related to the medical school) and the hospital are related by common ownership or control as described in §413.17 of this chapter—

(A) The costs of these services are allowable costs to the hospital under the provisions of §413.17 of this chapter; and

(B) The reimbursable costs to the hospital are determined under the provisions of this section in the same manner as the costs incurred for physicians on the hospital staff and without regard to payments made to the medical school by the hospital.

(ii) *When the medical school and the hospital are not related organizations.* (A) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school for the costs of those services furnished to all patients, payment is made by Medicare to the hospital for the reasonable cost incurred by the hospital for its payments to the medical school for services furnished to beneficiaries.

(B) Costs incurred under an arrangement must be allocated to the full range of services furnished to the hospital by the medical school physicians on the same basis as provided for under paragraph (j) of this section, and costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided for under paragraph (g) of this section.

(C) If the medical school and the hospital are not related organizations under the provisions of §413.17 of this chapter and the hospital makes payment to the medical school only for the costs of those services furnished to beneficiaries, costs of the medical school not to exceed 105 percent of the sum of physician direct salaries, applicable fringe benefits, employer's portion of FICA taxes, Federal and State unemployment taxes, and workmen's compensation paid by the medical school or an organization related to the medical school may be recognized as allowable costs of the medical school.

(D) These allowable medical school costs must be allocated to the full range of services furnished by the physicians of the medical school or organization related as provided by paragraph (j) of this section.

(E) Costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided by paragraph (g) of this section.

(2) *Reasonable costs of other than direct medical and surgical services.* These costs

are determined in accordance with paragraph (c)(1) of this section except that—

(i) If the hospital makes payment to the medical school for other than direct medical and surgical services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries, these payments are subject to the required cost-finding and apportionment methods applicable to the cost of other hospital services (except for direct medical and surgical services furnished to beneficiaries); or

(ii) If the hospital makes payment to the medical school only for these services furnished to beneficiaries, the cost of these services is not subject to cost-finding and apportionment as otherwise provided by this subpart, and the reasonable cost paid by Medicare must be determined on the basis of the health insurance ratio(s) used in the apportionment of all other provider costs (excluding physician direct medical and surgical services furnished to beneficiaries) applied to the allowable medical school costs incurred by the medical school for the services furnished to all patients of the hospital.

(d) *''Salary equivalent'' payments for direct medical and surgical services furnished by physicians on the voluntary staff of the hospital.* (1) CMS makes payments under the Medicare program to a fund as defined in § 415.164 for direct medical and surgical services furnished to beneficiaries on a regularly scheduled basis by physicians on the unpaid voluntary medical staff of the hospital (or medical school under arrangement with the hospital).

(i) These payments represent compensation for contributed medical staff time which, if not contributed, would have to be obtained through employed staff on a payable basis.

(ii) Payments for volunteer services are determined by applying to the regularly scheduled contributed time an hourly rate not to exceed the equivalent of the average direct salary (exclusive of fringe benefits) paid to all full-time, salaried physicians (other than interns and residents) on the hospital staff or, if the number of full-time salaried physicians is minimal in absolute terms or in relation to the number of physicians on the voluntary staff, to physicians at like institutions in the area.

(iii) This ''salary equivalent'' is a single hourly rate covering all physicians regardless of specialty and is applied to the actual regularly scheduled time contributed by the physicians in furnishing direct medical and surgical services to beneficiaries including supervision of interns and residents in that care.

(iv) A physician who receives any compensation from the hospital or a medical school related to the hospital by common ownership or control (within the meaning of § 413.17 of this chapter) for direct medical and surgical services furnished to any patient in the hospital is not considered an unpaid voluntary physician for purposes of this paragraph.

(v) If, however, a physician receives compensation from the hospital or related medical school or organization only for services that are other than direct medical and surgical services, a salary equivalent payment for the physician's regularly scheduled direct medical and surgical services to beneficiaries in the hospital may be imputed. However, the sum of the imputed value for volunteer services and the physician's actual compensation from the hospital and the related medical school (or organization) may not exceed the amount that would have been imputed if all of the physician's hospital and medical school services (compensated and volunteer) had been volunteer services, or paid at the rate of $30,000 per year, whichever is less.

(2) The following examples illustrate how the allowable imputed value for volunteer services is determined. In each example, it has been assumed that the average salary equivalent hourly rate is equal to the hourly rate for the individual physician's compensated services.

Example No: 1. Dr. Jones received $3,000 a year from Hospital X for services other than direct medical services to all patients, for example, utilization review and administrative services. Dr. Jones also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000 for the cost reporting period. The full imputed value of Dr. Jones' volunteer direct medical services would be allowed since the total amount of

the imputed value ($10,000) and the compensated services ($3,000) does not exceed $30,000.

Example No: 2. Dr. Smith received $25,000 from Hospital X for services as a department head in a teaching hospital. Dr. Smith also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000. Only $5,000 of the imputed value of volunteer services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($25,000) exceeds the $30,000 maximum amount allowable for all of Dr. Smith's services.

COMPUTATION:

Maximum amount allowable for all services performed by Dr. Smith for purposes of this computation	$30,000
Less compensation received from Hospital X for other than direct medical services to individual patients	$25,000
Allowable amount of imputed value for the volunteer services furnished by Dr. Smith	$5,000

Example No. 3. Dr. Brown is not compensated by Hospital X for any services furnished in the hospital. Dr. Brown voluntarily furnished direct surgical services to beneficiaries for a period of 6 months, and the imputed value of these services amounted to $20,000. The allowable amount of the imputed value for volunteer services furnished by Dr. Brown would be limited to $15,000 ($30,000×6/12).

(3) The amount of the imputed value for volunteer services applicable to beneficiaries and payable to a fund is determined in accordance with the aggregate per diem method described in paragraph (g) of this section.

(4) Medicare payments to a fund must be used by the fund solely for improvement of care of hospital patients or for educational or charitable purposes (which may include but are not limited to medical and other scientific research).

(i) No personal financial gain, either direct or indirect, from benefits of the fund may inure to any of the hospital staff physicians, medical school faculty, or physicians for whom Medicare imputes costs for purposes of payment into the fund.

(ii) Expenses met from contributions made to the hospital from a fund are not included as a reimbursable cost when expended by the hospital, and depreciation expense is not allowed with respect to equipment or facilities donated to the hospital by a fund or purchased by the hospital from monies in a fund.

(e) *Requirements for payment*—(1) *Physicians on the hospital staff.* The requirements under which the costs of physician direct medical and surgical services (including supervision of interns and residents) to beneficiaries are the same as those applicable to the cost of all other covered provider services except that the costs of these services are separately determined as provided by this section and are not subject to cost-finding as described in §413.24 of this chapter.

(2) *Physicians on the medical school faculty.* Payment is made to a hospital for the costs of services of physicians on the medical school faculty, provided that if the medical school is not related to the hospital (within the meaning of §413.17 of this chapter, concerning cost to related organizations), the hospital does not make payment to the medical school for services furnished to all patients and the following requirements are met: If the hospital makes payment to the medical school for services furnished to all patients, these requirements do not apply. (See paragraph (c)(1)(ii) of this section.)

(i) There is a written agreement between the hospital and the medical school or organization, specifying the types and extent of services to be furnished by the medical school and specifying that the hospital must pay to the medical school an amount at least equal to the reasonable cost (as defined in paragraph (c) of this section) of furnishing the services to beneficiaries.

(ii) The costs are paid to the medical school by the hospital no later than the date on which the cost report covering the period in which the services were furnished is due to CMS.

(iii) Payment for the services furnished under an arrangement would have been made to the hospital had the services been furnished directly by the hospital.

(3) *Physicians on the voluntary staff of the hospital (or medical school under arrangement with the hospital).* If the conditions for payment to a fund outlined in §415.164 are met, payments are made

on a ''salary equivalent'' basis (as defined in paragraph (d) of this section) to a fund.

(f) *Requirements for payment for medical school faculty services other than physician direct medical and surgical services.* If the requirements for payment for physician direct medical and surgical services furnished to beneficiaries in a teaching hospital described in paragraph (e) of this section are met, payment is made to a hospital for the costs of medical school faculty services other than physician direct medical and surgical services furnished in a teaching hospital.

(g) *Aggregate per diem methods of apportionment*—(1) *For the costs of physician direct medical and surgical services.* The cost of physician direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined on the basis of an average cost per diem as defined in paragraph (h)(1) of this section for physician direct medical and surgical services to all patients (see §§ 415.172 through 415.184) for each of the following categories of physicians:

(i) Physicians on the hospital staff.

(ii) Physicians on the medical school faculty.

(2) *For the imputed value of physician volunteer direct medical and surgical services.* The imputed value of physician direct medical and surgical services furnished to beneficiaries in a teaching hospital is determined on the basis of an average per diem, as defined in paragraph (h)(1) of this section, for physician direct medical and surgical services to all patients except that the average per diem is derived from the imputed value of the physician volunteer direct medical and surgical services furnished to all patients.

(h) *Definitions.* (1) *Average cost per diem for physician direct medical and surgical services (including supervision of interns and residents) furnished in a teaching hospital to patients in each category of physician services described in paragraph (g)(1) of this section* means the amount computed by dividing total reasonable costs of these services in each category by the sum of—

(i) Inpatient days (as defined in paragraph (h)(2) of this section); and

(ii) Outpatient visit days (as defined in paragraph (h)(3) of this section).

(2) *Inpatient days* are determined by counting the day of admission as 3.5 days and each day after a patient's day of admission, except the day of discharge, as 1 day.

(3) *Outpatient visit days* are determined by counting only one visit day for each calendar day that a patient visits an outpatient department or multiple outpatient departments.

(i) *Application.* (1) The following illustrates how apportionment based on the aggregate per diem method for costs of physician direct medical and surgical services furnished in a teaching hospital to patients is determined.

TEACHING HOSPITAL Y

Statistical and financial data:

Total inpatient days as defined in paragraph (h)(2) of this section and outpatient visit days as defined in paragraph (h)(3) of this section	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days where Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the hospital staff as determined in accordance with paragraph (i) of this section	$1,500,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the medical school faculty as determined in accordance with paragraph (i) of this section	$1,650,000

Computation of cost applicable to program for physicians on the hospital staff:

Average cost per diem for direct medical and surgical services to patients by physicians on the hospital staff: $1,500,000 ÷ 75,000 = $20 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $20 per diem × 20,000	$400,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$20,000

Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $20 per diem × 5,000	$100,000

Computation of cost applicable to program for physicians on the medical school faculty:

Average cost per diem for direct medical and surgical services to patients by physicians on the medical school faculty: $1,650,000 ÷ 75,000 = $22 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $22 per diem × 20,000	$440,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$22,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $22 per diem × 5,000	$110,000

(2) The following illustrates how the imputed value of physician volunteer direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined.

Example: The physicians on the medical staff of Teaching Hospital Y donated a total of 5,000 hours in furnishing direct medical and surgical services to patients of the hospital during a cost reporting period and did not receive any compensation from either the hospital or the medical school. Also, the imputed value for any physician volunteer services did not exceed the rate of $30,000 per year per physician.

STATISTICAL AND FINANCIAL DATA:

Total salaries paid to the full-time salaried physicians by the hospital (excluding interns and residents)	$800,000
Total physicians who were paid for an average of 40 hours per week or 2,080 (52 weeks×40 hours per week) hours per year	20
Average hourly rate equivalent: $800,000 ÷ 41,600 (2,080 × 20)	$19.23

Computation of total imputed value of physician volunteer services applicable to all patients:

(Total donated hours × average hourly rate equivalent): 5,000 × $19.23	$96,150
Total inpatient days (as defined in paragraph (h)(2) of this section) and outpatient visit days (as defined in paragraph (h)(3) of this section)	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days if Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000

Computation of imputed value of physician volunteer direct medical and surgical services furnished to Medicare beneficiaries:

Average per diem for physician direct medical and surgical services to all patients: $96,150 ÷ 75,000 = $1.28 per diem

Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $1.28 per diem × 20,000	$25,600
Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $1.28 per diem × 1,000	$1,280
Imputed value of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $1.28 per diem × 5,000	$6,400
Total	$33,280

(j) *Allocation of compensation paid to physicians in a teaching hospital.* (1) In determining reasonable cost under this section, the compensation paid by a teaching hospital, or a medical school or related organization under arrangement with the hospital, to physicians in a teaching hospital must be allocated to the full range of services implicit in the physician compensation arrangements. (However, see paragraph (d) of this section for the computation of the ''salary equivalent'' payments for volunteer services furnished to patients.)

(2) This allocation must be made and must be capable of substantiation on the basis of the proportion of each physician's time spent in furnishing each type of service to the hospital or medical school.

§415.164 Payment to a fund.

(a) *General rules.* Payment for certain voluntary services by physicians in teaching hospitals (as these services are described in §415.160) is made on a salary equivalent basis (as described in §415.162(d)) subject to the conditions and limitations contained in parts 405 and 413 of this chapter and this part 415, to a single fund (as defined in paragraph (b) of this section) designated by

the organized medical staff of the hospital (or, if the services are furnished in the hospital by the faculty of a medical school, to a fund as may be designated by the faculty), if the following conditions are met:

(1) The hospital (or medical school furnishing the services under arrangement with the hospital) incurs no actual cost in furnishing the services.

(2) The hospital has an agreement with CMS under part 489 of this chapter.

(3) The intermediary, or CMS as appropriate, has received written assurances that—

(i) The payment is used solely for the improvement of care of hospital patients or for educational or charitable purposes; and

(ii) Neither the individuals who are furnished the services nor any other persons are charged for the services (and if charged, provision is made for the return of any monies incorrectly collected).

(b) *Definition of a fund.* For purposes of paragraph (a) of this section, a *fund* is an organization that meets either of the following requirements:

(1) The organization has and retains exemption, as a governmental entity or under section 501(c)(3) of the Internal Revenue Code (nonprofit educational, charitable, and similar organizations), from Federal taxation.

(2) The organization is an organization of physicians who, under the terms of their employment by an entity that meets the requirements of paragraph (b)(1) of this section, are required to turn over to that entity all income that the physician organization derives from the physician services.

(c) *Status of a fund.* A fund approved for payment under paragraph (a) of this section has all the rights and responsibilities of a provider under Medicare except that it does not enter into an agreement with CMS under part 489 of this chapter.

§ 415.170 Conditions for payment on a fee schedule basis for physician services in a teaching setting.

Services meeting the conditions for payment in § 415.102(a) furnished in teaching settings are payable under the physician fee schedule if—

(a) The services are personally furnished by a physician who is not a resident; or

(b) The services are furnished by a resident in the presence of a teaching physician except as provided in § 415.172 (concerning physician fee schedule payment for services of teaching physicians), § 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), § 415.176 (concerning renal dialysis services), and § 415.184 (concerning psychiatric services), as applicable.

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must

document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. In the case of evaluation and management procedures, the teaching physician must personally document his or her participation in the service in the medical records.

(c) *Payment level.* In the case of services such as evaluation and management for which there are several levels of service codes available for reporting purposes, the appropriate payment level must reflect the extent and complexity of the service when fully furnished by the teaching physician.

§415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes of lower and mid-level complexity (as specified by CMS in program instructions), carriers may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:

(1) The services must be furnished in a center that is located in an outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining intermediary payments to a hospital under §§413.75 through 413.83.

(2) Any resident furnishing the service without the presence of a teaching physician must have completed more than 6 months of an approved residency program.

(3) The teaching physician must not direct the care of more than four residents at any given time and must direct the care from such proximity as to constitute immediate availability. The teaching physician must—

(i) Have no other responsibilities at the time;

(ii) Assume management responsibility for those beneficiaries seen by the residents;

(iii) Ensure that the services furnished are appropriate;

(iv) Review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies; and

(v) Document the extent of the teaching physician's participation in the review and direction of the services furnished to each beneficiary.

(4) The range of services furnished by residents in the center includes all of the following:

(i) Acute care for undifferentiated problems or chronic care for ongoing conditions.

(ii) Coordination of care furnished by other physicians and providers.

(iii) Comprehensive care not limited by organ system, or diagnosis.

(5) The patients seen must be an identifiable group of individuals who consider the center to be the continuing source of their health care and in which services are furnished by residents under the medical direction of teaching physicians.

(b) Nothing in paragraph (a) of this section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical checkups.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 70 FR 47490, Aug. 12, 2005]

§415.176 Renal dialysis services.

In the case of renal dialysis services, physicians who are not paid under the physician monthly capitation payment method (as described in §414.314 of this chapter) must meet the requirements of §§415.170 and 415.172 (concerning physician fee schedule payment for services of teaching physicians).

§415.178 Anesthesia services.

(a) *General rule.* An unreduced physician fee schedule payment may be made if a physician is involved in a single anesthesia procedure involving an anesthesia resident. In the case of anesthesia services, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. The teaching physician cannot receive an unreduced fee if he or she performs

services involving other patients during the period the anesthesia resident is furnishing services in a single case. For additional rules for payment of anesthesia services involving residents, see § 414.46(c)(1)(iii)).

(b) *Documentation.* Documentation must indicate the physician's presence or participation in the administration of the anesthesia.

[60 FR 63178, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(b) *Documentation.* Documentation must indicate that the physician personally performed the interpretation or reviewed the resident's interpretation with the resident.

§ 415.184 Psychiatric services.

To qualify for physician fee schedule payment for psychiatric services furnished under an approved GME program, the physician must meet the requirements of §§ 415.170 and 415.172, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

§ 415.190 Conditions of payment: Assistants at surgery in teaching hospitals.

(a) *Basis, purpose, and scope.* This section describes the conditions under which Medicare pays on a fee schedule basis for the services of an assistant at surgery in a teaching hospital. This section is based on section 1842(b)(7)(D)(I) of the Act and applies only to hospitals with an approved GME residency program. Except as specified in paragraph (c) of this section, fee schedule payment is not available for assistants at surgery in hospitals with—

(1) A training program relating to the medical specialty required for the surgical procedure; and

(2) A resident in a training program relating to the specialty required for the surgery available to serve as an assistant at surgery.

(b) *Definition. Assistant at surgery* means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(c) *Conditions for payment for assistants at surgery.* Payment on a fee schedule basis is made for the services of an assistant at surgery in a teaching hospital only if the services meet one of the following conditions:

(1) Are required as a result of exceptional medical circumstances.

(2) Are complex medical procedures performed by a team of physicians, each performing a discrete, unique function integral to the performance of a complex medical procedure that requires the special skills of more than one physician.

(3) Constitute concurrent medical care relating to a medical condition that requires the presence of, and active care by, a physician of another specialty during surgery.

(4) Are medically required and are furnished by a physician who is primarily engaged in the field of surgery, and the primary surgeon does not use interns and residents in the surgical procedures that the surgeon performs (including preoperative and postoperative care).

(5) Are not related to a surgical procedure for which CMS determines that assistants are used less than 5 percent of the time.

Subpart E—Services of Residents

§ 415.200 Services of residents in approved GME programs.

(a) *General rules.* Services furnished in hospitals by residents in approved GME programs are specifically excluded from being paid as ''physician services'' defined in § 414.2 of this chapter and are payable as hospital services. This exclusion applies whether or not the resident is licensed to practice under the laws of the State in which he

or she performs the service. The payment methodology for services of residents in hospitals and hospital-based providers is set forth in §§413.75 through 413.83 of this chapter.

(b) *Exception*. For low and mid-level evaluation and management services furnished under certain conditions in centers located in hospital outpatient departments and other ambulatory settings, see §415.174.

(c) *Definitions*. See §415.152 for definitions of terms used in this subpart E.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.202 Services of residents not in approved GME programs.

(a) *General rules*. For services of a physician employed by a hospital who is authorized to practice only in a hospital setting and for the services of a resident who is not in any approved GME program, payment is made to the hospital on a Part B reasonable cost basis regardless of whether the services are furnished to hospital inpatients or outpatients.

(b) *Payment*. For services described in paragraph (a) of this section, payment is made under Part B by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount. No payment is made for other costs of unapproved programs, such as administrative costs related to teaching activities of physicians.

§415.204 Services of residents in skilled nursing facilities and home health agencies.

(a) *Medicare Part A payment*. Payment is made under Medicare Part A for interns' and residents' services furnished in the following settings that meet the specified requirements:

(1) *Skilled nursing facility*. Payment to a participating skilled nursing facility may include the cost of services of an intern or resident who is in an approved GME program in a hospital with which the skilled nursing facility has a transfer agreement that provides, in part, for the transfer of patients and the interchange of medical records.

(2) *Home health agency*. A participating home health agency may receive payment for the cost of the services of an intern or resident who is under an approved GME program of a hospital with which the home health agency is affiliated or under common control if these services are furnished as part of the home health visits for a Medicare beneficiary. (Nevertheless, see §§413.75 through 413.83 of this chapter for the costs of approved GME programs in hospital-based providers.)

(b) *Medicare Part B payment*. Medical services of a resident of a hospital that are furnished by a skilled nursing facility or home health agency are paid under Medicare Part B if payment is not provided under Medicare Part A. Payment is made under Part B for a resident's services by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.206 Services of residents in nonprovider settings.

Patient care activities of residents in approved GME programs that are furnished in nonprovider settings are payable in one of the following two ways:

(a) *Direct GME payments*. If the conditions in §413.78 regarding patient care activities and training of residents are met, the time residents spend in nonprovider settings such as clinics, nursing facilities, and physician offices in connection with approved GME programs is included in determining the number of full-time equivalency residents in the calculation of a teaching hospital's resident count. The teaching physician rules on carrier payments in §§415.170 through 415.184 apply in these teaching settings.

(b) *Physician fee schedule*. (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count

for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in GME program hospitals.* (1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§ 413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if all of the following criteria are met:

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in § 415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a ''teaching physician'' associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§ 412.105 of this chapter) and for the direct GME payment (§§ 413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in § 415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by CMS in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

Subpart B—General Conditions and Requirements

§ 416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in § 416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§ 416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§ 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless CMS determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

(g) *Additional provisions*. The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to CMS*. An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination*. The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination*. If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS*—(1) *Cause for termination*. CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination*. CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC*. An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination*. Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public*. Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS*. When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996]

Subpart C—Specific Conditions for Coverage

§ 416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§ 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a

safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§ 416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§ 416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed

in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(*1*) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(*2*) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Tracheostomy set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55339, Sept. 22, 2006, § 416.44 was amended by revising paragraphs, (b)(5)(iii) and (iv)(F) and (G) and by adding paragraph (b)(5)(v), effective October 23, 2006. For the convenience of the user, the revised and added text is set forth as follows:

§ 416.44 Conditions for coverage-Environment.

* * * * *

(b) * * *

(5) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) * * *

(F) The dispensers shall not be installed over or directly adjacent to an ignition source;

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§ 416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

[57 FR 7135, Feb. 28, 1992]

Subpart D—Scope of Benefits

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

Subpart E—Payment for Facility Services

§ 416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had

been performed on an inpatient basis in a hospital.

[56 FR 8844, Mar. 1, 1991]

§416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

§416.150 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

§416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that CMS determines meet the definition of ''new technology IOL'' under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved

postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that CMS determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

§ 416.185 Payment review process.

(a) CMS publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for CMS to review payment for an IOL.

(b) CMS receives a request to review the appropriateness of the payment amount for an IOL.

(c) CMS compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) CMS publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) CMS reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the FEDERAL REGISTER, and any other timely information that CMS deems relevant to decide whether to provide a payment adjustment as specified in § 416.200. CMS makes a determination of whether the IOL meets the definition of a new technology IOL in § 416.180.

(f) If CMS determines that a lens is a new technology IOL, CMS establishes a payment adjustment as follows:

(1) Before July 16, 2002—$50.

(2) After July 16, 2002—$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) CMS designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the ''class of new technology IOLs.''

(h) Within 90 days of the end of the comment period following the FEDERAL REGISTER notice identified in paragraph (d) of this section, CMS publishes in the FEDERAL REGISTER its determinations with regard to IOLs that it has determined are ''new technology'' lenses that qualify for a payment adjustment.

(i) Payment adjustments are effective beginning 30 days after the publication of CMS's determinations in the FEDERAL REGISTER.

§ 416.190 Who may request a review.

Any party who is able to furnish the information required in § 416.195 may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in § 416.180.

§ 416.195 A request to review.

(a) *Content of a request.* The request must include all of the following information:

(1) The name of the manufacturer, the model number, and the trade name of the IOL.

(2) A copy of the FDA's summary of the IOL's safety and effectiveness.

(3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(4) A copy of the IOL's original FDA approval notification.

(5) Reports of modifications made after the original FDA approval.

(6) Other information that CMS finds necessary for identification of the IOL.

(b) *Confidential information.* To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, CMS maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required

by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§ 416.200 Application of the payment adjustment.

(a) CMS recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that CMS recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that CMS subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with CMS's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of CMS's initial recognition of a new technology subset, payment adjustments cease for all IOLs that CMS designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

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

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 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).

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]

§ 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.

(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]

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-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]

[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.

§ 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 after-hours 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 means health benefits and services.

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]

§ 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

[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.

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, 2008, where-

(1) There were two or more coordinated care plan-model MA regional plans 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 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.* (i) With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to the Metropolitan Statistical Area, 5,000 enrolled individuals.

(ii) With respect to any service area or portion of a service area that is not within a Metropolitan Statistical Area described in paragraph (c)(3)(i) of this section, 1,500 individuals.

[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]

§ 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 recipients 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 recipients 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 recipients (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) recordkeeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

[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]

§ 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*. 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]

§ 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—

(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 and signs

the HMO's or CMP's application form 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); and

(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).

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

§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]

§ 417.428 Marketing activities.

(a) *Required marketing activities.* An HMO or CMP must meet the following requirements:

(1) Offer its plan to Medicare beneficiaries and provide to those interested in enrolling, adequate written descriptions of the HMO's or CMP's rules, procedures, benefits, fees and other charges, services, and other information necessary for beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time limited or continuous) in an appropriate manner through appropriate media, throughout its enrollment area.

(3) Submit all marketing materials to CMS at least 45 days before their planned distribution.

(4) Include in the HMO's or CMP's written materials provided to prospective enrollees prior to enrollment, notice that the HMO or CMP is authorized by law to terminate or refuse to renew its contract with CMS, that CMS may also choose to terminate or refuse to renew its contact with the HMO or CMP and that termination or nonrenewal may result in termination of the individual's enrollment in the HMO or CMP.

(b) *Prohibited marketing activities—general.* In offering its plan to Medicare beneficiaries, an HMO or CMP may not engage in any of the following practices or activities:

(1) Practices that are discriminatory. For example, the HMO or CMP may not engage in any activity intended to recruit Medicare beneficiaries from higher income areas (usually an indicator of better health) without making a comparable effort to enroll Medicare beneficiaries from lower income areas.

(2) Activities that could mislead or confuse Medicare beneficiaries, or misrepresent the HMO or CMP its marketing representatives, or CMS. For example, the HMO or CMP may not claim that it is recommended or endorsed by CMS or that CMS recommends that the beneficiary enroll in the HMO or CMP. It may, however, explain that the entity is approved as an HMO or CMP for purposes of participation in Medicare.

(3) Offers of gifts or payment as an inducement to enroll in the HMO or CMP. This does not prohibit the explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the HMO or CMP such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance or preventive services.

(4) Door-to-door solicitation of Medicare beneficiaries.

(5) Distribution of marketing materials if, before the expiration of the 45-day period described in paragraph (a)(3) of this section, the HMO or CMP receives written notice from CMS that CMS has disapproved the material because it is inaccurate or misleading or it misrepresents the HMO or CMP, its marketing representatives or CMS.

(c) *Marketing activities of risk HMOs or CMPs* In addition to the generally permitted or prohibited marketing activities described in paragraphs (a) and (b) of this section, a risk HMO or CMP must provide potential Medicare enrollees with adequate written descriptions of the additional benefits or services, or reductions in premiums, deductible or copayments that may pertain under payment on a risk basis.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.430 Application procedures.

(a) *Application forms.* (1) The application form must comply with CMS instructions regarding format and content and must include the beneficiary's signature and authorization for disclosure and exchange of necessary information between CMS 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 written notice of acceptance or rejection of the application.

(4) The notice of acceptance—

(i) Specifies the date on which the HMO or CMP will request CMS to make the enrollment effective; or

(ii) 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]

§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 sign an application form 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]

§ 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.

[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]

§ 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 area;

(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; or

(iv) Dies.

(3) *Related provisions.* Specific requirements, limitations, and exceptions are set forth in paragraphs (c) through (i) 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.

(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.* 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.

(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 (e)(3) of this section.

(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.

(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.

(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.

[60 FR 45678, Sept. 1, 1995]

§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''.

[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]

§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.

[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]

§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 recipients.

(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 recipients 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 recipients. 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 recipients. 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).

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

§ 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; and

(2) Any other information necessary for the administration or evaluation of the Medicare program.

(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]

§ 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;

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period; and

(iii) Notify the general public at least 30 days before the end of the contract period, by publishing a notice in one or more newspapers of general circulation in each community or county located in the HMO's or CMP's geographic area.

(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.

(iii) To the general public at least 30 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 subpart R of this part, 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]

§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 subpart R of this part.

(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]

§417.500 Sanctions against HMOs and CMPs.

(a) *Basis for imposition of sanctions.* CMS may impose the intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination of contract, if CMS determines that an HMO or CMP does one or more of the following:

(1) Fails substantially to provide the medically necessary services required to be provided to a Medicare enrollee and the failure adversely affects (or has

a substantial likelihood of adversely affecting) the enrollee.

(2) Requires Medicare enrollees to pay amounts in excess of premiums permitted.

(3) Acts, in violation of the provisions of subpart K of this part, to expel or to refuse to reenroll an individual.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by subpart K of this part) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes under this part to CMS, an individual, or to any other entity.

(6) Fails to comply with the requirements of section 1876(g)(6)(A) of the Act relating to the prompt payment of claims.

(7) Fails to meet the requirement in section 1876(f)(1) of the Act that not more than 50 percent of the organization's enrollment be Medicare beneficiaries and Medicaid recipients.

(8) Has a Medicare risk contract and—

(i) Employs or contracts with individuals or entities excluded from participation in Medicare under section 1128 or section 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of those services (directly or indirectly) through an excluded individual or entity.

(9) Fails to comply with the requirements of §§ 417.479(d) through (i) relating to physician incentive plans.

(b) *Notice of sanction and opportunity to respond*—(1) *Notice of sanction*. Before imposing the intermediate sanctions specified in paragraph (d) of this section, CMS—

(i) Sends a written notice to the HMO or CMP stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice (other than a notice regarding the restriction on Medicare and Medicaid enrollees as described in paragraph (a)(7) of this section), once the sanction has been confirmed following the notice period or the reconsideration.

(2) *Opportunity to respond*. CMS allows the HMO or CMP 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the HMO or CMP. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the HMO's or CMP's conduct poses a threat to an enrollee's health and safety.

(c) *Informal reconsideration*. If, consistent with paragraph (b)(2) of this section, the HMO or CMP submits a timely response to CMS's notice of sanction, CMS conducts an informal reconsideration that:

(1) Consists of a review of the evidence by a CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the HMO or CMP a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(d) *Specific sanctions*. If CMS determines that an HMO or CMP has acted or failed to act as specified in paragraph (a) of this section and affirms this determination in accordance with paragraph (c) of this section, CMS may—

(1) Require the HMO or CMP to suspend acceptance of applications for enrollment made by Medicare beneficiaries during the sanction period;

(2) Suspend payments to the HMO or CMP for Medicare beneficiaries enrolled during the sanction period; and

(3) Require the HMO or CMP to suspend all marketing activities to Medicare enrollees.

(e) *Effective date and duration of sanctions*—(1) *Effective date*. Except as provided in paragraph (e)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the

sanction or, if the HMO or CMP timely seeks reconsideration under paragraph (c) of this section, on the date specified in the notice of CMS's reconsidered determination.

(2) *Exception*. If CMS determines that the HMO's or CMP's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS's reconsidered determination.

(3) *Duration of sanction*. The sanction remains in effect until CMS notifies the HMO or CMP that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(f) *Termination by CMS*. In addition to or as an alternative to the sanctions described in paragraph (d) of this section, CMS may decline to renew a HMO's or CMP's contract in accordance with §417.492(b), or terminate the contract in accordance with §417.494(b).

(g) *Civil money penalties*. If CMS determines that a HMO or CMP has committed an act or failed to comply with a requirement described in paragraph (a) of this section (with the exception of the requirement to limit the percentage of Medicare and Medicaid enrollees described in paragraph (a)(7) of this section), CMS notifies the OIG of that determination. CMS also conveys to the OIG information when it reverses or terminates a sanction imposed under this subpart. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the HMO or CMP in addition to or in place of the sanctions that CMS may impose under paragraph (d) of this section.

[59 FR 36083, July 15, 1994, as amended at 60 FR 45681, Sept. 1, 1995; 61 FR 13448, Mar. 27, 1996]

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) In accordance with § 413.80 of this chapter, bad debts are deductions from revenue and may be included as allowable costs only if—

(i) They are attributable to Medicare deductible and coinsurance amounts for which the Medicare enrollee is liable; and

(ii) The HMO or CMP has made a reasonable, but unsuccessful, effort to collect those amounts.

(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 §413.80 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]

§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.

[60 FR 46231, Sept. 6, 1995]

§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 subpart R of part 405 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 under subpart R of part 405 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]

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 Determinations subject to appeal.

This subpart establishes the procedures for making and reviewing the following initial determinations:

(a) A determination that an HMO or CMP is not qualified to enter into a contract with CMS under section 1876 of the Act.

(b) A determination that an HMO or CMP is qualified only for a reasonable cost contract.

(c) A determination to terminate, or to refuse to renew, a contract with an HMO or CMP because—

(1) The HMO or CMP has failed substantially to carry out the terms of the contract;

(2) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of section 1876 of the Act;

(3) The HMO or CMP no longer meets the applicable conditions necessary to qualify as an HMO or CMP under section 1876 of the Act and this subpart; or

(4) The HMO or CMP has failed to comply with the composition of enrollment requirements specified in § 417.413(d).

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46572, Sept. 13, 1991; 58 FR 38080, July 15, 1993]

§ 417.642 Administrative actions that are not initial determinations.

Administrative actions that are not initial determinations under this subpart include, but are not limited to, CMS's refusal to renew a contract with an HMO or CMP when the refusal is not based on the causes specifed in § 417.640(c).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993]

§ 417.644 Notice of initial determination.

(a) When CMS makes an initial determination, it gives the HMO or CMP written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The HMO's or CMP's right to request reconsideration.

(c) CMS mails the notice to the HMO or CMP at least 90 days before the end of the contract period, or in the case of termination, at least 90 days before the effective date of the termination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46234, Sept. 6, 1995]

§ 417.646 Effect of initial determination.

The initial determination is final and binding on all parties unless—

(a) It is reconsidered in accordance with §§ 417.648 through 417.658;

(b) In the case of an initial determination described in § 417.640(c), a request for a hearing is filed; or

(c) It is revised as a result of a reopening under § 417.692.

§ 417.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing an organization determination specified in § 417.640(a) or (b).

(b) CMS reconsiders either of the specified determinations if the HMO or CMP files a written request in accordance with § 417.650.

[60 FR 46234, Sept. 6, 1995]

§ 417.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the initial determination.

(c) *Extension of time to file a request.* CMS may, in response to a party's written petition showing good cause, accept a request for reconsideration after the expiration of the 60 day period.

(d) *Proper party to file a request.* Only an authorized official of the entity that was a party to an initial determination may file the request for reconsideration.

(e) *Withdrawal of a request.* A request for reconsideration may be withdrawn by the party who filed the request at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS. If CMS approves, the request for reconsideration is withdrawn.

§ 417.652 Opportunity to submit evidence.

CMS provides the parties to the reconsideration reasonable opportunity to present as evidence any documents or written statements that are relevant and material to the matters at issue.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the initial determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the entity subsequent to the initial determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 417.656 Notice of reconsidered determination.

(a) CMS gives the parties written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the HMO's or CMP's qualifications to enter into a contract with CMS under section 1876 of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the party of its right to a hearing if it is dissatisfied with the determination.

[60 FR 46234, Sept. 6, 1995]

§ 417.658 Effect of reconsidered determination.

A reconsidered determination is final and binding on all parties unless a request for a hearing is filed in accordance with § 417.662 or it is revised in accordance with § 417.692.

§ 417.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) An entity that has been determined in a reconsidered determination to be unqualified to enter into a contract with CMS under section 1876 of the Act.

(b) An HMO or CMP that has been determined in a reconsidered determination to be qualified only for a reasonable cost contract.

(c) An HMO or CMP whose contract with CMS has been terminated or has not been renewed as a result of an initial determination as provided in § 417.640(c).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the entity or HMO or CMP that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, a request for a hearing must be filed within 60 days after the date of receipt of the notice of initial or reconsidered determination.

(c) *Extension of time to file a request.* If good cause is shown, the 60-day period to request a hearing may be extended by CMS.

(d) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 417.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.664 Postponement of effective date of initial determination.

When a request for a hearing with respect to an initial determination is filed timely—

(a) The effective date of the initial determination to terminate a contract with an HMO or CMP will be postponed until a hearing decision is reached; and

(b) The current contract will be extended at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract will be consistent with the purpose of section 1876 of the Act; and

(2) For such period as CMS and the HMO or CMP agree.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted to CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in the time or place of hearing, or of adjournment or postponement.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993; 60 FR 46234, Sept. 6, 1995]

§417.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before CMS or otherwise prohibited by law.

§417.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with §417.672 may, on behalf of the represented party—

(1) Give or accept any notice or request pertinent to the proceedings set forth in this subpart;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§417.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§ 417.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by CMS, and general instructions issued by CMS in implementing that Act.

§ 417.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reopened and revised in accordance with § 417.692.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.692 Reopening of initial or reconsidered determination or decision of a hearing officer.

(a) *Initial or reconsidered determination*. An initial or reconsidered determination may be reopened and revised by CMS upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. It may be reopened and revised by another hearing officer designated by CMS if the hearing officer who issued the decision is unavailable.

(c) *Notices*. (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.694 Effect of revised determination.

The revision of an initial or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 417.662.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

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; 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]

§ 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 as provided in part 405, subpart R 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 on the determination under the provisions of part 405, subpart R 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]

§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 §422.619 of this chapter to organization determinations that affect its Medicare enrollees, and to reconsiderations, hearings, Medicare Appeals Council review, and judicial review of those organization determinations.

[70 FR 4713, Jan. 28, 2005]

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 45 CFR 74.132; 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]

§ 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 break-even 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

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 56026, Dec. 16, 1983, unless otherwise noted.

Subpart A—General Provision and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act. Section 1861(dd) specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(7) and 1814(i) of the Act contain conditions and limitations on coverage of, and payment for, hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

[48 FR 56026, Dec. 16, 1983, as amended at 57 FR 36017, Aug. 12, 1992]

§ 418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility requirements and the benefit periods. Subpart C specifies conditions of participation for hospices. Subpart D describes the covered services and specifies the limits on services covered as hospice care. Subpart E specifies the reimbursement methods and procedures. Subpart F specifies coinsurance amounts applicable to hospice care.

§ 418.3 Definitions.

For purposes of this part—

Attending physician means a—(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education, and experience requirements as the Secretary may prescribe; and

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means counseling services provided to the individual's family after the individual's death.

Cap period means the twelve-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

Employee means an employee (defined by section 210(j) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. ''Employee'' also refers to a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that—is primarily engaged in providing care to terminally ill individuals.

Physician means physician as defined in § 410.20 of this chapter.

Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is mentally or physically incapacitated.

Social worker means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 50 FR 50834, Dec. 11, 1990; 70 FR 45144, Aug. 4, 2005]

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

(1) An initial 90-day period;

(2) A subsequent 90-day period; or

(3) An unlimited number of subsequent 60-day periods.

(b) The periods of care are available in the order listed and may be elected separately at different times.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 70546, Nov. 22, 2005]

§ 418.22 Certification of terminal illness.

(a) *Timing of certification*—(1) *General rule*. The hospice must obtain written certification of terminal illness for each of the periods listed in § 418.21, even if a single election continues in effect for an unlimited number of periods, as provided in § 418.24(c).

(2) *Basic requirement*. Except as provided in paragraph (a)(3) of this section, the hospice must obtain the written certification before it submits a claim for payment.

(3) *Exception*. If the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(b) *Content of certification*. Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:

(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(2) Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

(c) *Sources of certification*. (1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from—

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician, if the individual has an attending physician. The attending physician must meet the definition of physician specified in § 410.20 of this subchapter.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) *Maintenance of records*. Hospice staff must—

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 45144, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005]

§ 418.24 Election of hospice care.

(a) *Filing an election statement*. An individual who meets the eligibility requirement of § 418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in § 418.3) may file the election statement.

(b) *Content of election statement*. The election statement must include the following:

(1) Identification of the particular hospice that will provide care to the individual.

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in paragraph (d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

(c) *Duration of election*. An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice;

(2) Does not revoke the election; and

(3) Is not discharged from the hospice under the provisions of § 418.26.

(d) *Waiver of other benefits*. For the duration of an election of hospice care,

an individual waives all rights to Medicare payments for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice:

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(e) *Re-election of hospice benefits*. If an election has been revoked in accordance with § 418.28, the individual (or his or her representative if the individual is mentally or physically incapacitated) may at any time file an election, in accordance with this section, for any other election period that is still available to the individual.

[55 FR 50834, Dec. 11, 1990, as amended at 70 FR 70547, Nov. 22, 2005]

§ 418.25 Admission to hospice care.

(a) The hospice admits a patient only on the recommendation of the medical director in consultation with, or with input from, the patient's attending physician (if any).

(b) In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:

(1) Diagnosis of the terminal condition of the patient.

(2) Other health conditions, whether related or unrelated to the terminal condition.

(3) Current clinically relevant information supporting all diagnoses.

[70 FR 70547, Nov. 22, 2005]

§ 418.26 Discharge from hospice care.

(a) *Reasons for discharge*. A hospice may discharge a patient if—

(1) The patient moves out of the hospice's service area or transfers to another hospice;

(2) The hospice determines that the patient is no longer terminally ill; or

(3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(i) through (a)(3)(iv) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice must do the following before it seeks to discharge a patient for cause:

(i) Advise the patient that a discharge for cause is being considered;

(ii) Make a serious effort to resolve the problem(s) presented by the patient's behavior or situation;

(iii) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and

(iv) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(b) *Discharge order*. Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

(c) *Effect of discharge*. An individual, upon discharge from the hospice during a particular election period for reasons other than immediate transfer to another hospice—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(d); and

(3) May at any time elect to receive hospice care if he or she is again eligible to receive the benefit.

(d) *Discharge planning*. (1) The hospice must have in place a discharge planning process that takes into account the prospect that a patient's condition

might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill.

(2) The discharge planning process must include planning for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

[70 FR 70547, Nov. 22, 2005]

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

§ 418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

Subpart C—Conditions of Participation—General Provisions and Administration

§ 418.50 Condition of participation—General provisions.

(a) *Standard: Compliance.* A hospice must maintain compliance with the conditions of this subpart and subparts D and E of this part.

(b) *Standard: Required services.* A hospice must be primarily engaged in providing the care and services described in § 418.202, must provide bereavement counseling and must—

(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and

(3) Provide these services in a manner consistent with accepted standards of practice.

(c) *Standard: Disclosure of information.* The hospice must meet the disclosure of information requirements at § 420.206 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50834, Dec. 11, 1990]

§ 418.52 Condition of participation—Governing body.

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are

consistent with accepted standards of practice.

§ 418.54 Condition of participation—Medical director.

The medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

§ 418.56 Condition of participation—Professional management.

Subject to the conditions of participation pertaining to services in §§ 418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

(a) *Standard: Continuity of care.* The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.

(b) *Standard: Written agreement.* The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes at least the following:

(1) Identification of the services to be provided.

(2) A stipulation that services may be provided only with the express authorization of the hospice.

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

(5) Requirements for documenting that services are furnished in accordance with the agreement.

(6) The qualifications of the personnel providing the services.

(c) *Standard: Professional management responsibility.* The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.

(d) *Standard: Financial responsibility.* The hospice retains responsibility for payment for services.

(e) *Standard: Inpatient care.* The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in § 418.98 and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies, at a minimum—

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;

(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;

(4) The party responsible for the implementation of the provisions of the agreement; and

(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.58 Condition of participation—Plan of care.

A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.

(a) *Standard: Establishment of plan.* The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.

(b) *Standard: Review of plan.* The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.

(c) *Standard: Content of plan.* The plan must include an assessment of the individual's needs and identification of the

services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

§ 418.60 Condition of participation—Continuation of care.

A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.

§ 418.62 Condition of participation—Informed consent.

A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in § 418.3.

§ 418.64 Condition of participation—Inservice training.

A hospice must provide an ongoing program for the training of its employees.

§ 418.66 Condition of participation—Quality assurance.

A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must—

(a) Implement and report on activities and mechanisms for monitoring the quality of patient care;

(b) Identify and resolve problems; and

(c) Make suggestions for improving patient care.

§ 418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.* The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

(1) A doctor of medicine or osteopathy.

(2) A registered nurse.

(3) A social worker.

(4) A pastoral or other counselor.

(b) *Standard: Role of group.* The interdisciplinary group is responsible for—

(1) Participation in the establishment of the plan of care;

(2) Provision or supervision of hospice care and services;

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) *Standard: Coordinator.* The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

§ 418.70 Condition of participation—Volunteers.

The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(b) *Standard: Role.* Volunteers must be used in administrative or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document active and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of necessary positions which are occupied by volunteers;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) for the amount of time specified in paragraph (d)(2).

(e) *Standard: Level of activity*. A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must document a continuing level of volunteer activity. Expansion of care and services achieved through the use of volunteers, including the type of services and the time worked, must be recorded.

(f) *Standard: Availability of clergy*. The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

§ 418.72 Condition of participation—Licensure.

The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(a) *Standard: Licensure of program*. If State or local law provides for licensing of hospices, the hospice must be licensed.

(b) *Standard: Licensure of employees*. Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.

§ 418.74 Condition of participation—Central clinical records.

In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

(a) *Standard: Content*. Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record contains—

(1) The initial and subsequent assessments;

(2) The plan of care;

(3) Identification data;

(4) Consent and authorization and election forms;

(5) Pertinent medical history; and

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

(b) *Standard; Protection of information*. The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

Subpart D—Conditions of Participation: Core Services

§ 418.80 Condition of participation—Furnishing of core services.

Except as permitted in § 418.83, a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart.

[52 FR 7416, Mar. 11, 1987, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.82 Condition of participation—Nursing services.

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

(b) Patient care responsibilities of nursing personnel must be specified.

(c) Services must be provided in accordance with recognized standards of practice.

§ 418.83 Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) CMS may approve a waiver of the requirement in § 418.80 for nursing services provided by a hospice which is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. CMS bases its decision as to whether to approve a waiver application on the following:

(1) The current Bureau of the Census designations for determining non-urbanized areas.

(2) Evidence that a hospice was operational on or before January 1, 1983 including:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and

(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) Evidence that a hospice made a good faith effort to hire nurses, including:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;

(ii) Job descriptions for nurse employees;

(iii) Evidence that salary and benefits are competitive for the area; and

(iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area);

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for one year at a time.

(d) CMS may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to CMS, prior to the expiration of the waiver period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.

[52 FR 7416, Mar. 11, 1987]

§ 418.84 Condition of participation—Medical social services.

Medical social services must be provided by a qualified social worker, under the direction of a physician.

§ 418.86 Condition of participation—Physician services.

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

§ 418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

(a) *Standard: Bereavement counseling.* There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified § 418.204(c).

(b) *Standard: Dietary counseling.* Dietary counseling, when required, must be provided by a qualified individual.

(c) *Standard: Spiritual counseling.* Spiritual counseling must include notice to patients as to the availability of clergy as provided in § 418.70(f).

(d) *Standard: Additional counseling.* Counseling may be provided by other members of the interdisciplinary group

as well as by other qualified professionals as determined by the hospice.

Subpart E—Conditions of Participation: Other Services

§ 418.90 Condition of participation—Furnishing of other services.

A hospice must ensure that the services described in this subpart are provided directly by hospice employees or under arrangements made by the hospice as specified in § 418.56.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

(a) Physical therapy services, occupational therapy services, and speech-language patholgy services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

(b)(1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

[57 FR 7135, Feb. 28, 1992]

§ 418.94 Condition of participation—Home health aide and homemaker services.

Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in § 484.36 of this chapter.

(a) *Standard: Supervision*. A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

(b) *Standard: Duties*. Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in § 484.36(c) of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.96 Condition of participation—Medical supplies.

Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Administration*. All drugs and biologicals must be administered in accordance with accepted standards of practice.

(b) *Standard: Controlled drugs in the patient's home*. The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

(c) *Standard: Administration of drugs and biologicals*. Drugs and biologicals are administered only by the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(4) Any other individual in accordance with applicable State and local laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.

§ 418.98 Condition of participation—Short term inpatient care.

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom control*. Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the condition of participation for providing inpatient care directly as specified in § 418.100.

(2) A hospital or an SNF that also meets the standards specified in § 418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An ICF that also meets the standards specified in § 418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(c) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

(d) *Standard: Exemption from limitation.* Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.100 Condition of participation Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly must comply with all of the following standards.

(a) *Standard: Twenty-four-hour nursing services.* (1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) Each shift must include a registered nurse who provides direct patient care.

(b) *Standard: Disaster preparedness.* The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(c) *Standard: Health and safety laws.* The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(1) Construction, maintenance, and equipment for the hospice;

(2) Sanitation;

(3) Communicable and reportable diseases; and

(4) Post mortem procedures.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to a hospice.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of the patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State

law adequately protects patients in hospices.

(4) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(e) *Standard: Patient areas.* (1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.

(2) The hospice must have—

(i) Physical space for private patient/family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night;

(iii) Accommodations for family privacy after a patient's death; and

(iv) Decor which is homelike in design and function.

(3) Patients must be permitted to receive visitors at any hour, including small children.

(f) *Standard: Patient rooms and toilet facilities.* Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

(1) Each patient's room must—

(i) Be equipped with or conveniently located near toilet and bathing facilities;

(ii) Be at or above grade level;

(iii) Contain a suitable bed for each patient and other appropriate furniture;

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

(v) Contain no more than four beds;

(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and

(vii) Be equipped with a device for calling the staff member on duty.

(2) For an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(1) (v) and (vi) of this section for as long as it is considered appropriate if it finds that—

(i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and

(ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.

(g) *Standard: Bathroom facilities.* The hospice must—

(1) Provide an adequate supply of hot water at all times for patient use; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(h) *Standard: Linen.* The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(i) *Standard: Isolation areas.* The hospice must make provision for isolating patients with infectious diseases.

(j) *Standard: Meal service, menu planning, and supervision.* The hospice must—

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;

(3) Have a staff member trained or experienced in food management or nutrition who is responsible for—

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, DC 20418); and

(ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and

(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to ensure that the patient accepts the special diet.

(k) *Standard: Pharmaceutical services.* The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See § 405.1124(g), (h), and (i) of this chapter.)

(1) *Licensed pharmacist.* The hospice must—

(i) Employ a licensed pharmacist; or

(ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(2) *Orders for medications.* (i) A physician must order all medications for the patient.

(ii) If the medication order is verbal—

(A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(3) *Administering medications.* Medications are administered only by one of the following individuals:

(i) A licensed nurse or physician.

(ii) An employee who has completed a State-approved training program in medication administration.

(iii) The patient if his or her attending physician has approved.

(4) *Control and accountability.* The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(5) *Labeling of drugs and biologicals.* The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(6) *Storage.* In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug

distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.

(7) *Drug disposal.* Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983; 49 FR 23010, June 1, 1984, as amended at 53 FR 11509, Apr. 7, 1988; 55 FR 50835, Dec. 11, 1990; 68 FR 1386, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 69 FR 49266, Aug. 11, 2004; 70 FR 15237, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55339, Sept. 22, 2006, §418.100 was amended by revising paragraph (d)(6)(iii), by amending paragraph (d)(6)(iv) by removing the last sentence and by removing the period at the end of the paragraph and adding in its place ''; and'' and by adding paragraph (d)(6)(v), effective October 23, 2006. For the convenience of the user, the revised text is set forth as follows:

§418.100 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) * * *

(6) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

Subpart F—Covered Services

§418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with §418.24 and a plan of care must be established as set forth in §418.58 before services are provided. The services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in §418.22.

§418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in §410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in §418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in §418.98(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in §418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only

drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) *Home health aide services furnished by qualified aides as designated in § 418.94 and homemaker services.* Home health aides may provide personal care services as defined in § 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

(i) Effective April 1, 1998, any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994; 70 FR 70547, Nov. 22, 2005]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation or management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.205 Special requirements for hospice pre-election evaluation and counseling services.

(a) *Definition.* As used in this section the following definition applies.

Terminal illness has the same meaning as defined in § 418.3.

(b) *General.* Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in § 418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) *The beneficiary.* The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in § 418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) *Services provided.* The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling

regarding hospice and other care options. In addition, the services may include advising the individual regarding advanced care planning.

(3) *Provision of pre-election hospice services.* (i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) *Documentation.* (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

[69 FR 66425, Nov. 15, 2004]

Subpart G—Payment for Hospice Care

§418.301 Basic rules.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in §418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in §418.309.

(c) The hospice may not charge a patient for services for which the patient is entitled to have payment made under Medicare or for services for which the patient would be entitled to payment, as described in §489.21 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 70547, Nov. 22, 2005]

§418.302 Payment procedures for hospice care.

(a) CMS establishes payment amounts for specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in §418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom

management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are established by CMS in accordance with the procedures described in § 418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d)(1) The intermediary reimburses the hospice its appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(2) Effective December 8, 2003, if a hospice makes arrangements with another hospice to provide services under the circumstances specified in section 1861(dd)(5)(D) of the Act, the intermediary reimburses the hospice for which the beneficiary has made an election as described in paragraph (d)(1) of this section.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in § 418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows: (1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in § 418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care,

and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in §418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

(g) Payment for routine home care and continuous home care is made on the basis of the geographic location where the service is provided.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005]

§418.304 Payment for physician and nurse practitioner services.

(a) The following services performed by hospice physicians and nurse practitioners are included in the rates described in §418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician fee schedule for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in §418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in §418.309. These services are paid by the carrier under the procedures in subpart B, part 414 of this chapter.

(d) *Payment for hospice pre-election evaluation and counseling services.* The intermediary makes payment to the hospice for the services established in §418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

(e)(1) Effective December 8, 2003, Medicare pays for attending physician services provided by nurse practitioners to Medicare beneficiaries who have elected the hospice benefit and who have selected a nurse practitioner as their attending physician. This applies to nurse practitioners without regard to whether they are hospice employees.

(2) Nurse practitioners may bill and receive payment for services only if the—

(i) Nurse practitioner is the beneficiary's attending physician as defined in §418.3;

(ii) Services are medically reasonable and necessary;

(iii) Services are performed by a physician in the absence of the nurse practitioner; and

(iv) Services are not related to the certification of terminal illness specified in §418.22.

(3) Payment for nurse practitioner services are made at 85 percent of the physician fee schedule amount.

[48 FR 56026, Dec. 16, 1983, as amended at 69 FR 66426, Nov. 15, 2004; 70 FR 45145, Aug. 4, 2005; 70 FR 70547, Nov. 22, 2005]

§ 418.306 Determination of payment rates.

(a) *Applicability*. CMS establishes payment rates for each of the categories of hospice care described in § 418.302(b). The rates are established using the methodology described in section 1814(i)(1)(C) of the Act.

(b) *Payment rates*. The payment rates for routine home care and other services included in hospice care are as follows:

(1) The following rates, which are 120 percent of the rates in effect on September 30, 1989, are effective January 1, 1990 through September 30, 1990 and October 21, 1990 through December 31, 1990:

Routine home care	$75.80
Continuous home care:	
Full rate for 24 hours	442.40
Hourly rate	18.43
Inpatient respite care	78.40
General inpatient care	337.20

(2) Except for the period beginning October 21, 1990, through December 31, 1990, the payment rates for routine home care and other services included in hospice care for Federal fiscal years 1991, 1992, and 1993 and those that begin on or after October 1, 1997, are the payment rates in effect under this paragraph during the previous fiscal year increased by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act, otherwise applicable to discharges occurring in the fiscal year. The payment rates for the period beginning October 21, 1990, through December 31, 1990, are the same as those shown in paragraph (b)(1) of this section.

(3) For Federal fiscal years 1994 through 2002, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus—

(i) 2 percentage points in FY 1994;

(ii) 1.5 percentage points in FYs 1995 and 1996;

(iii) 0.5 percentage points in FY 1997; and

(iv) 1 percentage point in FY 1998 through FY 2002.

(4) For Federal fiscal year 2001, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase plus 5 percentage points. However, this payment rate is effective only for the period April 1, 2001 through September 30, 2001. For the period October 1, 2000 through March 31, 2001, the payment rate is based upon the rule under paragraph (b)(3)(iv) of this section. The payment rate in effect during the period April 1, 2001 through September 30, 2001 is considered the payment rate in effect during fiscal year 2001.

(5) The payment rate for hospice services furnished during fiscal years 2001 and 2002 is increased by an additional 0.5 percent and 0.75 percent, respectively. This additional amount is not included in updating the payment rate as described in paragraph (b)(3) of this section.

(c) *Adjustment for wage differences*. CMS will issue annually, in the FEDERAL REGISTER, a hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Metropolitan Statistical Areas. The payment rates established by CMS are adjusted by the intermediary to reflect local differences in wages according to the revised wage index.

(d) *Federal Register notices*. CMS publishes as a notice in the FEDERAL REGISTER any proposal to change the methodology for determining the payment rates.

[56 FR 26919, June 12, 1991, as amended at 59 FR 26960, May 25, 1994; 62 FR 42882, Aug. 8, 1997; 70 FR 70548, Nov. 22, 2005]

§ 418.307 Periodic interim payments.

Subject to the provisions of § 413.64(h) of this chapter, a hospice may elect to receive periodic interim payments (PIP) effective with claims received on or after July 1, 1987. Payment is made biweekly under the PIP method unless the hospice requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payments for the reporting period (as described in §§ 418.302–418.306). Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(5) of this chapter. Under certain circumstances that are described in § 413.64(g) of this chapter, a hospice

that is not receiving PIP may request an accelerated payment.

[59 FR 36713, July 19, 1994]

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in § 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in § 418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in § 405.1803 of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.309 Hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes—

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. (The hospice can obtain this information by contacting the intermediary.)

§ 418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§ 418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR part 405, subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under § 405.1874 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the payment rates by CMS are not subject to appeal.

Subpart H—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with § 418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by CMS for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with § 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§ 418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in § 418.400, that are considered covered hospice care (as described in § 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§ 418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by CMS in accordance with § 418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, CMS offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

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419.70 Transitional adjustment to limit decline in payment.

AUTHORITY: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 13951(t), and 1395hh).

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted.

Subpart A—General Provisions

§419.1 Basis and scope.

(a) *Basis*. This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope*. This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§419.2 Basis of payment.

(a) *Unit of payment*. Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Included costs*. The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to—

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and

(12) Costs incurred to procure donor tissue other than corneal tissue.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in §§ 413.75 through 413.83 of this chapter.

(2) The costs of nursing and allied health programs as described in § 413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in § 415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under § 415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in § 413.89(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition costs.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 70 FR 47490, Aug. 12, 2005]

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001]

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a comprehensive outpatient rehabilitation facility (CORF) when they are provided outside the patient's plan (of care); or by a home health agency (HHA) to patients who are not under an HHA plan or treatment; or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Hepatitis B vaccine.

(e) Effective January 1, 2005, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 6 months after the individual's initial Part B coverage date that begins on or after January 1, 2005.

[65 FR 18542, Apr. 7, 2000, as amended at 67 FR 66813, Nov. 1, 2002; 69 FR 65863, Nov. 15, 2004]

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Clinical diagnostic laboratory services.

(m) Services for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital ''under arrangements'' but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

(s) Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 69 FR 65863, Nov. 15, 2004]

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) CMS estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) CMS may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the median costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) CMS determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the ''labor-related portion'' of hospital outpatient costs.

(2) CMS standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* CMS calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001—

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional

percentage allowance equal to 0.32 percent.

(iii) For the portion of calendar year 2002 that is affected by these rules, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in §419.32(b)(ii)(B).

(iv) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates*. The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under §419.31(b).

(d) *Budget neutrality*. (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under §419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 67 FR 9568, Mar. 1, 2002; 69 FR 832, Jan. 6, 2004]

EFFECTIVE DATE NOTE: At 66 FR 59922, Nov. 30, 2001, §41932 was amended by revising paragraph (b)(1), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, paragraph (b)(1)(iii) was delayed indefinitely.

Subpart D—Payments to Hospitals

§419.40 Payment concepts.

(a) In addition to the payment rate described in §419.32, for each APC group there is a predetermined beneficiary copayment amount as described in §419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in §419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount*. The copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

[66 FR 59922, Nov. 30, 2001]

§419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted copayment amount for each APC group, CMS—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary copayment amount for the APC group.

(b) CMS calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted copayment amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, CMS makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the copayment amount.

(i) The copayment amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the copayment amount for multiple APCs for a single drug or biological furnished on the same day will be aggregated and treated as the copayment amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the copayment amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the copayment amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the copayment amount for one APC.

(ii) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(iii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years 2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

(iv) The copayment amount is computed as if the adjustments under § 419.43(d) and (e) (and any adjustment made under § 419.43(f) in relation to these adjustments) had not been paid.

(5) Adds the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001]

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's

wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001]

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

(a) *General rule.* CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the ''labor-related portion'' of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor.* CMS uses the hospital inpatient prospective payment system wage index established in accordance with part 412 of this chapter to make the adjustment referred to in paragraph (a) of this section.

(d) *Outlier adjustment*—(1) *General rule.* Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under paragraph (e) of this section.

(ii) At the option of CMS, a fixed dollar amount.

(2) *Amount of adjustment.* The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments*—(i) *In general.* The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage.* For purposes of paragraph (d)(3)(i) of this section, the term ''applicable percentage'' means a percentage specified by CMS up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority.* In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional passthrough payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(e) *Budget neutrality*. CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) *Excluded services and groups*. Drugs and biologicals that are paid under a separate APC and devices of brachytherapy, consisting of a seed or seeds (including a radioactive source) are excluded from qualification for outlier payments.

(g) *Payment adjustment for certain rural hospitals*—(1) *General rule*. CMS provides for additional payment for covered hospital outpatient services not excluded under paragraph (g)(4) of this section, furnished on or after January 1, 2006, if the hospital—

(i) Is a sole community hospital under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.64(b) of this chapter or is treated as being located in a rural area under § 412.103 of this chapter.

(2) *Amount of adjustment*. The amount of the additional payment under paragraph (g)(1) of this section is determined by CMS and is based on the difference between costs incurred by hospitals that meet the criteria in paragraphs (g)(1)(i) and (g)(1)(ii) of this section and costs incurred by hospitals located in urban areas.

(3) *Budget neutrality*. CMS establishes the payment adjustment under paragraph (g)(2) of this section in a budget neutral manner, excluding services and groups specified in paragraph (g)(4) of this section.

(4) *Excluded services and groups*. Drugs and biologicals that are paid under a separate APC, devices of brachytheraphy consisting of a seed or seeds (including a radioactive source), and devices paid under § 419.66 are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section.

(5) *Copayment*. The payment adjustment in paragraph (g)(2) of this section is applied before calculating copayment amounts.

(6) *Outliers*. The payment adjustment in paragraph (g)(2) of this section is applied before calculating outlier payments.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000; 66 FR 55856, Nov. 2, 2001; 69 FR 832, Jan. 6, 2004; 70 FR 68727, Nov. 10, 2005; 70 FR 76178, Dec. 23, 2005]

§ 419.44 Payment reductions for surgical procedures.

(a) *Multiple surgical procedures*. When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Terminated procedures*. When a surgical procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts if the procedure is discontinued after the induction of anesthesia or after the procedure is started; or

(2) One-half of the full program and the beneficiary coinsurance amounts if the procedure is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced.

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule*. Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement*. CMS will consult with an expert outside advisory

panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 55856, Nov. 2, 2001]

Subpart G—Transitional Pass-through Payments

SOURCE: 66 FR 55856, Nov. 2, 2001, unless otherwise noted.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For the portion of CY 2002 affected by these rules, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

[66 FR 55856, 55865, Nov. 2, 2001; 67 FR 9568, Mar. 1, 2002]

EFFECTIVE DATE NOTE: At 66 FR 55865, Nov. 2, 2001, § 419.62 was amended by adding paragraph (d), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, the amendment was delayed indefinitely.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following

drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

[65 FR 18542, Apr. 7, 2000, as amended at 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004]

§ 419.66 Transitional pass-through payments: Medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA

in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002; 70 FR 68728, Nov. 10, 2005]

Subpart H—Transitional Corridors

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted. Redesignated at 66 FR 55856, Nov. 2, 2001.

§ 419.70 Transitional adjustments to limit decline in payments.

(a) *Before 2002*. Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002*. Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003*. Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals*. For covered hospital outpatient services furnished in a calendar year before January 1, 2006 for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Permanent treatment for cancer hospitals and children's hospitals*. In the case of a hospital described in § 412.23(d) or § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(3) *Temporary treatment for sole community hospitals located in rural areas*. For covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act.

(e) *Prospective payment system amount defined*. In this paragraph, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this paragraph or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule*. In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined*. For purposes of this paragraph, CMS shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services furnished during one of the following periods, including any payment for these services through cost-sharing described in paragraph (e) of this section:

(A) The cost reporting period ending in 1996; or

(B) If the provider does not have a cost reporting period ending in 1996, the first cost reporting period ending on or after January 1, 1997, and before January 1, 2001; and

(ii) The reasonable costs of these services for the same cost reporting period.

(g) *Interim payments*. CMS makes payments under this paragraph to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance*. No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality*. The additional payments made under this paragraph—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004]

PART 420—PROGRAM INTEGRITY: MEDICARE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W–2 employee.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

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

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992; 71 FR 20775, Apr. 21, 2006]

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest

owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. *Similar capacity* means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to CMS's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by CMS, the provider or part B supplier must furnish CMS with the identity of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* CMS may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, CMS considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. CMS also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* CMS promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to CMS, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

[57 FR 27306, June 18, 1992]

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to CMS before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to CMS at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.* (1) CMS does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) CMS terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

§ 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

Books, documents, and records means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

Common ownership means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

Contract for services means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is $10,000 or more within a 12-month period.

Control means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

Provider means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in § 413.17 of this chapter) of any of these providers.

Related to the subcontractor means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

Subcontractor means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is $10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability*. This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(l)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is $10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth $10,000 or more over a 12-month period.

(b) *Requirement*. Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(l)(I)(ii) of the

Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.

(6) HHS reserves the right to examine the originals of any requested contracts, books, documents, and records, if they exist.

(c) *Refusal by subcontractor to furnish access to records.* If CMS determines that the books, documents, and records are necessary for the reimbursement determination and the subcontractor refuses to make them available, HHS may initiate legal action against the subcontractor.

Subpart E—Rewards for Information Relating to Medicare Fraud and Abuse, and Establishment of a Program to Collect Suggestions for Improving Medicare Program Efficiency and to Reward Suggesters for Monetary Savings

SOURCE: 63 FR 31128, June 8, 1998, unless otherwise noted.

§ 420.400 Basis and scope.

This subpart implements sections 203(b) and (c) of Public Law 104–191, which require the establishment of programs to encourage individuals to report suspected cases of fraud and abuse and submit suggestions on methods to improve the efficiency of the Medicare program. Sections 203(b) and (c) of Public Law 104–191 also provide the authority for CMS to reward individuals for reporting fraud and abuse and for submitting suggestions that could improve the efficiency of the Medicare program. This subpart sets forth procedures for rewarding individuals.

[64 FR 66401, Nov. 26, 1999]

§ 420.405 Rewards for information relating to Medicare fraud and abuse.

(a) *General rule.* CMS pays a monetary reward for information that leads to the recovery of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, section 1128A, or section 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program. The determination of whether an individual meets the criteria for an award, and the amount of the award, is at the discretion of CMS. CMS pays rewards only if a reward is not otherwise provided for by law. When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the recipient as specified in paragraph (d) of this section.

(b) *Information eligible for reward.* (1) In order for an individual to be eligible to receive a reward, the information he or she supplied must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities.

(2) CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or its contractors, or the OIG, the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency.

(c) *Persons eligible to receive a reward*—(1) *General rule.* Any person (other than one excluded under paragraph (c)(2) of this section) is eligible to receive a reward under this section if the person submits the information in the manner set forth in paragraph (f) of this section.

(2) *Excluded individuals.* (i) An individual who was, or is an immediate family member of, an officer or employee of HHS or its contractors, the SSA, the OIG, a State Medicaid Agency, or the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency at the time he or she came into possession of, or divulged, information leading to a recovery of Medicare funds is not eligible to receive a reward under this section.

(ii) Any other Federal or State employee or contractor or an HHS grantee is not eligible for a reward under this section if the information submitted came to his or her knowledge in the course of his or her official duties.

(iii) An individual who illegally obtained the information he or she submitted is excluded from receiving a reward under this section.

(iv) An individual who participated in the sanctionable offense with respect to which payment would be made is excluded from receiving a reward under this section.

(d) *Notification of eligibility*—(1) *General rule.* After all Medicare funds have been recovered and CMS has determined a participant eligible to receive a reward under the provisions of this section, it notifies the informant of his or her eligibility, by mail, at the most recent address supplied by the individual. It is the individual's responsibility to ensure that the reward program has been notified of any change in his or her address or other relevant personal information (for example, change of name, phone number).

(2) *Special circumstances.* (i) If the individual has relocated to an unknown address, the individual or his or her legal representative may claim the reward by contacting CMS within 1 year from the date on which CMS first attempted to notify the individual about a reward. CMS does not consider the individual or his or her legal representative eligible for a reward more than 1 year after the date on which it first attempted to give notice. CMS does not pay interest on rewards that are not immediately claimed.

(ii) If the individual has become incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the individual or the individual's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to show his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first gave or attempted to give notice of the reward.

(e) *Amount and payment of reward.* (1) In determining whether it will pay a reward and, if so, the amount of the reward, CMS takes into account all relevant factors, including the significance of the information furnished in relation to the ultimate resolution of the case and the recovery of Medicare funds.

(2) The amount of a reward represents what CMS considers to be adequate compensation in the particular case, not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less.

(3) If more than one person is eligible to receive a reward in a particular case, CMS allocates the total reward amount (not to exceed 10 percent of the overpayments recovered in that case or $1,000, whichever is less) among the participants.

(4) CMS bases rewards only on recovered Medicare payments and not on amounts collected as penalties or fines.

(5) CMS makes payments as promptly as the circumstances of the case permit, but not until it has collected all Medicare overpayments, fines, and penalties.

(6) No person may make any offer or promise or otherwise bind CMS or HHS with respect to the payment of any reward under this section or the amount of the reward.

(f) *Submission of information.* (1) An individual may submit information on persons or entities engaging in, or that have engaged in, fraud and abuse against the Medicare program to the Office of the Inspector General, or to the Medicare intermediary or carrier that has jurisdiction over the suspected fraudulent provider or supplier.

(2) A participant interested in receiving a reward must provide his or her name, address, telephone number, and any other requested identifying information so that he or she may be contacted, if necessary, for additional information and, when applicable, for the payment of a reward upon resolution of the case.

(g) *Confidentiality.* CMS does not reveal a participant's identity to any person, except as required by law.

(h) *Finding of ineligibility after reward is accepted.* If, after a reward is accepted, CMS finds that the awardee was ineligible to receive the reward, the Government is not liable for the reward

and the awardee must refund all monies received.

§ 420.410 Establishment of a program to collect suggestions for improving Medicare program efficiency and to reward suggesters for monetary savings.

(a) *Definitions.* As used in this section, the following definitions apply:

Payment means a monetary award given to a suggester in recognition of, and as a reward for, a suggestion adopted by CMS that improves the efficiency of, and results in monetary savings to, the Medicare program.

Savings means the monetary value of the net benefits the Medicare program derives from implementing the suggestion.

Suggester means an individual, a group of individuals, or a legal entity such as a corporation, partnership, or professional association, not otherwise excluded under § 420.410(d), who submits a suggestion under this section.

Suggestion means an original idea submitted in writing.

Suggestion program means the specific procedures and requirements established by CMS for receiving suggestions from the suggester on methods to improve the efficiency of the Medicare program, evaluating the suggestions and, if appropriate, paying a reward to the suggester for adopted suggestions that result in improved efficiency and produce monetary savings to the Medicare program.

(b) *General rule.* CMS may make payment for adopted suggestions that increase the efficiency of the Medicare program and result in monetary savings. CMS only makes payment for suggestions in instances in which a reward is not otherwise provided by law. The determination to adopt a suggestion, to reward the suggester, and the method of calculating a reward are at the sole discretion of CMS.

(c) *Eligibility.* Except as specified in paragraph (d) of this section, any individual, group of individuals or legal entity, such as a corporation, partnership or professional association, is eligible to submit a suggestion and be considered for a reward under this suggestion program if the suggestion is submitted to CMS in the manner set forth in paragraph (e) of this section.

(d) *Exclusions.* Medicare contractors, their officers and employees, individuals who work for Federal agencies under a contract, employees of Federally-sponsored research and demonstration projects, Federal officers and employees, and immediate family members of these individuals, are excluded from receiving payment under the suggestion program. If, after the suggester receives a reward payment, CMS determines that the suggester was ineligible to receive the reward, CMS is not liable for the reward payment and the suggester must refund all monies received.

(e) *Requirements for submitting suggestions*—(1) To be considered, the suggestion must be in writing, mailed to CMS, and must include the following information:

(i) A description of an existing problem or need;

(ii) A suggested method for solving the problem or filling the need; and

(iii) If known, an estimate of the savings potential that could result from implementing the suggestion.

(2) Suggestions must be mailed to: Centers for Medicare & Medicaid Services Suggestion Program, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

(3) Any suggesters interested in receiving a reward must provide CMS with the following information: An individual suggester must provide his or her name, a group of suggesters must provide the names of all the group members, and a legal entity must provide its name and the name of its representative. All suggesters must provide an address, telephone number, and any other identifying information that CMS needs to contact the suggester for additional information and, where applicable, to mail the reward.

(f) *Evaluation process*—(1) *Relevant factors.* CMS evaluates all suggestions on the basis of the following factors:

(i) Originality of suggestion.

(ii) An estimate of potential monetary savings to the Medicare program.

(iii) The extent to which Medicare program efficiency would be improved if CMS adopts the suggestion.

(iv) Accuracy of the information reflected in the suggestion.

(v) Feasibility of implementation.

(vi) Nature and complexity of the suggestion.

(vii) Any other factors that appear to be relevant.

(2) *Evaluation time limit.* CMS concludes the evaluation process in a reasonable amount of time, not to exceed 2 years from the receipt date, taking into consideration the complexity of the suggestion, the number of possible implementation strategies, and CMS's current workload.

(g) *Basis for reward payment*—(1) *General rule.* If CMS determines that it is appropriate to make a reward payment for a suggestion adopted in whole or in part, that results in improved efficiency and monetary savings to the Medicare program, the payment is based on—

(i) The actual first-year net savings to the Medicare program, or

(ii) The average annual net savings to the Medicare program expected to be realized over a period of not more than 3 years if—

(A) An improvement is expected to yield monetary savings for more than 1 year and implementation involves substantial costs; or

(B) Monetary savings are negligible in the first year but are expected to substantially increase in subsequent years.

(2) *Reward payment amount.* CMS determines the amount of a reward payment using the following formula:

(i) Net savings from $1,000 to $10,000—10 percent of the savings, with a minimum award amount of $100;

(ii) Net savings of $10,001 to $100,000—$1,000 for the first $10,000 of savings, plus 3 percent of the net savings over $10,000;

(iii) Net savings of more than $100,000—$3,700 for the first $100,000 of savings, plus 0.5 percent of savings over $100,000, with a maximum award amount of $25,000.

(h) *Adoption of suggestion and issuance of reward payment*—(1) *Adoption.* Upon completing its evaluation, CMS decides whether to adopt a suggestion. If CMS receives the same or an overlapping suggestion from two or more unrelated parties, CMS will consider a reward only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment.* After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions.* When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(l) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

PART 421—INTERMEDIARIES AND CARRIERS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

Subpart A—Scope, Definitions, and General Provisions

§ 421.1 Basis and scope.

(a) This part is based on the indicated provisions of the following sections of the Act:

1124—Requirements for disclosure of certain information.

1816 and 1842—Use of organizations and agencies in making Medicare payments to providers and suppliers of services.

(b) Section 421.118 is also based on 42 U.S.C.1395b–1(a)(1)(F), which authorizes demonstration projects involving intermediary agreements and carrier contracts.

(c) The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries and contracts with Part B (Supplementary Medical Insurance) carriers. They also state that CMS may perform certain functions directly or by contract. They specify criteria and standards to be used in selecting intermediaries and evaluating their performance, in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions set forth the instances where there is the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. In some circumstances, the adversely affected intermediaries may request a judicial review of hearings decisions on—

(1) Assignment or reassignment of a provider or providers; or

(2) Designation of an intermediary or intermediaries to serve a class of providers.

[49 FR 3659, Jan. 30, 1984, as amended at 60 FR 50442, Sept. 29, 1995]

§ 421.3 Definitions.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the Prospective Payment System for hospitals) and to perform other related functions. For purposes of designating regional or alternative regional intermediaries for home health agencies and of designating intermediaries for hospices under § 421.117 as well as for applying the performance criteria in § 421.120 and the performance standards in § 421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[59 FR 681, Jan. 6, 1994]

§ 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

Subpart B—Intermediaries

§ 421.100 Intermediary functions.

An agreement between CMS and an intermediary specifies the functions to be performed by the intermediary, which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The intermediary ensures that it makes payments only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for which the QIO has assumed review responsibility under its contract with CMS.

(2) The intermediary takes appropriate action to reject or adjust the claim if—

(i) The intermediary or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting; or

(ii) The intermediary determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Fiscal management.* The intermediary must receive, disburse, and account for funds in making Medicare payments.

(c) *Provider audits.* The intermediary must audit the records of providers of services as necessary to assure proper payments.

(d) *Utilization patterns.* The intermediary must assist providers to—

(1) Develop procedures relating to utilization practices;

(2) Make studies of the effectiveness of those procedures and recommend methods to improve them;

(3) Evaluate the results of utilization review activity; and

(4) Assist in the application of safeguards against unnecessary utilization of services.

(e) *Resolution of cost report disputes.* The intermediary must establish and maintain procedures approved by CMS to consider and resolve any disputes that may result from provider dissatisfaction with an intermediary's determinations concerning provider cost reports.

(f) *Reconsideration of determinations.* The intermediary must establish and maintain procedures approved by CMS for the reconsideration of its determinations to deny payments to an individual or to the provider that furnished services to the individual. The QIO performs reconsideration of cases in which it made a determination subject to reconsideration.

(g) *Information and reports.* The intermediary must furnish to CMS any information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(h) *Other terms and conditions.* The intermediary must comply with all applicable laws and regulations and with any other terms and conditions included in its agreement.

(i) *Dual intermediary responsibilities.* With respect to the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or hospice and its parent provider will be served by different intermediaries under § 421.117 of this part, the designated regional intermediary will process bills, make coverage determinations and make payments to the HHAs and hospices. The intermediary serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

[45 FR 42179, June 23, 1980, as amended at 48 FR 7178, Feb. 18, 1983; 49 FR 3659, Jan. 30, 1984; 51 FR 43198, Dec. 1, 1986; 53 FR 17944, May 19, 1988; 54 FR 4026, Jan. 27, 1989]

§ 421.103 Options available to providers and CMS.

(a) Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries—

(1) Directly from CMS (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both CMS and the intermediary consent.

(b) Whenever CMS determines it appropriate, it may contract with any organization (including an intermediary with which CMS has previously entered into an agreement under § 421.105 and § 421.110 or designated as a regional or alternative regional intermediary under § 421.117) for the purposes of making payments to any provider that does not elect to receive payment from an intermediary.

[49 FR 3659, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984]

§ 421.104 Nominations for intermediary.

(a) *Nomination by groups or associations of providers.* (1) An association of providers, except for hospices, may nominate an organization or agency to serve as intermediary for its members.

(2) The nomination is not binding on any member of the association if it notifies CMS of its nonconcurrence with the nomination.

(3) The nomination must be made in writing, to CMS, and must—

(i) Identify the proposed intermediary by giving the complete name and address;

(ii) Include, or furnish as an attachment, the name, address, and bed capacity (or patient care capacity in the case of home health agencies) of each member of the association;

(iii) List the members that have concurred in the nomination of the proposed intermediary; and

(iv) Be signed by an authorized representative of the association.

(b) *Action by nonmembers or nonconcurring members.* Providers that nonconcur in their association's nomination, or are not members of an association, may—

(1) Form a group of 2 or more providers for the specific purpose of nominating an intermediary, in accordance with provisions of paragraph (a) of this section;

(2) Elect to receive payments from a fiscal intermediary with which CMS already has an agreement, if CMS and the intermediary agree to it (see §421.106); or

(3) Elect to receive payment from CMS as provided in §421.103.

(c) CMS is not required to enter into an agreement with a proposed intermediary solely because it has been nominated.

[45 FR 42179, June 23, 1980, as amended at 48 FR 56035, Dec. 16, 1983; 49 FR 3659, Jan. 30, 1984]

§421.105 Notification of action on nomination.

(a) CMS will send, to each member of a nominating association or group, written notice of a decision to enter into or not enter into an agreement with the nominated organization or agency.

(b) Any member of a group or association having more than one nominated intermediary approved by CMS to act on its behalf must withdraw its nomination from all but one or exercise the option provided in §421.103(a), subject to §421.103(b), to receive payment directly from CMS.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§421.106 Change to another intermediary or to direct payment.

(a) Any provider may request a change of intermediary, or except for a hospice, that it be paid directly by CMS, by—

(1) Giving CMS written notice of its desire at least 120 days before the end of its current fiscal year; and

(2) Concurrently giving written notice to its intermediary.

(b) If CMS finds the change is consistent with effective and efficient administration of the program and approves the request under paragraph (a) of this section, it will notify the provider, the outgoing intermediary, and the newly-elected intermediary (if any) that the change will be effective on the first day following the close of the fiscal year in which the request was filed.

[45 FR 42179, June 23, 1980, as amended at 49 FR 56036, Dec. 16, 1983; 49 FR 3660, Jan. 30, 1984]

§421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§421.120) and standards (§421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, determinations may be made by the Secretary with respect to the termination of an intermediary agreement, or by CMS with respect to the—

(1) Renewal of an intermediary agreement (§ 421.110);

(2) Assignment or reassignment of providers to an intermediary (§ 421.114); or

(3) Designation of a regional or national intermediary to serve a class of providers (§ 421.116).

(b) When taking the actions listed in paragraph (a), the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria (§ 421.120) and performance standards (§ 421.122).

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

§ 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will result in a more effective and efficient administration of the Medicare program. Before making this determination CMS will consider—

(a) The preferences of the provider;

(b) The availability of an intermediary as specified in § 421.5(e); and

(c) Intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.116 Designation of national or regional intermediaries.

(a) After considering intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122, CMS may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. CMS may make this designation if it determines that the designation will result in a greater degree of effectiveness and efficiency in the administration of the Medicare program than could be achieved by an assignment of providers to an intermediary preferred by the providers.

(b) No designation may be made until the affected providers and intermediaries are given an explanation and the intermediaries are advised of their right to a hearing and judicial review as specified in § 421.128. This provision does not apply to experimental contracts awarded under § 421.118.

(c) To designate an intermediary, CMS may establish classes of providers on the basis of—

(1) The type of provider, for example, hospital, skilled nursing facility, home health agency; or

(2) Common characteristics.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.117 Designation of regional and alternative designated regional intermediaries for home health agencies and hospices.

(a) This section is based on section 1816(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for home health agencies (HHAs) other than hospital-based HHAs but permits him or her to designate regional intermediaries for hospital-based HHAs only if the designation meets promulgated criteria concerning administrative efficiency and effectiveness; on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices; and on section 1874 of the Act, which permits CMS to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from CMS.

(b) CMS applies the following criteria to determine whether the assignment of hospital-based HHAs to designated regional intermediaries will result in the more effective and efficient administration of the Medicare program:

(1) Uniform interpretation of Medicare rules;

(2) Expertise in bill processing;

(3) Control of administrative costs;

(4) Ease of communication of program policy and issues to affected providers;

(5) Ease of data collection;

(6) Ease of CMS's monitoring of intermediary performance; and

(7) Other criteria as the Secretary believes to be pertinent.

(c) Except as provided in paragraphs (e), (f), and (g) of this section, an HHA must receive payment through a regional intermediary designated by CMS.

(d) Except as provided in paragraphs (f) through (h) of this section, a hospice must receive payment for covered services furnished to Medicare beneficiaries through an intermediary designated by CMS.

(e) An HHA chain not desiring to receive payment from designated regional intermediaries may request service by one lead intermediary with the assistance of a local designated regional intermediary. Alternatively, the chain may request to be serviced by a single intermediary. A lead, local, or a single intermediary must be an organization that is a designated regional intermediary. Any request made under this paragraph is evaluated by CMS in accordance with the criteria contained at § 421.106 of this subpart.

(f) An HHA or hospice not wishing to receive payment from a regional intermediary designated under paragraph (c) or (d) of this section may submit a request to the CMS Regional Office to receive payment through an alternative regional intermediary designated by CMS.

(g) Except as provided in paragraph (h) of this section, any request that an HHA or hospice may make to change from a designated regional intermediary to an alternative designated regional intermediary, in accordance with paragraph (f) of this section, is evaluated by CMS in accordance with the criteria set forth at § 421.106(b) of this subpart and must be filed within the timeframe established at § 421.106(a) of this subpart.

(h) *Exception:* An HHA or a hospice that, as of June 20, 1988 is receiving payment from a designated regional intermediary may, without regard to the limitations contained in § 421.106 of this subpart, continue to receive payment from that intermediary. It may do so even if that intermediary is not the designated regional intermediary or the alternative designated regional intermediary for the particular State in which the HHA or hospice is located.

[53 FR 17944, May 19, 1988]

§ 421.118 Awarding of experimental contracts.

Notwithstanding the provisions of §§ 421.103 and 421.104, CMS may award a fixed price or performance incentive contract under the experimental authority contained in 42 U.S.C. 1395b–1 for performance of any of the functions specified in § 421.100. Action taken by CMS under this paragraph is not subject to—

(a) The administrative and judicial review which would otherwise be available under § 421.128; or

(b) Performance criteria and performance standards review as provided for in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost incurred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost

which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) CMS has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between CMS and a carrier, other than a regional DMEPOS carrier, specifies the functions to be performed by the carrier which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The carrier ensures that payment is made only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for

which the QIO has assumed review responsibility under its contract with CMS.

(2) The carrier takes appropriate action to reject or adjust the claim if—

(i) The carrier or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting;

(ii) The carrier determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Payment on a cost basis.* If payment is on a cost basis, the carrier must assure that payments are based on reasonable costs, as determined under part 413 of this chapter.

(c) *Payment on a charge basis.* If payment is on a charge basis, under part 405, subpart E of this chapter, the carrier must ensure that—

(1) Charges are reasonable and not higher than the charge for a comparable service furnished under comparable circumstances to the carrier's policy holders and subscribers; and

(2) The payment is based on one of the following—

(i) An itemized bill.

(ii) An assignment under the terms of which the reasonable charge is the full charge for the service, as specified in § 424.55 of this chapter.

(iii) If the beneficiary has died, the procedures set forth in §§ 424.62 and 424.64 of this chapter.

(d) *Fiscal management.* The carrier must receive, disburse, and account for funds in making payments under Medicare.

(e) *Provider audits.* The carrier must audit the records of providers to whom it makes Medicare Part B payments to assure that payments are made properly.

(f) *Utilization patterns.* (1) The carrier must have methods and procedures for identifying utilization patterns that deviate from professionally established norms and bring the deviant patterns to the attention of appropriate professional groups.

(2) The carrier must assist providers and other persons who furnish Medicare Part B services to—

(i) Develop procedures relating to utilization practices;

(ii) Make studies of the effectiveness of those procedures and devise methods to improve them;

(iii) Apply safeguards against unnecessary utilization of services; and

(iv) Develop procedures for utilization review, and establish groups to perform such reviews of providers to whom it makes Medicare Part B payments.

(g) *Information and reports.* The carrier must furnish to CMS any information and reports that CMS requests in order to carry out CMS's responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

(h) *Maintenance and availability of records.* The carrier must maintain and make available to CMS the records necessary for verification of payments and for other related purposes.

(i) *Hearings to Part B beneficiaries.* (1) The carrier must provide an opportunity for a fair hearing if it denies the beneficiary's request for payment, does not act upon the request with reasonable promptness, or pays less than the amount claimed.

(2) The hearing procedures must be in accordance with part 405, subpart H, of this chapter (Review and Hearing Under the Supplementary Medical Insurance Program).

(j) *Other terms and conditions.* The carrier must comply with any other terms and conditions included in its contract.

[45 FR 42183, June 23, 1980; 45 FR 64913, Oct. 1, 1980, as amended at 49 FR 3660, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984; 51 FR 34833, Sept. 30, 1986; 51 FR 41350, Nov. 14, 1986; 51 FR 43198, Dec. 1, 1986; 52 FR 4499, Feb. 12, 1987; 53 FR 6648, Mar. 2, 1988; 54 FR 4027, Jan. 27, 1989; 57 FR 27307, June 18, 1992]

§ 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

§ 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a)(12) and 1834(h) of the Act, which authorize the Secretary to designate one carrier for one or more entire regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics, and other supplies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a

physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation*. (1) The boundaries of the initial four regions for processing claims described in paragraph (b) of this section contain the following States and territories:

(i) Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware.

(ii) Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota.

(iii) Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico, and the Virgin Islands.

(iv) Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa, and Missouri.

(2) CMS has the option to modify the number and boundaries of the regions established in paragraph (c)(1) of this section based on appropriate criteria and considerations, including the effect of the change on beneficiaries and DMEPOS suppliers. To announce changes, CMS publishes a notice in the FEDERAL REGISTER that delineates the regional boundary or boundaries changed, the States and territories affected, and supporting criteria or considerations.

(d) *Criteria for designating regional carriers*. CMS designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program. In making this designation, CMS will award regional carrier contracts in accordance with applicable law and will consider some or all of the following criteria—

(1) Timeliness of claim processing;

(2) Cost per claim;

(3) Claim processing quality;

(4) Experience in claim processing, and in establishing local medical review policy; and

(5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation*. (1) Each carrier designated a regional carrier must process claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within that carrier's region as designated under paragraph (c) of this section. When processing the claims, the carrier must use the payment rates applicable for the State of residence of the beneficiary, including a qualified Railroad Retirement beneficiary. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) CMS notifies affected Medicare beneficiaries and suppliers when it designates a regional carrier (in accordance with paragraph (d) of this section) to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated under paragraph (c) of this section).

(3) CMS may contract for the performance of National Supplier Clearinghouse functions through a contract amendment to one of the DME regional carrier contracts or through a contract

amendment to any Medicare carrier contract under §421.200.

(4) CMS periodically recompetes the contracts for the DME regional carriers. CMS also periodically recompetes the National Supplier Clearinghouse function.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993; 70 FR 9239, Feb. 25, 2005]

§421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in §421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

§421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the carrier in response to a claim that it is unable to process within established time limits.

(c) *When advance payments may be made.* An advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) A carrier must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid the supplier.

(ii) ''Historical data'' are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a ''payment'' under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS's discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier's reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier's right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier's reconciliation of amounts advanced and recouped is not an initial determination as defined at §405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

[61 FR 49275, Sept. 19, 1996]

PART 422—MEDICARE ADVANTAGE PROGRAM

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 18134, Apr. 14, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 422 appear at 70 FR 4741, Jan. 28, 2005.

Subpart A—General Provisions

SOURCE: 63 FR 35068, June 26, 1998, unless otherwise noted.

§ 422.1 Basis and scope.

(a) *Basis*. This part is based on the indicated provisions of the following sections of the Act:

1851—Eligibility, election, and enrollment.
1852—Benefits and beneficiary protections.
1853—Payments to Medicare Advantage (MA) organizations.
1854—Premiums.
1855—Organization, licensure, and solvency of MA organizations.
1856—Standards.
1857—Contract requirements.
1858—Special rules for MA Regional Plans.
1859—Definitions; enrollment restriction for certain MA plans.

(b) *Scope*. This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage organizations through Medicare Advantage plans.

[63 FR 35068, June 26, 1998, as amended at 70 FR 4714, Jan. 28, 2005]

§ 422.2 Definitions.

As used in this part—

Arrangement means a written agreement between an MA organization and a provider or provider network, under which—

(1) The provider or provider network agrees to furnish for a specific MA plan(s) specified services to the organization's MA enrollees;

(2) The organization retains responsibilities for the services; and

(3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an MA enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an MA plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR); or an inpatient psychiatric facility.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an MA contract.

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

MA eligible individual means an individual who meets the requirements of § 422.50.

MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

MA plan means health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan (or in individual segments of a service area, under § 422.304(b)(2)).

MA plan enrollee is an MA eligible individual who has elected an MA plan offered by an MA organization.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes an MA MSA. A trustee may be a bank, an insurance company, or any other entity that—

(1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and

(2) Meets the requirements of § 422.262(b).

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that CMS makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS ruling. (The term does not include coverage changes mandated by statute.)

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for service payment system.

Point of service (POS) is a benefit option that an MA coordinated care plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the MA plan allows members the option of receiving specified services outside of

the MA plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, where offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Prescription drug plan (PDP). PDP has the definition set forth in §423.4 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in §423.4 of this chapter.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an MA organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an MA coordinated care plan or network PFFS plan.

Religious Fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an MA plan that is offered by an RFB society.

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and availability standards set forth in §422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means a MA coordinated care plan that exclusively enrolls or enrolls a disproportionate percentage of special needs individuals as set forth in §422.4(a)(1)(iv) and that, beginning January 1, 2006, provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of a MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates

against sicker members of the target population.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005]

§ 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section, and other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS'SNP requirements and either—

(A) Exclusively enrolls special needs individuals as defined in § 422.2; or

(B) Enrolls a greater proportion of special needs individuals than occur nationally in the Medicare population as defined by CMS.

(v) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO.

(2) *A combination of an MA MSA plan and a contribution into the MA MSA established in accordance with § 422.262.* (i) *MA MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d); and

(B) Meets all other applicable requirements of this part.

(ii) *MA MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the MA program, or a trustee-to-trustee transfer or rollover from another MA MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *MA private fee-for-service plan.* An MA private fee-for-service plan is an MA plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Does not vary the rates for a provider based on the utilization of that provider's services; and

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(b) *Multiple plans.* Under its contract, an MA organization may offer multiple plans, regardless of type, provided that the MA organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a waiver of the State licensing requirement). If an MA organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing

requirement for any other type of MA plan.

(c) *Rule for MA Plans' Part D coverage.* (1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.6 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees*—(1) *Timing of collection.* CMS collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by CMS in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2006 and each succeeding year, the applicable portion (as defined in paragraph (e) of this section) of $200 million.''

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs: C divided by A times B where—A is the total estimated January payments to all PDP sponsors subject to the assessment; B is the 9-month (January through September) assessment period; and C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata

share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

(4) If assessments reach the amount authorized for the year before the end of September, CMS discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), CMS may adjust the assessment time period and the fee percentage amount.

[65 FR 40315, June 29, 2000. Redesignated and amended at 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined in § 422.2 unless specifically noted otherwise.

(a) An individual is eligible to elect an MA plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the MA organization as an MA plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that—

(i) An individual who develops end-stage renal disease while enrolled in an MA plan or in a health plan offered by the MA organization is eligible to elect an MA plan offered by that organization;

(ii) An individual with end-stage renal disease whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, because CMS or the MA organization terminated the MA organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another MA plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another MA plan; and

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the MA plan.

(ii) Resides outside of the service area of the MA plan and is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements of § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected MA plan, even if the individual lives outside of the MA plan service area, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements at § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form or completes another CMS-approved election method offered by the

MA organization and provides information required for enrollment; and

(6) Agrees to abide by the rules of the MA organization after they are disclosed to him or her in connection with the election process.

(b) An MA eligible individual may not be enrolled in more than one MA plan at any given time.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule*. In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements*. Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50*. CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility*. If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting Enrollment*. An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) *Exceptions*. (1) As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs individuals, as defined in § 422.2 as SNPs.

(2) Individuals already enrolled in an MA plan that CMS subsequently designates as an SNP may continue to be enrolled in the plan and may not be involuntarily disenrolled because they do not meet the definition of special needs individuals in § 422.2.

[70 FR 4716, Jan. 28, 2005]

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition*. *Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule*. An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) *General requirements*. (1) An MA organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain CMS's approval of the continuation area, the marketing materials that describe the option, and the MA organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) *Specific requirements*—

(1) *Continuation of enrollment benefits*. The MA organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

(2) *Reasonable access.* The MA organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet the requirement in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) Reasonable cost sharing. For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

(4) *Protection of enrollee rights.* An MA organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements remain with the organization that is receiving payment from CMS; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the marketing materials.

(e) *Capitation payments.* CMS's capitation payments to all MA organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005]

§ 422.56 Enrollment in an MA MSA plan.

(a) *General.* An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program.* Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an MA MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the MA MSA plan may not enroll in an MA MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice benefit, supplemental insurance policies not specifically permitted under § 422.104, and retirement health benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 70 FR 4716, Jan. 28, 2005]

§ 422.57 Limited enrollment under MA RFB plans.

An RFB society that offers an MA RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§ 422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraph (a)(2) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (b)(4).

(2) MA organizations must accept elections during the open enrollment periods specified in § 422.62(a)(3), (a)(4), and (a)(5) if their MA plans are open to new enrollees.

(b) *Capacity to accept new enrollees.* (1) MA organizations may submit information on enrollment capacity of plans.

(2) If CMS determines that an MA plan offered by an MA organization has a capacity limit, and the number of MA eligible individuals who elect to enroll in that plan exceeds the limit, the MA organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the CMS determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms.* (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.80. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(2) The MA organization must file and retain election forms for the period specified in CMS instructions.

(d) *When an election is considered to have been made.* An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections.* The MA organization must have an effective system for receiving, controlling, and processing elections. The system must meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

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

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

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (f)(1) of this section, the beneficiary must certify that, at the time of enrollment in the MA organization, he or she received the disclosure statement specified in § 422.111.

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 63 FR 54526, Oct. 9, 1998; 64 FR 7980, Feb. 17, 1999; 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods*—(1) *Initial coverage election period for*

MA. The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period*. (i) Beginning with 2002, the annual coordinated election period for the following calendar year is November 15th through December 31st, except for 2006.

(ii) For 2006, the annual coordinated election period

begins on November 15, 2005 and ends on May 15, 2006.

(iii) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan. If an individual changes his or her election to original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005*. Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006*. (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual*. An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2007*. (i) For 2007 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. An individual who is in original Medicare and has coverage under a PDP may elect a MA-PD plan. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. An individual who is in original Medicare and does not have coverage under a PDP may elect an MA plan that does not provide qualified prescription drug coverage. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2007 or later may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of the entitlement, or on December 31, whichever is earlier subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) The limitation to one election or change in paragraph (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections made or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

(1) CMS or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior.

(3) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(4) The individual meets such other exceptional conditions as CMS may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an MA eligible individual who elects an MA plan during the initial enrollment period, as defined under section 1837(d) of the Act, that surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the MA plan.

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an MA MSA plan only during—

(A) An annual election period; or

(B) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an MA MSA plan during an annual election period and has never before elected an MA MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the MA MSA plan a signed and dated request in the form and manner prescribed by CMS or by filing the appropriate disenrollment form through other mechanisms as determined by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4717, Jan. 28, 2005]

§ 422.64 Information about the MA program.

Each MA organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by CMS, the information necessary to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

[65 FR 40317, June 29, 2000]

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

(a) *Enrollment.* An individual who wishes to elect an MA plan offered by an MA organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an MA plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization.

(3) *Responsibilities of the MA organization.* The MA organization must—

(i) Submit a disenrollment notice to CMS within timeframes specified by CMS;

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the MA organization nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in CMS instructions.

(4) *Effect of failure to submit disenrollment notice to CMS promptly.* If the MA organization fails to submit the correct and complete notice required in paragraph (b)(3)(i) of this section, the MA organization must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(c) *Election by default: Initial coverage election period.* An individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which

he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

(2) *Reserved vacancies.* Subject to CMS's approval, an MA organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other MA eligible individuals.

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the MA organization as an MA enrollee, the individual's conversion to an MA enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

(4) *Prohibition against disenrollment.* The MA organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1) unless otherwise provided in a form and manner approved by CMS.

(6) *Submittal of information to CMS.* The MA organization must transmit the information necessary for CMS to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i) The individual changes the election under this section.

(ii) The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3) An individual enrolled in an MA plan that, as of

December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) *Exception for employer group health plans.* (1) In cases when an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4718, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B.

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the

first calendar month following the month in which the election is made.

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the effective date of coverage shall be determined by CMS, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

[63 FR 35071, June 26, 1998, as amended at 65 FR 40317, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4718, Jan. 28, 2005]

§ 422.74 Disenrollment by the MA organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an MA organization may not—

(1) Disenroll an individual from any MA plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional disenrollment.* An MA organization may disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An MA organization must disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) The individual no longer resides in the MA plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(3) *Plan termination or reduction of area where plan is available*—(i) *General rule.* An MA organization that has its contract for an MA plan terminated, that terminates an MA plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an MA organization discontinues offering an MA plan in a portion of its service area, the MA organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an MA plan offered by the organization, provided that there is no other MA plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to a hearing under the MA organization's grievance procedures.

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period will be, at minimum, one month and will begin on the first day of the month for which the premium is unpaid.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(2) *Disruptive behavior.* (i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (iii), and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

(v) *CMS review of the proposed disenrollment.* CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the

case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

(3) *Individual commits fraud or permits abuse of enrollment card.*—(i) *Basis for disenrollment.* An MA organization may disenroll the individual from an MA plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the MA plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the MA plan.

(ii) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The MA organization must report to CMS any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the MA plan's service area*—(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the MA plan's service area; or

(B) From the residence in which the individual resided at the time of enrollment in the MA plan to an area outside the MA plan's service area, for those individuals who enrolled in the MA plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule.* If the individual has not moved from the MA plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the MA organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(iii) *Exception.* If the MA plan covers services other than emergent, urgent, maintenance and poststabilization, and renal dialysis services (as described in § 422.100(b)(1)(iv) and § 422.113) when the individual is out of the service area for a period of consecutive days longer than 6 months but less than 12 months, but within the United States (as defined in § 400.200 of this chapter), the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period; and

(C) The MA organization makes this option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. However, MA organizations may limit this option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care.

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, CMS notifies the MA organization that the disenrollment is effective the first day of the calendar month following

the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) When an MA organization has its contract for an MA plan terminated, terminates an MA plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the MA organization must give each affected MA plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the MA program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

(e) *Consequences of disenrollment*—(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B.* An individual who is disenrolled under paragraph (b)(1)(i), (b)(1)(ii), (b)(1)(iii), or paragraph (b)(2)(ii) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4718, Jan. 28, 2005]

§ 422.80 Approval of marketing materials and election forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, an MA organization may not distribute any marketing materials (as defined in paragraph (b) of this section), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c); and

(ii) CMS does not disapprove the distribution of new material or form.

(2) The MA organization may distribute the marketing materials 5 days following their submission to CMS if—

(i) The MA organization is deemed by CMS to meet certain performance requirements established by CMS; or

(ii) The MA organization certifies that in the case of certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the MA organization, or any MA plan offered by the MA organization;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization;

(3) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage;

(5) Examples of marketing materials include, but are not limited to:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (*e.g.*, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities (*e.g.*, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

(c) *Guidelines for CMS review*. In reviewing marketing material or election forms under paragraph (a) of this section, CMS determines that the marketing materials:

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written description of any supplemental benefits and services.

(iii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iv) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its service and continuation area.

(3) Include in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(4) Are not materially inaccurate or misleading or otherwise make material misreprepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(d) *Deemed approval (one-stop shopping)*. If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

(e) *Standards for MA organization marketing*. (1) In conducting marketing activities, MA organizations may not:

(i) Provide for cash or other monetary rebates as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the MA plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services.

(ii) Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period (or 10 days as provided in paragraph (a)(1) of this section), the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all MA organizations involved and have received prior approval by CMS. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the MA organization must:

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(f) *Employer group retiree marketing.* MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, CMS will not review portions of these materials that relate to employer group benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005]

Subpart C—Benefits and Beneficiary Protections

SOURCE: 63 FR 35077, June 26, 1998, unless otherwise noted.

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of § 422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An MA organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the MA organization to provide services covered by the MA plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the MA organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the MA organization.

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An MA plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An MA organization offering an MA plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the MA plan;

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).

(e) *Multiple plans in one service area.* An MA organization may offer more than one MA plan in the same service area subject to the conditions and limitations set forth in this subpart for each MA plan.

(f) *CMS review and approval of MA benefits.* CMS reviews and approves MA benefits using written policy guidelines and requirements in this part and other CMS instructions to ensure that—

(1) Medicare-covered services meet CMS fee-for-service guidelines;

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services; and

(3) Benefit design meets other MA program requirements.

(g) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of MA organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) MA organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their MA plan enrollees.

(h) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in § 422.204(b)(3).

(i) *Provider networks.* The MA plans offered by an MA organization may share a provider network as long as each MA plan independently meets the access and availability standards described at § 422.112, as determined by CMS.

[65 FR 40319, June 29, 2000, as amended at 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.101 Requirements relating to basic benefits.

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering

such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

(i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in §422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.

(4) Instead of applying rules in paragraph (b)(3)(ii) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

(c) MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

(d) *Special cost-sharing rules for MA regional plans.* In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible.* MA regional plans, to the extent they apply a deductible, are permitted to have only a single deductible related to combined Medicare Part A and Part B services (to the extent they have a deductible). Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

(2) *Catastrophic limit.* MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare fee-for-service program (Part A and Part B benefits).

(3) *Total catastrophic limit.* MA regional plans are required to provide a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section.

(4) *Tracking of deductible and catastrophic limits and notification.* MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members

and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans.* (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

[65 FR 40319, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005]

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

(2) If the MA organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the MA plan.

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each MA organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the MA plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the MA plan.

(d) *Marketing of supplemental benefits.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

[65 FR 40320, June 29, 2000, as amended at 70 FR 4720, Jan. 28, 2005]

§ 422.103 Benefits under an MA MSA plan.

(a) *General rule.* An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

(b) *Countable expenses.* An MA organization offering an MA MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an MA organization offering an MA MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an MA MSA plan—

(1) For contract year 1999, may not exceed $6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under § 422.306(a)(2).

[63 FR 35077, June 26, 1998, as amended at 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.104 Special rules on supplemental benefits for MA MSA plans.

(a) An MA organization offering an MA MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in § 422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that CMS may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an MA coordinated care plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under a coordinated care plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan as an optional supplemental benefit as described in § 422.102(b).

(4) An MA regional plan or local MA PPO is permitted to offer a POS–LIKE benefit as described in paragraphs (b)(2) or (b)(3) of this section as a supplemental benefit. An MA regional plan or local MA PPO may offer a POS–LIKE option as a supplemental benefit where cost sharing for out-of-network services is reduced, in a limited manner, for services obtained from out-of-network providers. Offering a POS–LIKE supplemental benefit does not affect the MA regional plan's or local MA PPO's responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

(c) *Ensuring availability and continuity of care.* An MA network plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* MA organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The MA organization must provide to beneficiaries enrolling in a plan with a POS benefit an ''evidence of coverage'' document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS-related data.* An MA organization that offers a POS benefit through an MA plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an MA organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an MA plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an MA plan, the enrollees must be provided the same benefits as all other enrollees in the MA plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the MA plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the MA program apply to the MA plan coverage and benefits provided to enrollees eligible for benefits under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an MA plan, which are not part of the MA plan, are not subject to review or approval by CMS.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate CMS review under the Medicaid program. MA plan benefits provided to individuals entitled to Medicaid benefits provided by the MA organization under a contract with the State Medicaid agency are subject to MA rules and requirements.

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the MA basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the MA plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

(c) *Waiver or modification of contracts with MA organizations.* (1) MA organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, MA plans under contracts between MA organizations and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an MA plan (including an MA-PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this

part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4721, Jan. 28, 2005]

§ 422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* CMS does 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.

(b) *Responsibilities of the MA organization.* The MA organization must, for each MA plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Identify the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

(c) *Collecting from other entities.* The MA organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an MA organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the MA organization may bill, or authorize a provider to bill any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An MA organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) *Definitions.* The term *significant cost,* as it relates to a particular NCD or legislative change in benefits, means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is $100,000; and

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in § 422.308(a).

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

(b) *General rule.* If CMS determines and announces that an individual NCD or legislative change in benefits meets

the criteria for significant cost described in paragraph (a) of this section, a MA organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the ''significant cost'' threshold described in § 422.109(a), the MA organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective.* Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the MA organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the MA organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

(iii) Any service that is already a Medicare-covered service and included in the annual MA capitation rate or previously adjusted payments; and

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective.* For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the MA organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the MA organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. MA organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for MA plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

[68 FR 50856, Aug. 22, 2003, as amended at 70 FR 4721, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception*. An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

[63 FR 35077, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.111 Disclosure requirements.

(a) *Detailed description*. An MA organization must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee electing an MA plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description*. The description must include the following information:

(1) *Service area*. The MA plan's service area and any enrollment continuation area.

(2) *Benefits*. The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MA-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

(ii) For an MA MSA plan, the benefits under other types of MA plans; and

(iii) The availability of the Medicare hospice option and any approved hospices in the service area, including those the MA organization owns, controls, or has a financial interest in.

(3) *Access*. (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of § 422.112 and § 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) *Emergency coverage*. Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

(iii) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

(iv) The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the MA plan.

(6) *Supplemental benefits*. Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules*. Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The MA organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality improvement program.* A description of the quality improvement program required under § 422.152.

(10) *Disenrollment rights and responsibilities.*

(11) *Catastrophic caps and single deductible.* MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an MA plan, an MA organization must provide to the individual the following information:

(1) The information required in paragraph (f) of this section.

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as

(i) Grievances according to § 422.564; and

(ii) Appeals according to § 422.578 et. seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan.

(d) *Changes in rules.* If an MA organization intends to change its rules for an MA plan, it must:

(1) Submit the changes for CMS review under the procedures of § 422.80.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the MA program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Potential for contract termination.* The fact that an MA organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's MA plan.

(5) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

(v) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vi) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(vii) The coverage of emergency and urgently needed services.

(6) *Premiums.* (i) The MA monthly basic beneficiary premiums.

(ii) The MA monthly supplemental beneficiary premium.

(iii) The reduction in Part B premiums, if any.

(7) *The plan's service area.*

(8) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(9) *Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at §422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in §422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(12) To the extent an MA organization has a web site or provides MA plan information through the Internet, then it must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an Internet web site. Such posting does not relieve the MA organization of its responsibility under §422.111(a) to provide hard copies to enrollees.

[63 FR 35077, June 26, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40321, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4722, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§422.112 Access to services.

(a) *Rules for coordinated care plans.* An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network.* (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the MA organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in §422.2). The MA organization arranges for specialty

care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

(4) *Service area expansion.* If seeking a service area expansion for an MA plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(5) *Credentialed providers.* Demonstrate to CMS that its providers in an MA plan are credentialed through the process set forth at § 422.204(a).

(6) *Written standards.* Establish written standards for the following:

(i) Timeliness of access to care and member services that meet or exceed standards established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary.

(ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

(iii) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(7) *Hours of operation.* Ensure that—

(i) The hours of operation of its MA plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(8) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(9) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

(b) *Continuity of care.* MA organizations offering coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers that include—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services; and

(4) Procedures to ensure that the MA organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that—

(i) The MA organization makes a ''best-effort'' attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the MA organization, taking into account professional standards; and

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(6) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified

as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services.

(5) The hospital that is an essential hospital under this paragraph provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in §422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

[64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4722, Jan. 28, 2005; 70 FR 76197, Dec. 23, 2005]

§422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The MA organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services*—(1) *Definitions.* (i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the

services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

(2) *MA organization financial responsibility*. The MA organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the MA organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other MA organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency department services of $50 or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

(3) *Stabilized condition*. The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as ''post-stabilization care services'').

(1) *Definition*. *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *MA organization financial responsibility*. The MA organization—

(i) Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the MA organization that are pre-approved by a plan provider or other MA organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the MA organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The MA organization does not respond to a request for pre-approval within 1 hour;

(B) The MA organization cannot be contacted; or

(C) The MA organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the MA organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

(3) *End of MA organization's financial responsibility*. The MA organization's financial responsibility for post-stabilization care services it has not preapproved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An MA organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

[65 FR 40322, June 29, 2000, as amended at 70 FR 4723, Jan. 28, 2005]

§ 422.114 Access to services under an MA private fee-for-service plan.

(a) *Sufficient access*. (1) An MA organization that offers an MA private fee-for-service plan must demonstrate to CMS that it has sufficient number and range of providers willing to furnish services under the plan.

(2) CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(b) *Freedom of choice*. MA fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

(c) *Contracted network*. Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4723, Jan. 28, 2005]

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an MA organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The MA organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

[65 FR 40323, June 29, 2000]

§ 422.128 Information on advance directives.

(a) Each MA organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An MA organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the MA organization.

(1) An MA organization must provide written information to those individuals with respect to the following:

(i) 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 their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The 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.

(ii) The MA organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the MA organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

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

(D) Provide the information specified in paragraph (a)(1) 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 MA organization 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 MA organization 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.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

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

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

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) 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 MA organization. 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 MA organization must be able to document its community education efforts.

(2) The MA organization—

(i) Is not required to provide care that conflicts with an advance directive; and

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

(3) The MA organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of MA organizations are entitled to the protections specified in § 422.504(g).

[63 FR 35077, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005

§ 422.133 Return to home skilled nursing facility.

(a) *General rule*. MA plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the MA organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the MA organization.

(b) *Definitions*. In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the MA plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

(c) *Coverage no less favorable*. The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the MA plan.

(d) *Exceptions*. The requirement to allow an MA plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the MA plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

[68 FR 50857, Aug. 22, 2003, as amended at 70 FR 4723, Jan. 28, 2005]

Subpart D—Quality Improvement

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality improvement program.

(a) *General rule*. Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the

requirements of paragraph (d) of this section; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64.

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(c) *Chronic care improvement program requirements.* Develop criteria for a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects.* (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan.* For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection

and reporting instruments required by CMS.

(ii) Evaluate the continuity and coordination of care furnished to enrollees.

(iii) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information*. For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review*. For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action*. For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule*. An MA organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the MA organization's compliance with Medicare requirements.

(b) *Deemable requirements*. The requirements relating to the following areas are deemable:

(1) Quality improvement.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) Part D prescription drug benefit programs that are offered by MA programs.

(c) *Effective date of deemed status*. The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed MA organizations*. An MA organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status*. CMS removes part or all of an MA organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the MA organization.

(3) The MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority*. CMS retains the authority to initiate enforcement action against any MA organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the

Medicare requirements for which deemed status was granted.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000; 70 FR 4724, Jan. 28, 2005]

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting MA organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed MA organizations.

(iv) Information about any MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS—

(i) An acknowledgment of CMS's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the time-frames specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited MA organizations.

(6) Provide, on an annual basis, summary data specified by CMS that relate

to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming based on accreditation no longer guarantees that the MA organization meets the MA requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

(1) The types of MA plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to

verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until the reconsideration is administratively final.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40324, June 29, 2000]

Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An MA organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the MA organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The MA organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An MA organization that operates an MA plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An MA organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4724, Jan. 28, 2005]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An MA organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An MA organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality improvement programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and

that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005]

§ 422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available to MA plan enrollees, an MA organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an MA organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an MA organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the MA organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for MA private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection*. The general rule in paragraph (a) of this section does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction*. Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions*. An MA organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52026, Sept. 1, 2005]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions*. In this subpart, the following definitions apply:

Bonus means a payment made 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) paid to 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.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

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. This is set at 25 percent risk.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted 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.

(b) *Applicability*. The requirements in this section apply to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements*. Any physician incentive plan operated by an MA organization must meet the following requirements:

(1) The MA organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section.

(3) For all physician incentive plans, the MA organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis*. Substantial financial risk occurs when risk is based on the use or costs of referral services, and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold*. The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk*. The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) 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.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) 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%.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private MA fee-for-service plans*. An MA fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—(1) *Basic rule*. The MA organization must assure 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:

(2) *Specific requirements*. (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size

of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1–1,000	$6,000	$10,000	$3,000
1,001–5,000	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	(1)	(1)	(1)

1 None.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Sanctions.* An MA organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.210 Assurances to CMS.

(a) Assurances to CMS. Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

(b) Disclosure to Medicare Beneficiaries. Each MA organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the MA organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

[70 FR 52026, Sept. 1, 2005]

§ 422.212 Limitations on provider indemnification.

An MA organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that

does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an MA plan also apply to the payment described in paragraph (a)(1) of this section.

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under § 412.105(g) and § 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.76 concerns calculating payment for direct medical education costs.)

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 47490, Aug. 12, 2005]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The MA organization must establish uniform payment rates for items and services that apply to all contracting providers, regardless of whether the contract is signed or deemed under paragraph (f) of this section.

(ii) Contracting providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Payment to contract providers.* For each service, the MA organization pays a contract provider (including one deemed to have a contract) an amount that is equal to the payment rate under paragraph (a)(1) of this section minus any applicable cost-sharing.

(3) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment mounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees*—(1) *Contract providers* (i) Contract providers and ''deemed'' contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The MA organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(iv) The MA organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce

the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the MA private fee-for-service plan as specified in § 422.256(b)(3), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit*—(1) *Contract providers.* An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An MA organization that offers an MA private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability*—(1) *General information.* An MA organization that offers an MA fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The MA organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to § 489.24 of this chapter, to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an MA fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the MA organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual's enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in § 422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the MA organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The MA organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The MA organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in § 422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credential requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in §§ 422.204(b)(1)(i) and (b)(3).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52056, Sept. 1, 2005; 70 FR 47490, Aug. 12, 2005; 70 FR 76197, Dec. 23, 2005]

§ 422.220 Exclusion of services furnished under a private contract.

An MA organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval

SOURCE: 70 FR 4725, Jan. 28, 2005, unless otherwise noted.

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average

bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(1).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually, and for local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at §422.101(d).

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at §422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in §422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at §422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined §422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under §422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in §422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in §422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for the counties in a plan's service area, for the purposes of adjusting payment under §422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under §422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at §422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option;

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority*. Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference*. (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review*. Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing*. For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans:

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(c) *Negotiation process*. The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the outcome of CMS' regional benchmark calculations required under § 422.258(c) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans*. For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans*. CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005]

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) *For MA local plans with service areas entirely within a single MA local area*, 1/12th of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(2) *For MA local plans with service areas including more than one MA local*

area, an amount equal to the weighted average of annual capitation rates for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the county capitation rate by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

§ 422.262 Beneficiary premiums.

(a) Determination of MA monthly basic beneficiary premium. (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug

benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) Consolidated monthly premiums. Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks.* (1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258),

adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount by a regional MA plan (defined at § 422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

§ 422.266 Beneficiary rebates.

(a) *General rule.* An MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in § 422.102, which may

include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under

subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

Subpart G—Payments to Medicare Advantage Organizations

SOURCE: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help

pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees.* In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology.* ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section.

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the greater of—

(1) 102 percent of the annual capitation rate for the preceding year; or

(2) The annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs.* The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education; and

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage.* The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(b) *Adjustment for over or under projection of national per capita growth percentages.* CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule.* CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation.* CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(d) *Adjustment for intra-area variations.* CMS makes the following adjustments to payments.

(1) *Intra-regional variations.* For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment.* CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory

non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments.* For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the application of a risk adjustment payment model.

(b) *Data collection: Basic rule.* Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data.* (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Services covered under the original Medicare program.

(ii) Medicare covered services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements.* (1) MA organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician,

or other practitioner that furnished the services.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factor used to adjust payments, as required under § 422.304(a)(1), (a)(2), and (a)(3). CMS may also use the data for other purposes except for medical records data.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the March deadline until December 31 of the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual December 31 late data submission deadline will not be accepted for the purposes of reconciliation.

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 45 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization (which includes the cost sharing amount the FQHC may charge an enrollee, as established in the contract between the FQHC and the MA organization); and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 76198, Dec. 23, 2005]

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability.* This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay.* If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay.* If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment*. (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug payment described in § 423.315 (if any). 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 election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug payment described in § 423.315 (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments*. (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(b) *Payments to the MA organization*. Subject to § 412.105(g) and § 413.86(d) of this chapter and § 422.109, § 422.316, and § 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment*. Subject to § 422.314, § 422.316, § 422.318, § 422.320, and § 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H appear at 63 FR 35098, 35099, June 26, 1998.

§ 422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, (PSOs), to contract as a MA plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to the type, cost, or frequency of services furnished.

Cash equivalent means those assets excluding accounts receivable that can be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for

the purpose of furnishing health care services directly or through its provider members or entities.

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by CMS as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with CMS as an MA organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

Insolvency means a condition in which the liabilities of the debtor exceed the fair valuation of its assets.

Net worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a provider or group of affiliated providers;

(2) Provides a substantial proportion (as defined in § 422.352) of the health care services under the MA contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under § 422.356, for the provision of services that are the obligation of the PSO under the MA contract; and

(ii) Have at least a majority financial interest in the PSO.

Qualified actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made that are acceptable to CMS. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 25376, May 7, 1998; 63 FR 35098, June 26, 1998]

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a MA contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to CMS's satisfaction that it is capable of delivering to Medicare

enrollees the range of services required under a contract with CMS. Each PSO must deliver a substantial proportion of those services directly through the provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare services covered under the contract.

(2) For a rural PSO, not less than 60% of Medicare services covered under the contract.

(c) *Rural PSO*. To qualify as a rural PSO, a PSO must—

(1) Demonstrate to CMS that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more providers must demonstrate to CMS'S satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls, is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk*. The PSO must demonstrate to CMS's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the MA contract to each affiliated provider. The PSO must demonstrate that the financial arrangements among its affiliated providers constitute ''substantial'' risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Affiliated providers agree to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest*. Majority financial interest means maintaining effective control of the PSO.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an MA plan under this subpart, CMS may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(a) The organization requests a waiver no later than November 1, 2002; and

(b) CMS determines there is a basis for a waiver under § 422.372.

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.372 Basis for waiver of State licensure.

(a) *General rule*. Subject to this section and to paragraphs (a) and (e) of § 422.374, CMS may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an MA plan.

(b) *Basis for waiver of State licensure*. Any of the following may constitute a basis for CMS's waiver of State licensure.

(1) *Failure to act timely on application*. The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment*. The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an MA plan.

(3) *Denial of application based on different solvency requirements*. (i) The State has denied the application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) CMS determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by CMS to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application*. The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request*. The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) CMS gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(c) *Subsequent waiver requests*. An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date*. A waiver granted under § 422.370 will be effective on the effective date of the organization's MA contract.

(e) *Consistency in application*. CMS reserves the right to revoke waiver eligibility if it subsequently determines

that the organization's MA application is significantly different from the application submitted by the organization to the State licensing authority.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the MA contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

[63 FR 25377, May 7, 1998]

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other MA organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, CMS incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* CMS may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

[63 FR 25377, May 7, 1998]

§ 422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under § 422.370 must have a fiscally sound operation that meets the requirements of §§ 422.382 through 422.390.

[63 FR 25377, May 7, 1998]

§ 422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with CMS as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under § 422.384) demonstrating to CMS's satisfaction that the organization has available to it an administrative infrastructure that CMS considers appropriate to reduce, control or eliminate start-up administrative costs.

(b) After the effective date of a PSO's MA contract, a PSO must maintain a minimum net worth amount equal to the greater of—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with CMS for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with CMS; or

(4) Using the most recent financial statement filed with CMS, an amount equal to the sum of—

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application, the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's MA contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if CMS has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health care delivery assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

[63 FR 25377, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

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

(3) Cash-flow statements;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's MA contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in § 422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets CMS's requirements for guarantors and guarantee documents as specified in § 422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's MA contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's MA contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's MA contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter, may notify CMS of its intent to reduce the period of advance funding of projected losses. CMS will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, CMS may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. CMS retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to CMS. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to CMS, and for periods beginning one year after the effective date of a PSO's MA contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use guarantees, letters of credit and, beginning one year after the effective date of a PSO's MA contract, other means of funding projected losses, but only in a combination or sequence that CMS considers appropriate.

[63 FR 25378, May 7, 1998, as amended at 63 FR 35098, June 26, 1998; 64 FR 71678, Dec. 22, 1999]

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, CMS will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If CMS determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, CMS will require the PSO to initiate corrective action and pay all overdue obligations.

(d) If CMS determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, CMS may require the PSO to initiate corrective action to—

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If CMS determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, CMS requires the PSO to obtain funding from alternative financial resources.

[63 FR 25378, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to CMS.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an MA contract and, thereafter, upon CMS's request, a PSO must provide CMS with proof of the insolvency deposit, such proof to be in a form that CMS considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to CMS.

(2) The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for CMS's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon CMS's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from CMS, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

[63 FR 25379, May 7, 1998]

§ 422.390 Guarantees.

(a) *General policy.* A PSO, or the legal entity of which the PSO is a component, may apply to CMS to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. CMS has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor.* To apply to use the financial resources of a guarantor, a PSO must submit to CMS—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor.* To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document.* If the guarantee request is approved, a PSO must submit to CMS a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as CMS may establish from time to time.

(e) *Reporting requirement.* A PSO must submit to CMS the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that CMS requests.

(f) *Modification, substitution, and termination of a guarantee.* A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification.* If at any time the guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each MA organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and

(c) Demonstrate to CMS that—

(1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

[70 FR 4733, Jan. 28, 2005]

§ 422.404 State premium taxes prohibited.

(a) *Basic rule*. No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

(b) *Construction*. Nothing in this section shall be construed to exempt any MA organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

[63 FR 35099, June 26, 1998, as amended at 70 FR 4733, Jan. 28, 2005]

Subpart J—Special Rules for MA Regional Plans

SOURCE: 70 FR 4733, Jan. 28, 2005, unless otherwise noted.

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region*. The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region*. The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment*. By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas*. CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions*. CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions*. There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans*. The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis*. Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan*. An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology*. For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the

original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the

total of the monthly payments made to the organization offering the plan for the year under §422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under §422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to §422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in §422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment.* The MA Regional Plan Stabilization Fund (referred to in this paragraph (f) as the ''Fund'') is available beginning in 2007 for two purposes:

(i) *Plan entry.* To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention.* To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings.* Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, ''payments From Trust Funds,'' on a monthly basis.

(3) *Funding limitation*—(i) *General rule.* The total amount expended from the Fund as a result of the application of

this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation.* CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments or computing lower payment amounts, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule.* Funding is available under this paragraph for a year in the following situations:

(A) *National plan.* For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *MA Regional Plans.* Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on MA regional plan funding in case of national plan.* There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus payment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment.* The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule.* The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding.* Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region.* Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year.* If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application.* Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule.* Funding is available under this

paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase.* The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of-

(*1*) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i)of the Act, ''the risk-adjusted benchmark amount'' for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(*2*) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4)of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements.* The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit.* CMS has received notice (as specified by CMS), before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region.* CMS determines that if the plans referred to in paragraph (f)(5)(iii)(A) of this section are not offered in the year, fewer than two MA organizations will be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average.* For the previous year, CMS determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application.* Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2–consecutive-year limitation.* In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

Subpart K—Contracts With Medicare Advantage Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions.* For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

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

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

(ii) Health services furnished to the MA organization's enrollees by hospitals and other providers, and by MA organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.310(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an MA organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an MA organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the MA organization by common ownership or control and—

(1) Performs some of the MA organization'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 MA organization at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of ''business transaction'' that, during any fiscal year of the MA organization, have a total value that exceeds $25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.501 Application requirements.

(a) *Scope*. This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health

care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(d) *Resubmittal of application.* An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *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 exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits, public hearings, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets the applicable requirements of § 422.501.

(b) *Use of information from a prior contracting period.* If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny.* (i)If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(d) *Oversight of continuing compliance.* (1) CMS oversees an MA organization's continued compliance with the requirements for an MA organization.

(2) If an MA organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

[70 FR 4736, Jan. 28, 2005]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an MA organization.* Any entity seeking to contract as an MA organization must:

(1) Complete an application as described in § 422.501.

(2) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an MA plan as defined in § 422.2.

(3) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the MA organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the MA organization to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the MA organization, 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 MA organization.

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

(vi) A compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for internal monitoring and auditing.

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's MA contract.

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(H) For MA-PDs, A comprehensive fraud and abuse plan to detect and prevent fraud, waste, and abuse as specified at § 423.504(b)(4)(vi)(H) of this chapter.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority*. Under the authority of section 1857(c)(5) of the Act, CMS may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the bid) of at least one-third of the MA organizations offering MA plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the MA contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the MA organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts*. The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005, and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005]

§ 422.504 Contract provisions.

The contract between the MA organization and CMS must contain the following provisions:

(a) *Agreement to comply with regulations and instructions*. The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An MA organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The MA organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in § 422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under § 422.101 and, to the extent applicable, supplemental benefits under § 422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification

requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.310 for submitting data to CMS;

(9) That it will be paid under the contract in accordance with the payment rules in subpart G of this part;

(10) To develop its annual bid, and submit all required information on premiums, benefits, and cost-sharing by not later than the first Monday in June, as provided in subpart F of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of MA plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) An MA organization's compliance with paragraphs (a)(1) through (a)(13) and (c) of this section is material to performance of the contract.

(b) *Communication with CMS.* The MA organization must have the capacity to communicate with CMS electronically.

(c) *Prompt payment.* The MA organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by CMS, as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The MA organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid) of MA organizations.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the MA organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid proposal.

(v) Establish component rates of the bid for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the MA organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the MA organization; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the MA organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The MA organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(f) *Disclosure of information*. The MA organization agrees to submit—

(1) To CMS, certified financial information that must include the following:

(i) Such information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

(2) To CMS, all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under §422.64 and, upon

an enrollee's, request the financial disclosure information required under § 422.516.

(g) *Beneficiary financial protections.* The MA organization agrees to comply with the following requirements:

(1) Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's beneficiary enrollees.

(2) The MA organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the MA organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) *MA organization relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the MA organization may have with related entities, contractors, or subcontractors, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to the MA contract; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between MA organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the MA organization.

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the requirements set forth at paragraph (i)(4)of this section.

(iii) A provision requiring that any services or other activity performed by

a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Written arrangements must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA organization; or

(B) The credentialing process will be reviewed and approved by the MA organization and the MA organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions.

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's written arrangements with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The MA organization agrees to include in the contract such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the data it submits under § 422.310 are accurate, complete, and truthful.

(3) If such data are generated by a related entity, contractor, or subcontractor of an MA organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who

reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.254.

[63 FR 35099, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.505 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the MA organization and CMS and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if—

(1) CMS informs the MA organization that it authorizes a renewal; and

(2) The MA organization has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 and amended at 70 FR 4737, Jan. 28, 2005]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an MA organization.* (1) An MA organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an MA organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the MA organization's service area.

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if—

(i) The MA organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(2)(ii) and (a)(2)(iii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an MA organization does not renew a contract under this paragraph (a), CMS will not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) The MA organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in § 422.152(d).

(ii) For any of the reasons listed in § 422.510(a), which would also permit CMS to terminate the contract.

(iii) The MA organization has committed any of the acts in § 422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(2) *Notice.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the MA organization by May 1 of the contract year.

(ii) If CMS decides not to authorize a renewal of the contract, to the MA organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS decides not to authorize a renewal of the contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(3) *Notice of appeal rights.* CMS gives the MA organization written notice of its right to appeal the decision not to renew in accordance with § 422.644.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002; 70 FR 4737, Jan. 28, 2005]

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the MA organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the MA organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new MA contract, the MA organization is not required to provide the notice specified in paragraph (a)(1) of this section.

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons:

(1) The MA organization has failed substantially to carry out the terms of its contract with CMS.

(2) The MA organization is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part.

(3) CMS determines that the MA organization no longer meets the requirements of this part for being a contracting organization.

(4) There is credible evidence that the MA organization committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

(5) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.

(6) The MA organization substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(7) The MA organization fails to provide CMS with valid data as required under § 422.310.

(8) The MA organization fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(9) The MA organization substantially fails to comply with the prompt payment requirements in § 422.520.

(10) The MA organization substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(11) The MA organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(12) The MA organization substantially fails to comply with the marketing requirements in § 422.80.

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the MA organization in writing 90 days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations prescribed in § 422.510(a)(5), CMS notifies the MA organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

(ii) CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(c) *Corrective action plan*—(1) *General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, CMS provides the MA organization with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under § 422.510(a)(5), the MA organization will not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the MA organization informing it of its termination appeal rights in accordance with subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 52027, Sept. 1, 2005]

§ 422.512 Termination of contract by the MA organization.

(a) *Cause for termination.* The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice.* The MA organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options, original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the MA organization's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002]

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule*. Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an MA organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver*. (1) For a contract applicant or MA organization that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract or during the first 3 years of the contract, CMS may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or MA organization must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or MA organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or MA organization has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(iii) The contract applicant or MA organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(2) If an MA organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an MA contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an MA organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an MA organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.516 Reporting requirements.

(a) *Required information*. Each MA organization 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 MA organization has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization 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 § 422.500) between the MA organization 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 MA organization 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 MA organization go to a party in interest.

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

(c) *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 MA organization and each of the parties in interest.

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

(3) The 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 MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

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

(2) The MA organization 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.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information.* Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

§ 422.520 Prompt payment by MA organization.

(a) *Contract between CMS and the MA organization.* (1) The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the ''clean claims'' within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b)(1) *Contracts between MA organizations and providers and suppliers.* Contracts or other written agreements between MA organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

(c) *Failure to comply.* If CMS determines, after giving notice and opportunity for hearing, that an MA organization has failed to make payments in accordance with paragraph (a) of this section, CMS may provide—

(1) For direct payment of the sums owed to providers, or MA private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an MA organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the MA RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

[70 FR 4738, Jan. 28, 2005]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership*—(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the MA organization's corporation into another corporation or the consolidation of the MA organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the MA organization's corporation, with the MA organization surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An MA organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The MA organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the MA organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the MA organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(e) *Effect of change of ownership with novation agreement.* If the MA organization submits a novation agreement that meets the requirements of § 422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The MA organization notifies CMS at least 60 days before the date of the proposed change of ownership. The MA organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The MA organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an MA organization under subpart K of this part.

(b) *Provisions of a novation agreement*—(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to

CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

§ 422.553 Effect of leasing of an MA organization's facilities.

(a) *General effect of leasing*. If an MA organization leases all or part of its facilities to another entity, the other entity does not acquire MA organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities*. (1) If an MA organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an MA organization, it must apply for and enter into a contract in accordance with subpart K of this part.

(c) *Effect of partial lease of facilities*. If the MA organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the MA organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis*. (1) Section 1852(f) of the Act provides that an MA organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an MA organization must meet concerning organization determinations and appeals.

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

(b) *Scope*. This subpart sets forth—

(1) Requirements for MA organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of MA enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an MA enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

(c) *Relation to ERISA requirements*. Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.561 Definitions.

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

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the MA organization, and if necessary, an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review.

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 68 FR 16667, Apr. 4, 2003; 70 FR 4738, Jan. 28, 2005]

§ 422.562 General provisions.

(a) *Responsibilities of the MA organization.* (1) An MA organization, with respect to each MA plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations;

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An MA organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the MA organization; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the MA organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the MA organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

(v) The right to request MAC review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the MA organization; and

(ii) The QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply*. Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4738, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.564 Grievance procedures.

(a) *General rule*. Each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers.

(b) *Distinguished from appeals*. Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in § 422.566(b). Upon receiving a complaint, an MA organization must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process*. Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the MA organization. For quality of care issues, an enrollee may file a grievance with the MA organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance*. (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification*. (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances*. An MA organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an MA organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an MA organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

(g) *Recordkeeping*. The MA organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the MA

organization notified the enrollee of the disposition.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

(4) Discontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her authorized representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) An enrollee (including his or her authorized representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 70 FR 4739, Jan. 28, 2005]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

(b) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the

''prompt payment'' provisions set forth in § 422.520.

(c) *Written notice for MA organization denials.* If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

(d) *Written notice for MA Organization denials.* If an enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item or service, in whole or in part, the MA organization must give the enrollee a written notice.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the MA organization) may request that an MA organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the determination, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The MA organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the MA organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the MA organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements of this section.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee with timely notice

of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the MA organization) determined to have an appealable interest in the proceeding.

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the MA organization or CMS obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for reconsideration within 60 calendar days from the date of the notice of the organization determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If a party shows good cause, the MA organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the MA organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4739, Jan. 28, 2005]

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the MA organization) may request that an MA organization

expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The MA organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the MA organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the MA organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.586 Opportunity to submit evidence.

The MA organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the MA organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue

the determination (and effectuate it in accordance with §422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with §422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration*—(1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, an MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail

written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the MA organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the MA organization's reconsideration, with the addition of the MA organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ

hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the MA organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

[65 FR 40331, June 29, 2000]

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter.

(c) If the basis for the appeal is the MA organization's refusal to provide services, CMS uses the projected value of those services to compute the amount remaining in controversy.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the MA organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal. The regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate.

[70 FR 4740, Jan. 28, 2005]

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The Board denied the party's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, a

party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4740, Jan. 28, 2005]

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the MA organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization*—(1) *Requests for service*. If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment*. If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service*. If, on reconsideration of a request for service, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment*. If, on reconsideration of a request for payment, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*.—(1) *General rule*. If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision or that it has appealed the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council*. If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its

appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization.* If on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council.* If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it authorizes or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[65 FR 40331, June 29, 2000, as amended at 68 FR 50859, Aug. 22, 2003]

§ 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care.

(a) *Enrollee's entitlement.* (1) Where an MA organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), the MA organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when—

(i) The beneficiary disagrees with the discharge decision; or

(ii) The MA organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

(2) An enrollee is entitled to coverage until at least noon of the day after such notice is provided. If QIO review is requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before discharging an individual or changing the level of care in an inpatient hospital setting, the MA organization must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee.* When applicable, the written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed or covered;

(2) The effective date and time of the enrollee's liability for continued inpatient care;

(3) The enrollee's appeal rights;

(4) If applicable, the new lower level of care being covered in the hospital setting; and

(5) Any additional information specified by CMS.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4740, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.620 was revised. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an MA organization or hospital that inpatient care is no longer necessary must request immediate QIO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate QIO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate QIO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate QIO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the QIO that has an agreement with the hospital under parts 476 and 478 of this chapter.

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the MA organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the QIO must notify the MA organization that the enrollee has filed a request for immediate review.

(3) The MA organization must supply any information that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the MA organization, the hospital must submit medical records and other pertinent information to the QIO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The QIO must solicit the views of the enrollee who requested the immediate QIO review.

(6) The QIO must make a determination and notify the enrollee, the hospital, and the MA organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the MA organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the QIO notifies the enrollee of its review determination. If coverage of the hospital admission was never approved by the MA organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the noncoverage determination made by the MA organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient

hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the QIO notifies the enrollee of its review determination.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability*. (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined*. For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the MA organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination*. Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the MA organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice*. The provider must notify the enrollee of the MA organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice*. The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other MA appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid*. Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice*. An MA organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.624 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an MA organization's termination decision.* An enrollee of an MA organization has a right to a fast-track appeal of an MA organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) When an enrollee fails to make a timely request to an IRE, he or she may request an expedited reconsideration by the MA organization as described in § 422.584.

(3) If, after delivery of the termination notice, an enrollee chooses to leave a provider or discontinue receipt of covered services on or before the proposed termination date, the enrollee may not later assert fast-track IRE appeal rights under this section relative to the services or expect the services to resume, even if the enrollee requests an appeal before the discontinuation date in the termination notice.

(b) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the MA organization's decision. If the IRE's decision is delayed because the MA organization did not timely supply necessary information or records, the MA organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the MA organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an MA organization's decision to terminate services to an IRE, the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the MA organization must supply any and all information that an IRE requires to sustain the MA organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The MA organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the MA organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the MA organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the MA organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the MA organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the MA organization, and the provider of services, by close of business of the day

after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an MA organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the MA organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the MA organization.* (1) When an IRE notifies an MA organization that an enrollee has requested a fast-track appeal, the MA organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the MA organization, including records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the MA organization that an appeal has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An MA organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(5) If an IRE reverses an MA organization's termination decision, the MA organization must provide the enrollee with a new notice consistent with § 422.624(b).

(f) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an MA organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may to appeal the IRE's reconsidered determination to an ALJ, the MAC, or a federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on

appeal. If the IRE's decision is reversed on appeal, the MA organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the MA organization or provider.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.626 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(c) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the MA organization written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The MA organization's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 422.510(a)(5), CMS immediately notifies the MA organization of its decision to terminate the organization's MA contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by May 1 of the current contract year.

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with §§ 422.648 through 422.658;

(b) A timely request for a hearing is filed under § 422.662; or

(c) The reconsideration decision is revised as a result of a reopening under § 422.696.

§ 422.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 422.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the MA organization files a written request in accordance with § 422.650.

(c) Notice of any redetermination favorable to the MA organization applicant, including those resulting from a hearing or Administrator review conducted under this subpart, must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4741, Jan. 28, 2005]

§ 422.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or MA organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The MA organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the

notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000]

§ 422.652 Opportunity to submit evidence.

CMS provides the MA organization or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an MA organization could choose to request a hearing as described at § 422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

[65 FR 40332, June 29, 2000]

§ 422.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the MA organization subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 422.656 Notice of reconsidered determination.

(a) CMS gives the MA organization or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the contract applicant's qualifications to enter into, or the MA organization's qualifications to remain under, a contract with CMS under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the MA organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.658 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 422.662 or it is revised in accordance with § 422.696.

§ 422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) An MA organization whose contract with CMS has been terminated or has not been renewed as a result of a contract determination as provided in § 422.641.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with an MA organization until a hearing decision is

reached and affirmed by the Administrator following review under § 422.692 in instances where an MA organization requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract will be consistent with the purpose of this part; and

(2) For such period as CMS and the MA organization agree.

(c) Exception: A contract terminated in accordance with § 422.510(a)(5) will be immediately terminated and will not be postponed if a hearing is requested.

§ 422.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit

evidence that would be inadmissible under rules applicable to court procedures.

§ 422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 422.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 422.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator*. An MA organization that has received a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 422.690(b).

(b) *Review by the Administrator*. The Administrator shall review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization, whether the termination decision should be upheld, reversed, or modified.

(c) *Decision by the Administrator*. The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination*. CMS may reopen and revise an initial or reconsidered determination upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator*. A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within

one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 422.698 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662.

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the MA organization for Medicare beneficiaries who enroll.

(4) Require the MA organization to suspend all marketing activities to Medicare beneficiaries for the MA plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), we may impose one, or more, of the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to an MA enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to an MA enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on MA enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and subpart F of this part.

(3) Expels or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of § 422.206, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with § 422.216, which requires the organization to enforce the limit on balance billing under a private fee-for service plan.

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination under § 422.510(a), CMS may impose the intermediate sanctions in § 422.750(a)(2) and (a)(4).

[63 FR 35115, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 69 FR 78338, Dec. 30, 2004; 70 FR 4741, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.756 Procedures for imposing sanctions.

(a) *Notice of Sanction and opportunity to respond*—(1) *Notice of sanction.* Before imposing the intermediate sanctions

specified in paragraph (c) of this section CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 422.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the MA organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the MA organization's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section the MA organization submits a timely response to CMS's notice of sanction, CMS conducts an informal reconsideration that:

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the MA organization a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that an MA organization has acted or failed to act as specified in § 422.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the MA organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned MA plan during the sanction period;

(2) In the case of a violation under § 422.752(a), suspend payments to the MA organization for Medicare beneficiaries enrolled in the sanctioned MA plan during the sanction period; and

(3) Require the MA organization to suspend all marketing activities for the sanctioned MA plan to Medicare enrollees.

(d) Effective date and duration of sanctions—(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the MA organization timely seeks reconsideration under paragraph (b) of this section, on the date specified in the notice of CMS's reconsidered determination.

(2) *Exception.* If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the MA organization that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3), or terminate the contract in accordance with § 422.510.

(f) *Civil money penalties.* (1) If CMS determines that an MA organization has committed an act or failed to comply with a requirement described in § 422.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the MA organization in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 422.752(b) other than a determination based upon a violation under § 422.510(a)(4), CMS may impose civil

money penalties on the MA organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003; 70 FR 4741, Jan. 28, 2005]

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 422.510(a), as described in § 422.752(b) excepting those determinations under § 422.510(a)(4), CMS may impose civil money penalties in addition to, or in place of, the sanctions that CMS may impose under § 422.756(c) in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Medicare Advantage enrollees—up to $25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the Medicare Advantage organization receives CMS' notice of the determination—up to $10,000.

(c) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100, 000, whichever is greater.

[69 FR 78338, Dec. 30, 2004, as amended at 70 FR 4741, Jan. 28, 2005]

§ 422.760 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

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AUTHORITY: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

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1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

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1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope*. This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286

for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or

PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

§ 423.34 Enrollment of full-benefit dual eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans full-benefit dual eligible individuals who fail to enroll in a Part D plan.

(b) *Definition of full-benefit dual eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is:

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. ; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a).

(c) *Enrolling a full-benefit duel eligible individual.* Notwithstanding § 423.32(e), during the annual coordinated election period, CMS may enroll a full-benefit dual eligible individual in another PDP if CMS determines that the further enrollment is warranted.

(d) *Automatic enrollment rules*—(1) *General rule.* CMS must automatically enroll full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount (as defined in § 423.780(b)). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals must be enrolled in such PDPs on a random basis.

(2) Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit. Full-benefit dual eligible individuals enrolled in an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be automatically enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a full-benefit dual eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual eligible individuals as of December 31, 2005;

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006; and

(3) For individuals who are eligible for Part D under § 423.30(a)(1) and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective as soon as practicable after being identified as a newly full-benefit dual eligible individual, in a process to be determined by CMS.

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment*. CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule*. The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005*. An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006*. An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months*. (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period*—(1) *For 2006*. This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years*. For coverage beginning 2007 or any subsequent year, the annual coordinated election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods*. A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.40 Effective dates.

(a) *Initial enrollment period*. (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods*—(1) *General rule*. Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006*. Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods*. For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.44 Involuntary disenrollment by the PDP.

(a) *General rule*. Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional involuntary disenrollment*. A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment*. A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment*—(1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) Reenrollment in the PDP. If an individual is

disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive behavior.* (i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligiblity.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies,

disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any

creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(c) *Examples of marketing materials.* Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(6) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval.* If CMS has not disapproved the distribution of a marketing materials or form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified-

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either

standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Contracted pharmacy network means pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600, § 423.610, § 423,620, and § 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. In the case of pharmacies owned and operated by a Part D plan itself, notwithstanding number (3) of this definition, dispensing fees are understood to be the equivalent of all reasonable costs discussed in the previous sentence, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy; and

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Incurred costs means costs incurred by a Part D enrollee for covered Part D drugs—

(1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health

plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.454); or

(iii) Under § 423.782.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that-

(1) Are available to beneficiaries at the point of sale at network pharmacies;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company,

trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General*. Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plans*. A PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits*. The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage*. Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible*. An annual deductible equal to—

(i) *For 2006*. $250; or

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit*—(i) *25 Percent coinsurance*. Coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments*. A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraph (d)(2)(i)(B) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit*. The initial coverage limit is equal to—

(i) *For 2006*. $2,250.

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold*. Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs.

(5) *Protection against high out-of-pocket expenditures*. (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments*. (1) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance*. Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold*. For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006*. $3,600.

(B) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in

paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in §422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.* (i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under §417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under §417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under §417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under §417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*—(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in §423.4; or

(iii) A qualified retiree prescription drug plan (as defined in §423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in §423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

§423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans.* The service area for a prescription drug plan other than a fallback prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*—(1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at §422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for

States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access*—(1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area(as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed

at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an adequate benefit. A Part D plan's formulary must-

(i) Except as provided in paragraph (b)(2)(ii) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included

in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(3) *Transition Process.* A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes* (i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information-

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)((i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs.* (1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician's office access. A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including-

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments,

deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered

Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage*. Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, and appeals procedures*. All grievance, reconsideration, exceptions, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance policies and procedures*. A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities*.

(10) Potential for contract termination. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information*. Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information*. General coverage information, including—

(i) *Enrollment procedures*. Information and instructions on how to exercise election options under this part;

(ii) *Rights*. A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits*. (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information*. Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part, including for covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy;

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section by providing such information to Part D plans for inclusion in the written explanations of benefits required under § 423.128(e); and

(2) Under other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the

privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Consumer satisfaction surveys of Part D plans.

(c) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

(d) Quality improvement organization (QIO) activities.

(e) Compliance deemed on the basis of accreditation.

(f) Accreditation organizations.

(g) Procedures for the approval of accreditation

organizations as a basis for deeming compliance.

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that—

(1) Includes incentives to reduce costs when medically appropriate;

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a

sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP)*—(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media has the same meaning given this term in 45 CFR 160.103.

E-prescribing means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

(b) [Reserved]

(c) *Requirement*. Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans*. An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.160 Standards for electronic prescribing.

(a) *General rules*. (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3) *Exemptions*. (i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(ii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(iii) Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(4) In accordance with section 1860D–4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits,

and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(b) *Standards.* (1) *Prescription.* The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, or Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(i) Get message transaction.

(ii) Status response transaction.

(iii) Error response transaction.

(iv) New prescription transaction.

(v) Prescription change request transaction.

(vi) Prescription change response transaction.

(vii) Refill prescription request transaction.

(viii) Refill prescription response transaction.

(ix) Verification transaction.

(x) Password change transaction.

(xi) Cancel prescription request transaction.

(xii) Cancel prescription response transaction.

(2) *Eligibility.* (i) The Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1, for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill); the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, and the National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record. You may inspect copies of these materials at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For information on the availability of this material at CMS, call 410–786–0273. For information on the availability of this

material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. You may obtain a copy of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004 or the Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and fax (480) 767–1042 or *http://www.ncpdp.org*. You may obtain a copy of the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, 004010X092A1, October 2002, from the Washington Publishing Company,301 West North Bend Way, Suite 107, P.O. Box 15388, North Bend, WA 98045; Telephone (425) 831–4999; and fax (425) 831–3233 or *http://www.wpc-edi.com/*. You may obtain a copy of the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or *http://www.ncpdp.org*.

Authority: Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e))

[70 FR 67593, Nov. 7, 2005, as amended at 71 FR 36023, June 23, 2006]

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the FEDERAL REGISTER indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E [Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding*. An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*. Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid*. Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs*. The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs*. The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation*. The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids*. The bid and supplemental information submission must include the following information:

(1) *Coverage*. A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components*. The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area*. A description of the service area of the plan.

(4) *Level of risk assumed*. For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score*. An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees

for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited

risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007*. In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance*. The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans*. The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule*. Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty*. CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty*—(1) *Collection through withholding*. In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan*. In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans*. This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other

price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs means those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal-

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income

cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans*—(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 423.329 Determination of payments.

(a) *Subsidy payments*—(1) *Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment*—(1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the

organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount*—(1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount*—(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk*—(1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments*—(1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor*—(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this

section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor*—(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year,

the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations*—(1) *Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration*—(1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the adverse determination.

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

Subpart H [Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—-

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process

in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a fully completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for nonlicensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited*—(1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D

plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction*. Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C*. Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver*. CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver*. Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers*. Organizations offering or

seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver*—(1) *General rule*. CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *Use of waiver*. Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(d) *Other waivers*. CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver*. Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers*. Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1934 of the Act, with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule*. A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(b) *Medicare as primary payer*. The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees*. CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such

procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs*—(1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage*—(1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health centers.* Rural health centers as defined under section 1861(aa)(2) of the Act.

(viii) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly

from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

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

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

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor'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 Part D plan sponsor at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the requirements described in this part.

(c) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(d) *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 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an entity's application on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the application meets the applicable requirements specified in § 423.504 and § 423.505.

(b) *Use of information from a prior contracting period.* If a Part D plan sponsor fails to comply with the terms of a previous year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor and/or has not provided enough information to evaluate the application, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant 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 CMS identified.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N.

(d) *Oversight of continuing compliance.* (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

(2) If a Part D plan sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this Part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, 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 Part D plan sponsor.

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

(vi) A compliance plan that consists of the following—

(A)Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B)The designation of a compliance officer and compliance committee accountable to senior management.

(C)Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(D)Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

(E)Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for effective internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(H) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction*. For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority*. CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(c) *Communication with CMS.* The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the Part D plan sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical record s, patient care documentation, and other records of the Part D plan sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3)To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor 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 Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs

furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The Part D plan sponsor agrees to comply with—

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with related entities, contractors, or subcontractors, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D plan sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the Part D plan sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between Part D plan sponsors and pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment*—(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with § 423.507 of this subpart, an entity is determined qualified to renew its contract annually only if—

(1) CMS informs the Part D plan sponsor that it is qualified to renew its contract; and

(2) The Part D plan sponsor has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans , and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision of whether a Part D plan sponsor is qualified to renew its contract as follows:

(i) To the Part D plan sponsor by May 1 of the current contract year.

(ii) If CMS decides that a Part D plan sponsor is not qualified to renew its contract, to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS determines that the Part D plan sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) The notice provisions in paragraphs (b)(2)(ii) and (iii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the Part D sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the Part D sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in paragraph (a)(4) or paragraph (a)(5) of this section, CMS notifies the Part D plan sponsor in writing that its contract is terminated

effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan*—(1) *General rule*. Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception*. If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights*. If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with §423.642.

§423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination*. The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination*. The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination*. The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability*. CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization*. CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *Timely transfer of data and files*. If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§423.512 Minimum enrollment requirements.

(a) *Basic rule*. Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver*. CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information*. Each Part D plan sponsor 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, statistics indicating 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) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions*. Each Part D plan sponsor 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 § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication 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.

(2) A combined financial statement for the Part D plan sponsor 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 Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements*. (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

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

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA)*. (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor 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.

(e) *Loan information*. Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information*. Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership*. The following constitute a change of ownership:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer*. Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation*. The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception*. Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement*. (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined*. A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement*. Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement*. If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement*. CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification*. The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement*. The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed

copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination*. When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement*. A valid novation agreement requires the following:

(1) *Assumption of contract obligations*. The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement*. The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance*. The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access*. The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing*. If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities*. (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities*. If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

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

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means the charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor*. A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees*. In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630.

(c) *When other regulations apply*. Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements*. Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

§ 423.564 Grievance procedures.

(a) *General rule*. Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals*. Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process*. Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance*. (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification*. (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the

Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

(b) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

(c) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

Use approved notice language in a readable and understandable form;

State the specific reasons for the denial;

Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process; and

Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (a) or (b) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor, or if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees or prescribing physicians.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72 hour timeframe established in § 423.568(a) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's supporting statement.

(2) Give the enrollee and prescribing physician prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) Content of the notice of expedited determination.

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the

preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life

or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to

the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination*—(1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2) or (b)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. The IRE may solicit the views of the prescribing physician orally or in writing. A written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed

the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy*—(1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

The appeals have previously been reconsidered by an IRE;

The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will

be set in accordance with § 405.1020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable.

§ 423.630 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) How to request judicial review. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor*—(1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*—(1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is

reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor*. If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*. If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

(c) Any favorable redetermination, including those resulting from a hearing or Administrator review, must be made by July 15 for the contract in question to be effective on January of the following year.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may

be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) Exception: A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by the Administrator*. A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator*. The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator*. The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination*. CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by

the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator*. A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices*. (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions*. For the violations listed below, we may impose one, or more, of the sanctions specified in § 423.750(a)(2), (a)(3) or (a)(4) on any Part D sponsor that has a contract in effect. The Part D sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 *et seq*. of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing*. If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.750(a)(2) and (a)(4).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond*—(1) *Notice of sanction*. Before imposing the intermediate sanctions specified in paragraph (c) of this section, CMS—

(i) Sends a written notice to the Part D sponsor stating the nature and basis of the proposed sanction; and

(ii)Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D sponsor 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the Part D sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the Part D sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the Part D sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the Part D sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions*—(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the Part D sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the Part D sponsor in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), CMS may impose civil money penalties on the Part D sponsor in the amounts specified in § 423.758 in

addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.509(a), as described in § 423.752(b), excepting those determinations under § 423.509(a)(4), CMS may impose civil money penalties, in addition to, or in place of, the sanctions that CMS may impose under § 423.756(c), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D plan enrollees—up to $25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000 per week.

(c) If CMS makes a determination that a Part D sponsor has terminated its contract with CMS other than in a manner described in § 423.510 and that the sponsor has therefore failed to substantially carry of the terms of the contract, $250 per Medicare enrollee from the terminated Part D plan or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3)An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2)Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Recipient of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full subsidy eligible under this paragraph (c) of this section that he or she does not need to apply for the subsidies available under this subpart, and is deemed eligible for a full subsidy for a period up to one year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount

allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility*—(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) Multiple applications. If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.* (1) The premium subsidy amount is equal to an amount which is the lesser of:

(i) Under the Part D plan selected by the beneficiary, the monthly beneficiary premium for a Part D plan other than a MA-PD plan that is basic prescription drug coverage, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan other than a MA-PD plan that is enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium as defined under section 1854(b)(2)(B) of the Act, or

(ii) The greater of the low-income benchmark premium amount for a PDP region as determined under paragraph (b)(2) of this section or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in

this paragraph (b)(2)(ii) of this section , with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans)in a PDP region in the reference month.

(ii) Premium amounts: The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C)The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual eligible individuals who are institutionalized have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals*. Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed $2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy*. CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization*. The Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy*. The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part

D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area*—(1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids*—(1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids*—(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the

manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to

operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs, in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs that are actually paid (net any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf).

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs means*, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§. § 1003(b), for governmental plans or church plans).

Part D drug is defined in § 423.100 of this part.

Part D eligible individual is defined in § 423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884 of this

chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in § 411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General*. Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information*. The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*—(1) *Submitting an application*. The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information*. In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses

and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions*. To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iii) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor*. An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing*. (i) *General rule*. An application for a given plan year must be submitted by no later than 90 days prior to the beginning of the plan year, unless a request for an extension has been filed and approved under procedures established by CMS.

(ii) *Transition rule*. For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates*. The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match*. Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information of the individuals submitted as qualifying covered retirees with the Medicare Beneficiary Database (MBD) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation-general*. The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription drug coverage (as defined at §423.100). The attestation must meet all of the following standards.

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for the plan year in question.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant

uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3)The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) Methodology. (i) *Basis of the attestation*. The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage*. (A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D*. (A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(1) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(2) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year. The attestation, however, must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year otherwise, such valuation is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D for the upcoming calendar year.

(D) Example. If a sponsor's retiree prescription drug plan operates under a

plan year that ends March 30, the attestation for the year April 1, 2007–March 30, 2008 is based on the coverage limit, cost-sharing and out-of-pocket threshold that apply to defined standard prescription drug coverage under Part D in 2007 provided the attestation is submitted within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options for which the sponsor provided assurances under paragraph (d)(1)(i) of this section.

(6) Timing. (i) *Annual submission*. The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) *Submission following material change*. The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's plan that impacts the actuarial value of the coverage.

(e) *Disclosure of creditable prescription drug coverage status*. The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit*. The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment*. (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision*. For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit*. The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually

under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data.* (i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan

year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans.* (i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section , may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR § 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

§ 423.890 Appeals.

(a) *Informal written reconsideration*—(1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy*. An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request*. A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request*. The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration*. In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration*. CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration*. A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing*. A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request*. A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request*. The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures*. (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer*. The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision*. The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator*. (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision

and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening*—(1) *Ability to reopen*. CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening*. (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening*. The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause*. For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership*. Any of the following constitutes a change of ownership:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale*. Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation*. The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception*. Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement*. A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements*. The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act

(medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule*. The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS*. The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan*. States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process*—(1) *Assistance with application*. No later

than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application*. The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States*. (i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information*. States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906 General payment provisions.

(a) *Regular Federal matching*. Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer*. Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs*. States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules*. (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements*. Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be

provided.

(2) The low-income population (income less than 150

percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the

amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts*. The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment*—(1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D.	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	$500,000,000	CMS–64
(iv)	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans.	$1,600	(1) × [1 − (4)]
(vi)	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003.	$1,500	To be Determined
(vii)	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans.	90,000	CY MSIS data
(viii)	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans.	10,000	CY MSIS data
(ix)	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion).	0.4000	FEDERAL REGISTER
(xi)	Applicable growth factor (cumulative increase from 2003 through 2006).	50.0%	NHE projections
(xii)	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii)	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv)	Phased-down State contribution for the month	$8,586,000	1 / 12 × (9) × (10) × [1 + (11)] × (12) × (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting*. Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting*. Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match*. CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor*. CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures*. CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 53 FR 6634, Mar. 2, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.
1815—Payment to providers for Part A services.
1820—Conditions for designating certain hospitals as critical assess hospitals.
1833(e)—Requirement to furnish information to determine payment.
1835—Procedures for payment to providers for Part B services.
1842(b)(3)(B)(ii)—Assignment of Part B Medicare claims.
1842(b)(6)—Payment to entities other than the supplier.
1848—Payment for physician services.
1870(e) and (f)—Settlement of claims after death of the beneficiary.

(2) Section 424.444(c) is also based on section 216(j) of the Act.

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) *Other applicable rules.* Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 481 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 60 FR 38271, July 26, 1995; 60 FR 50442, Sept. 29, 1995; 62 FR 46035, Aug. 29, 1997; 71 FR 20775, Apr. 21, 2006]

EFFECTIVE DATE NOTE: At 71 FR 48409, Aug. 18, 2006, § 424.1 was amended by adding in two statutory sections, effective October 2, 2006. For the convenience of the user, the added text appears as follows:

§ 424.1 Basis and scope.

* * * * *

1834(a)—Payment for durable medical equipment.
1834(j)—Requirements for suppliers of medical equipment and supplies.

* * * * *

§ 424.3 Definitions.

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

HCPCS means Healthcare Common Procedure Coding System.

ICD–9–CM means International Classification of Diseases, Ninth Revision, Clinical Modification.

Nonparticipating hospital means a hospital that does not have in effect a provider agreement to participate in Medicare.

Participating hospital means a hospital that has in effect a provider agreement to participate in Medicare.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) *Types of services.* The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) *Sources of services.* The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) *Recipient of services.* Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) *Certification of need for services.* When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

(5) *Claim for payment.* The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with subpart C of this part.

(6) *Sufficient information.* The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 60 FR 38271, July 26, 1995]

§ 424.7 General limitations.

(a) *Utilization review finding on medical necessity.* When a QIO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) *Hospitals subject to PPS.* Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) *Hospitals not subject to PPS and SNFs*—(i) *Basic rule.* Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) *Exception.* Payment may be made for 1 or 2 additional days if the QIO or UR committee approves them as necessary for planning for post-discharge care.

(b) *Failure to make timely utilization review.* Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after CMS has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a QIO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Certification and Plan of Treatment Requirements

§ 424.10 Purpose and scope.

(a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

Section 1814(a)(2) of the Act also permits nurse practitioners or clinical nurse specialists to certify and recertify the need for post-hospital extended care services.

(b) *Scope.* This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

[60 FR 38271, July 26, 1995]

§ 424.11 General procedures.

(a) *Responsibility of the provider.* The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

(d) *Timeliness.* (1) The succeeding sections of this subpart also specify the time frames for certifications and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations, or vary the time frame (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reason for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(e) *Limitation on authorization to sign statements.* A certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in § 424.13(c).

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

(4) A nurse practitioner or clinical nurse specialist, as defined in paragraph (e)(5) or (e)(6) of this section, in the circumstances specified in § 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by CMS that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by CMS that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a

certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

[53 FR 6634, Mar. 2, 1988, as amended at 56 FR 8845, Mar. 1, 1991; 60 FR 38272, July 26, 1995]

§ 424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.

(a) *Content of certification and recertification*. Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) *Certification of need for hospitalization when a SNF bed is not available*. (1) A physician may certify or recertify need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(c) *Signatures*—(1) *Basic rule*. Except as specified in paragraph (c)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) *Exception*. If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(d) *Timing of certifications and recertifications: Cases not subject to the prospective payment system* (PPS). (1) For cases that are not subject to PPS, certification is required no later than as of the 12th day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories.

(2) The first recertification is required no later than as of the 18th day of hospitalization.

(3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Timing of certification and recertification: Cases subject to PPS*. For cases subject to PPS, certification is required as follows:

(1) For day-outlier cases, certification is required no later than one day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with § 412.80(a)(1)(i) of this chapter, or no later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost-outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(f) *Recertification requirement fulfilled by utilization review*. (1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent physician recertifications required for cases not

subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the physician recertification would have been required. The next physician recertification would need to be made no later than the 30th day following such review; if review by the UR committee took the place of this physician recertification, the review could be performed as late as the seventh day following the 30th day.

(g) *Description of procedures.* The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all cases not subject to PPS and of PPS day outlier cases.

§ 424.14 Requirements for inpatient services of inpatient psychiatric facilities.

(a) *Content of certification and recertification: General considerations.* The content requirements differ from those for other hospitals because the care furnished in psychiatric hospitals is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient care in a psychiatric hospital only if a physician certifies and recertifies the need for services consistent with the content of paragraphs (b) or (c) of this section, as appropriate.

(b) *Content of certification.* Inpatient psychiatric services were required—

(1) For treatment that could reasonably be expected to improve the patient's condition; or

(2) For diagnostic study.

(c) *Content of recertification.* (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required—

(i) For treatment that could reasonably be expected to improve the patient's condition; or

(ii) For diagnostic study; and

(2) The hospital records show that the services furnished were—

(i) Intensive treatment services;

(ii) Admission and related services necessary for diagnostic study; or

(iii) Equivalent services.

(3) The patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel.

(d) *Timing of certification and recertification.* (1) Certification is required at the time of admission or as soon thereafter as is reasonable and practicable.

(2) The first recertification is required as of the 12th day of hospitalization. Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Other requirements.* Psychiatric hospitals must also meet the requirements set forth in § 424.13 (b), (c), (f), and (g).

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 27087, May 9, 2006; 71 FR 37504, June 30, 2006]

§ 424.15 Requirements for inpatient CAH services.

(a) *Content of certification.* Medicare Part A pays for inpatient CAH services only if a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH.

(b) *Timing of certification.* Certification is required no later than 1 day before the date on which the claim for payment for the inpatient CAH services is submitted.

[58 FR 30671, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995; 62 FR 46035, 46037, Aug. 29, 1997]

§ 424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

(a) *Basic rule.* If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for

the time limits specified in § 424.13(e) for certification and recertification.

(b) *Example. (Hospital that is not a psychiatric hospital and is not subject to PPS).* For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by an SNF, or a hospital or CAH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) *Content of certification*—(1) *General requirements.* Posthospital SNF care is or was required because—

(i) The individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in an SNF or a swing-bed hospital on an inpatient basis, and the SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter; or

(ii) The individual has been correctly assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30 of this chapter.

(2) *Special requirement for certifications performed prior to July 1, 2002: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swing-bed patient to a SNF within 5 days of the availability date.* Transfer of the extended care patient to the SNF is not medically appropriate.

(b) *Timing of certification*—(1) *General rule.* The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) *Special rules for certain swing-bed hospitals.* For swing-bed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in § 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

(c) *Content of recertifications.* (1) The reasons for the continued need for posthopsital SNF care:

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) *Timing of recertifications.* (1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) *Signature.* Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A nurse practitioner or clinical nurse specialist, neither of whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section—

(i) *Collaboration* means a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. The services are delivered within the scope of the nurse's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the nurse and the physician or other mechanisms defined by Federal regulations and the law of

the State in which the services are performed.

(ii) A *direct employment relationship* with the facility is one in which the nurse practitioner or clinical nurse specialist meets the common law definition of the facility's ''employee,'' as specified in § 404.1005, § 404.1007, and § 404.1009 of title 20 of the regulations. When a nurse practitioner or clinical nurse specialist meets this definition with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an *indirect employment relationship* with the nurse practitioner or clinical nurse specialist. An indirect employment relationship does not exist if the agreement between the entity and the facility involves only the performance of delegated physician tasks under § 483.40(e) of this chapter.

(f) *Recertification requirement fulfilled by utilization review.* A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) *Description of procedures.* The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization review is used as an alternative to the second and subsequent recertifications.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 37275, Sept. 7, 1989; 58 FR 30671, May 26, 1993; 60 FR 38272, July 26, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39600, July 31, 2001; 70 FR 45055, Aug. 4, 2005]

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1]

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of treatment is established or as soon thereafter as possible and must be signed by the physician who establishes the plan.

(b) *Recertification*—(1) *Timing and signature of recertification.* Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical or speech therapy.

(c) [Reserved]

[1] As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.354 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991, as amended at 65 FR 41211, July 3, 2000; 66 FR 962, Jan. 4, 2001; 70 FR 70334, Nov. 21, 2005]

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following: (1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1), (c)(4) or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech-language pathology services*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

(2) *Timing.* The certification statement must be obtained at the time the plan of treatment is established, or as soon thereafter as possible.

(3) *Signature.* (i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(4) *Recertification*—(i) *Timing.* Recertification statements are required at least every 30 days and must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(ii) *Content.* The recertification statement must indicate the continuing need for physical therapy or speech-language pathology services and an estimate of how much longer the services will be needed.

(iii) *Signature.* Recertifications must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(d) [Reserved]

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—(1) *Content of certification.* (i) The individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation

with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) *Signature*. The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing*. The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content*. The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

(f) *All other covered medical and other health services furnished by providers*—(1) *Content of certification*. The services were medically necessary,

(2) *Signature*. The certificate must be signed by a physician, nurse practioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing*. The physician, nurse practioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification*. Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, 8853, Mar. 1, 1991; 63 FR 58912, Nov. 2, 1998; 65 FR 18548, Apr. 7, 2000]

§ 424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Medicare Part B pays for CORF services only if a physician certifies, and the facility physician recertifies, the content specified in paragraphs (a) and (b)(2) of this section, as appropriate.

(a) *Certification: Content*. (1) The services were required because the individual needed skilled rehabilitation services;

(2) The services were furnished while the individual was under the care of a physician; and

(3) A written plan of treatment has been established and is reviewed periodically by a physician.

(b) *Recertification*—(1) *Timing*. Recertification is required at least every 60 days, based on review by a facility physician who, when appropriate, consults with the professional personnel who furnish the services.

(2) *Content*. (i) The plan is being followed;

(ii) The patient is making progress in attaining the rehabilitation goals; and,

(iii) The treatment is not having any harmful effect on the patient.

Subpart C—Claims for Payment

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP). Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.32 Basic requirements for all claims.

(a) A claim must meet the following requirements:

(1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions.

(2) A claim for physician services, clinical psychologist services, or clinical social worker services must include appropriate diagnostic coding for those services using ICD–9–CM.

(3) A claim must be signed by the beneficiary or the beneficiary's representative (in accordance with § 424.36(b)).

(4) A claim must be filed within the time limits specified in § 424.44.

(5) All Part B claims for services furnished to SNF residents (whether filed by the SNF or by another entity) must include the SNF's Medicare provider number and appropriate HCPCS coding.

(b) The prescribed forms for claims are the following:

CMS–1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

CMS–1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

CMS–1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

CMS–1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) *Where claims forms are available.* Excluding forms CMS–1450 and CMS–1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The CMS–1450 and CMS–1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from CMS or any Social Security branch or district office, or from Medicare intermediaries or carriers. The CMS–1490S is also available at local Social Security Offices.

(d) *Submission of electronic claims*—(1) *Definitions.* For purposes of this paragraph, the following terms have the following meanings:

(i) *Claim* means a transaction defined at 45 CFR 162.1101(a).

(ii) *Electronic claim* means a claim that is submitted via electronic media. A claim submitted via direct data entry is considered to be an electronic claim.

(iii) *Direct data entry* is defined at 45 CFR 162.103.

(iv) *Electronic media* is defined at 45 CFR 160.103.

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for initial processing, including claims sent to Medicare for the first time for secondary payment purposes. Initial Medicare claim excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider or supplier other than a provider of services.

(vii) *Provider of services* means a provider of services as defined in section 1861(u) of the Act.

(viii) *Small provider of services or small supplier* means—

(A) A provider of services with fewer than 25 full-time equivalent employees; or

(B) A physician, practitioner, facility, or supplier with fewer than 10 full-time equivalent employees.

(2) *Submission of electronic claims required.* Except for claims to which paragraph (d)(3) or (d)(4) of this section applies, an initial Medicare claim may be paid only if submitted as an electronic claim for processing by the Medicare fiscal intermediary or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

(3) *Exceptions to requirement to submit electronic claims.* The requirement of paragraph (d)(2) of this section is waived for any initial Medicare claim when—

(i) There is no method available for the submission of an electronic claim. This exception includes claims submitted by Medicare beneficiaries and

situations in which the standard adopted by the Secretary at 45 FR 162.1102 does not support all of the information necessary for payment of the claim. The Secretary may identify situations coming within this exception in guidance.

(ii) The entity submitting the claim is a small provider of services or small supplier.

(4) *Unusual cases.* The Secretary may waive the requirement of paragraph (d)(2) of this section in unusual cases as the Secretary finds appropriate. Unusual cases are deemed to exist in the following situations:

(i) The submission of dental claims.

(ii) There is a service interruption in the mode of submitting the electronic claim that is outside the control of the entity submitting the claim, for the period of the interruption.

(iii) The entity submitting the claim submits fewer than 10 claims to Medicare per month, on average.

(iv) The entity submitting the claim only furnishes services outside of the U.S. territory.

(v) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

(5) *Effective date.* This paragraph (d) is effective October 16, 2003, and applies to claims submitted on or after October 16, 2003.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39601, July 31, 2001; 68 FR 48813, Aug. 15, 2003; 70 FR 71020, Nov. 25, 2005; 71 FR 48143, Aug. 18, 2006]

§ 424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless CMS instructions waive this requirement.

§ 424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) *Basic rule.* A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a ''report of services'', as specified in paragraphs (b) and (c) of this section.

(b) *Itemized bill from the hospital or supplier.* The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.

(3) The date each service was furnished.

(4) A listing of the services in sufficient detail to permit determination of payment under the fee schedule for physicians' services; for itemized bills from physicians, appropriate diagnostic coding using ICD–9–CM must be used.

(5) The charges for each service.

(c) *Report of services furnished by a supplier.* For Medicare Part B services furnished by a supplier, the beneficiary claims may include the ''Report of Services'' portion of the appropriate claims form, completed by the supplier in accordance with CMS instructions, in lieu of an itemized bill.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 59 FR 26740, May 24, 1994]

§ 424.36 Signature requirements.

(a) *General rule.* The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraph (b), (c), or (d) of this section apply.

(b) *Who may sign when the beneficiary is incapable.* If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on

his or her behalf by one of the following:

(1) The beneficiary's legal guardian.

(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.

(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.

(4) A representative of an agency or institution that did not furnish the services for which payment is claimed but furnished other care, services, or assistance to the beneficiary.

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b) (1), (2), (3), or (4) of this section.

(c) *Who may sign if the beneficiary was not present for the service.* If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* If good cause is shown, CMS may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) *Beneficiary incapable.* When a party specified in § 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—

(1) Describes his or her relationship to the beneficiary; and

(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) *Beneficiary not present for services.* When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment statement under § 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: ''Patient not physically present for test.'')

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.40 Request for payment effective for more than one claim.

(a) *Basic procedure.* A separate request for payment statement prescribed by CMS and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) *Claims filed by a provider or nonparticipating hospital*—(1) *Inpatient services.* A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) *Home health services and outpatient physical therapy or speech pathology services.* A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) *Signed statement in the provider record*—(1) *Services to inpatients.* A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) *Services to outpatients: Providers and renal dialysis facilities.* A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics and Federally qualified health centers.* A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

§ 424.44 Time limits for filing claims.

(a) *Basic limits.* Except as provided in paragraph (b) of this section, the claim must be mailed or delivered to the intermediary or carrier, as appropriate—

(1) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(2) On or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year.

(b) *Extension of filing time because of error or misrepresentation.* (1) The time for filing a claim will be extended if failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

(2) The time will be extended through the last day of the 6th calendar month following the month in which the error or misrepresentation is corrected.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

(d) *Outpatient diabetes self-management training.* CMS makes payment in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date CMS approves the entity to furnish the services under part 410, subpart H of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 65 FR 83153, Dec. 29, 2000]

Subpart D—To Whom Payment Is Ordinarily Made

§ 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

§ 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an

amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

§ 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

§ 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if the hospital does not have in effect an election to claim payment in accordance with subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

§ 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

§ 424.55 Payment to the supplier.

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount approved by the carrier as the basis for determining the Medicare Part B payment (the reasonable charge or the lesser of the fee schedule amount and the actual charge).

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the Medicare approved amount.

(ii) To collect only the difference between the Medicare approved amount and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under § 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount.

(3) Not to charge the beneficiary when Medicare paid for services determined to be ''not reasonable or necessary'' if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

(c) *Exception*. In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

[53 FR 6634, Mar. 2, 1988, as amended at 63 FR 20130, Apr. 23, 1998; 69 FR 66426, Nov. 15, 2004]

§ 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment.* If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier.* Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(c) *Payment to the beneficiary.* Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) *Examples.*

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $325 on which partial payment of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) *Definitions.* As used in this section, the following definitions apply:

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraph (c) of this section.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

(3) CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.

(4) A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)

(5) The supplier has furnished to CMS all information or documentation required to process the claim.

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:

(1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;

(2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The

supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);

(3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;

(4) Fills orders, frabicates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;

(5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in § 414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in § 414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location;

(8) Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section. The supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation;

(9) Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation;

(10) Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month

period preceding the date on which the supplier makes such contact.

(12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) Must comply with the disclosure provisions in § 420.206 of this subchapter;

(18) Must not convey or reassign a supplier number;

(19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);

(20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

(d) *Failure to meet standards.* CMS will revoke a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. (The revocation is effective 15 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.)

(e) *Renewal of billing privileges.* A supplier must renew its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last renewal of privileges.)

[65 FR 60377, Oct. 11, 2000]

EFFECTIVE DATE NOTE: At 71 FR 48409, Aug. 18, 2006, § 424.57 was amended by adding the definitions ''Accredited DMEPOS suppliers,'' ''CMS approved accreditation organization'' and ''Independent accreditation organization'' in paragraph (a) and by adding paragraphs (c)(22) through (25), effective October 2, 2006. For the convenience of the user, the added text is set forth as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS Suppliers and issuance of DMEPOS Supplier billing privileges.

(a) *Definitions.* * * *

Accredited DMEPOS suppliers means suppliers that have been accredited by a recognized independent accreditation organization approved by CMS in accordance with the requirements at § 424.58.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under § 424.58.

* * * * *

Independent accreditation organization means an accreditation organization that accredits a supplier of DMEPOS and other items and services for a specific DMEPOS product category or a full line of DMEPOS product categories.

* * * * *

(c) *Application certification standards.* * * *

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

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§ 424.58 Accreditation.

EFFECTIVE DATE NOTE: At 71 FR 48409, Aug. 18, 2006, § 424.58 was added, effective October 2, 2006.

(a) *Scope and purpose.* This part implements section 1834(a)(20)(B) of the Act, which requires the Secretary to designate and approve one or more independent accreditation organizations for purposes of enforcing the DMEPOS quality standards for suppliers of DMEPOS and other items or services. Section 1847(b)(2)(A)(i) of the Act requires a DMEPOS supplier to meet the DMEPOS quality standards under section 1834(a)(20) of the Act before being awarded a contract.

(b) *Application and reapplication procedures for accreditation organizations.* (1) An independent accreditation organization applying for approval or re-approval of authority to survey suppliers for compliance with the DMEPOS quality standards is required to furnish the following to CMS:

(i) A list of the types of DMEPOS supplies, and a list of products and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements, and dispute resolution processes and policies when there is a negative survey finding or decision.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the accreditation organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the

independent accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(viii) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(ix) Procedures for responding to, and investigating complaints against, accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the National Supplier Clearinghouse, and CMS.

(x) The organization's policies and procedures for notifying CMS of facilities that fail to meet the accreditation organization's requirements.

(xi) A description of all types, categories, and durations of accreditations offered by the organization.

(xii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types and categories of accreditation currently held by each supplier.

(C) The expiration date of each supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiii) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xiv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xv) An agreement that the accreditation organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(2) *Validation survey*. CMS surveys suppliers of DMEPOS and other items and services accredited under this section on a representative sample basis, or in response to substantial allegations of noncompliance, in order to validate the accreditation organization's survey process. When conducted—

(i) On a representative sample basis, the CMS survey may be comprehensive or focus on a specific standard;

(ii) In response to a substantial allegation, CMS surveys for any standard that CMS determines is related to the allegations.

(3) *Discovery of a deficiency*. If CMS discovers that a DMEPOS supplier was not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

(4) *Authorization*. A supplier selected for a validation survey must authorize the—

(i) Validation survey to take place; and

(ii) CMS survey team to monitor the correction of any deficiencies found through the validation survey.

(5) *Refusal to cooperate with survey*. If a supplier selected for a validation survey fails to comply with the requirements specified at paragraph (b)(4) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its supplier billing number revoked.

(6) *Validation survey findings*. If a validation survey results in a finding that the supplier was not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its supplier billing number revoked.

(c) *Ongoing responsibilities of a CMS-approved accreditation organization*. An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS all of the following in written format (either electronic or hard copy) and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to suppliers of DMEPOS and other items and services.

(iv) Information about any supplier of DMEPOS and other items and services against which the CMS-approved accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation.

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 calendar days of a change in CMS requirements, submit to CMS:

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised cross walk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization.

(5) Within 10 calendar days after CMS's notice to a CMS-approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal to all of the CMS-approved accreditation organization's accredited suppliers.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation survey.* CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of a CMS-approved accreditation organization's survey of a supplier, or observe a CMS-approved accreditation organization's onsite survey of a DMEPOS supplier, in order to validate the CMS-approved accreditation organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS or its designated survey team on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between findings by the accreditation organization and findings by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, irrespective of the rate of disparity, there are widespread or systemic problems in an organization's accreditation process such that accreditation by that accreditation organization no longer provides CMS with adequate assurance that suppliers meet or exceed the Medicare requirements.

(3) *Notice of intent to withdraw approval.* CMS provides the organization written notice of its intent to withdraw approval if an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not

meeting the requirements of this section.

(4) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Accreditation by the organization no longer adequately assures that the suppliers of DMEPOS and other items and services are meeting the DMEPOS quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations with respect to application or reapplication procedures.

(e) *Reconsideration.* (1) An accreditation organization dissatisfied with a determination that its accreditation requirements do not provide or do not continue to provide reasonable assurance that the entities accredited by the accreditation organization meet the applicable supplier quality standards is entitled to a reconsideration. CMS reconsiders any determination to deny, remove, or not renew the approval of deeming authority to accreditation organizations if the accreditation organization files a written request for reconsideration by its authorized officials or through its legal representative.

(2) The request must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(3) The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees and the reasons for the disagreement.

(4) A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(5) In response to a request for reconsideration, CMS provides the accreditation organization the opportunity for an informal hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accreditation organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

(6) CMS provides written notice of the time and place of the informal hearing at least 10 calendar days before the scheduled date.

(7) The informal reconsideration hearing is open to CMS and the organization requesting the reconsideration, including authorized representatives; technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and legal counsel.

(i) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(ii) Testimony and other evidence may be accepted by the hearing officer even though it is inadmissible under the rules of court procedures.

(iii) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) Within 45 calendar days of the close of the hearing, the hearing officer presents the findings and recommendations to the accreditation organization that requested the reconsideration.

(9) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer. The hearing officer's decision is final.

Subpart E—To Whom Payment is Made in Special Situations

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

(b) The provisions applicable to payment for services excluded as custodial care or services not reasonable and necessary are set forth in §§ 405.332 through 405.336 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.62 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the

conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.* (1) The beneficiary has received covered services for which he could receive direct payment under § 424.53.

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this section. If none of those relatives survive. Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on a CMS-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must also submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she

must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed ''Report of Services'' section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence.

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 424.64 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope.* This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation.* (1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made.* In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier.* Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a CMS-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services.* If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a CMS-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment.* Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 424.36) to receive the Part B payment for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the

beneficiary, his or her survivors or estate.

(5) Submits any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid for by the entity*. An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for which it will pay and claim reimbursement.

[53 FR 28388, July 28, 1988; 53 FR 40231, Oct. 14, 1988]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis*. This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope*. This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that CMS may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

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

Court of competent jurisdiction means a court that has jurisdiction over the subject matter and the parties before it.

Facility means a hospital or other institution that furnishes health care services to inpatients.

Entity means a person, group, or facility that is enrolled in the Medicare program.

Power of attorney means any written documents by which a principal authorizes an agent to—

(1) Receive, in the agent's name, any payments due the principal;

(2) Negotiate checks payable to the principal; or

(3) Receive, in any other manner, direct payment of amounts due the principal.

[53 FR 6634, Mar. 2, 1988, as amended at 69 FR 66426, Nov. 15, 2004]

§ 424.73 Prohibition of assignment of claims by providers.

(a) *Basic prohibition*. Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a provider to any other person under assignment, or power of attorney, or any other direct payment arrangement.

(b) *Exceptions to the prohibition*—(1) *Payment to a government agency or entity*. Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by the provider.

(2) *Payment under assignment established by court order*. Medicare may pay under an assignment established by, or in accordance with, the order of a court of competent jurisdiction if the assignment meets the conditions set forth in § 424.90.

(3) *Payment to an agent*. Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

(i) The agent receives the payment under an agency agreement with the provider;

(ii) The agent's compensation is not related in any way to the dollar amounts billed or collected;

(iii) The agent's compensation is not dependent upon the actual collection of payment;

(iv) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and

(v) The agent, in receiving the payment, acts only on behalf of the provider.

Payment to an agent will always be made in the name of the provider.

§ 424.74 Termination of provider agreement.

CMS may terminate a provider agreement, in accordance with § 489.53(a)(1) of this chapter, if the provider—

(a) Executes or continues a power of attorney, or enters into or continues any other arrangement, that authorizes or permits payment contrary to the provisions of this subpart; or

(b) Fails to furnish, upon request by CMS or the intermediary, evidence necessary to establish compliance with the requirements of this subpart.

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition*. Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter), or any other applicable Medicare laws, rules, or regulations.

(b) *Exceptions to the basic rule*—(1) *Payment to employer*. Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services.

(2) *Payment to an entity under a contractual arrangement*. Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

(3) *Payment to a government agency or entity*. Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under a reassignment by the supplier.

(4) *Payment under a reassignment established by court order*. Medicare may pay under a reassignment established by, or in accordance with, the order of a court competent jurisdiction, if the reassignment meets the conditions set forth in § 424.90.

(5) *Payment to an agent*. Medicare may pay an agent who furnishes billing and collection services to the supplier, or to the employer, facility, or system specified in paragraphs (b) (1), (2) and (3) of this section, if the conditions of § 424.73(b)(3) for payment to a provider's agent are met by the agent of the supplier or of the employer, facility, or system. Payment to an agent will always be made in the name of the supplier or the employer, facility, or system.

(c) *Rules applicable to an employer or entity*. An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) *Reassignment to an entity under a contractual arrangement: Conditions and limitations*—(1) *Liability of the parties*. An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) *Access to records*. The supplier furnishing the service has unrestricted access to claims submitted by an entity for services provided by that supplier.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 4027, Jan. 27, 1989; 69 FR 66426, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 424.82 Revocation of right to receive assigned benefits.

(a) *Scope*. This section sets forth the conditions and procedures for revocation of the right of a supplier or other party to receive Medicare payments.

(b) *Definition*. As used in this section, *other party* means an employer, facility, or health care delivery system to which Medicare may make payment under § 424.80(b) (1), (2), or (3).

(c) *Basis for revocation*. CMS may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by CMS or the carrier—

(1) Violates the terms of assignment in § 424.55(b).

(2) Continues collection efforts or fails to refund moneys incorrectly collected, in violation of the terms of assignment in § 424.55(b).

(3) Executes or continues in effect a reassignment or power of attorney or any other arrangement that seeks to obtain payment contrary to the provisions of § 424.80; or

(4) Fails to furnish evidence necessary to establish its compliance with the requirements of § 424.80.

(d) *Proposed revocation: Notice and opportunity for review*. If CMS proposes to revoke the right to payment in accordance with paragraph (c) of this section, it will send the supplier or other party a written notice that—

(1) States the reasons for the proposed revocation; and

(2) Provides an opportunity for the supplier or other party to submit written argument and evidence against the proposed revocation. CMS usually allows 15 days from the date on the notice, but may extend or reduce the time as circumstances require.

(e) *Actual revocation: Timing, notice, and opportunity for hearing*—(1) *Timing*. CMS determines whether to revoke after considering any written argument or evidence submitted by the supplier or other party or, if none is submitted, at the expiration of the period specified in the notice of proposed revocation.

(2) *Notice and opportunity for hearing*. The notice of revocation specifies—

(i) The reasons for the revocation;

(ii) That the revocation is effective as of the date on the notice;

(iii) That the supplier or other party may, within 60 days from the date on the notice (or a longer period if the notice so specifies), request an administrative hearing and may be represented by counsel or other qualified representative.

(iv) That the carrier will withhold payment on any claims submitted by the supplier or other party until the period for requesting a hearing expires or, if a hearing is requested, until the hearing officer issues a decision;

(v) That if the hearing decision reverses the revocation, the carrier will pay the supplier's or other party's claims; and

(vi) That if a hearing is not requested or the hearing decision upholds the revocation, payment will be made to the beneficiary or to another person or agency authorized to receive payment on his or her behalf.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.83 Hearings on revocation of right to receive assigned benefits.

If the supplier or other party requests a hearing under § 424.82(e)(2)—

(a) The hearing is conducted—

(1) By a CMS hearing official who was not involved in the decision to revoke; and

(2) In accordance with the procedures set forth in §§ 405.824 through 405.833 (but excepting § 405.832(d)) and 405.860 through 405.872 of this chapter. In applying those procedures, ''CMS'' is substituted for ''carrier''; and ''hearing official'', for ''hearing officer''.

(b) As soon as practicable after the close of the hearing, the official who conducted it issues a hearing decision that—

(1) Is based on all the evidence presented at the hearing and included in the hearing record; and

(2) Contains findings of fact and a statement of reasons.

§ 424.84 Final determination on revocation of right to receive assigned benefits.

(a) *Basis of final determination*—(1) *Final determination without a hearing*. If the supplier or other party does not request a hearing, CMS's revocation determination becomes final at the end of the period specified in the notice of revocation.

(2) *Final determination following a hearing.* If there is a hearing, the hearing decision constitutes CMS's final determination.

(b) *Notice of final determination.* CMS sends the supplier or other party a written notice of the final determination and, if there was a hearing, includes a copy of the hearing decision.

(c) *Application of the final determination*—(1) A final determination not to revoke is the final administrative decision by CMS on the matter.

(2) A final determination to revoke remains in effect until CMS finds that the reason for the revocation has been removed and that there is reasonable assurance that it will not recur.

(d) *Effect of revocation when supplier or other party has a financial interest in another entity.* Revocation of the party's right to accept assignment also applies to any corporation, partnership, or other entity in which the party, directly or indirectly, has or acquires all or all but a nominal part of the financial interest.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.86 Prohibition of assignment of claims by beneficiaries.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a beneficiary under § 424.53 to any other person under assignment, power of attorney, or any other direct payment arrangement.

(b) *Exceptions*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by a beneficiary (or by the beneficiary's legal guardian or representative payee).

(2) *Payment under an assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, a court order if the assignment meets the conditions set forth in § 424.90.

§ 424.90 Court ordered assignments: Conditions and limitations.

(a) *Conditions for acceptance.* An assignment or reassignment established by or in accordance with a court order is effective for Medicare payments only if—

(1) Someone files a certified copy of the court order and of the executed assignment or reassignment (if it was necessary to execute one) with the intermediary or carrier responsible for processing the claim; and

(2) The assignment or reassignment—

(i) Applies to all Medicare benefits payable to a particular person or entity during a specified or indefinite time period; or

(ii) Specifies a particular amount of money, payable to a particular person or entity by a particular intermediary or carrier.

(b) *Retention of authority to reduce interim payments to providers.* A court-ordered assignment does not preclude the intermediary or carrier from reducing interim payments, as set forth in § 413.64(i) of this chapter, if the provider or assignee is in imminent danger of insolvency or bankruptcy.

(c) *Liability of the parties.* The party that receives payments under a court-ordered assignment or reassignment that meets the conditions of paragraph (a) of this section and the party that would have received payment if the court order had not been issued are jointly and severally responsible for any Medicare overpayment to the former.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

§ 424.100 Scope.

This subpart sets forth procedures and criteria that are followed in determining whether Medicare will pay for emergency services furnished by a hospital that is located in the United States and does not have in effect a provider agreement, that is, an agreement to participate in Medicare.

§ 424.101 Definitions.

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

Emergency services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of

the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Hospital means a facility that—

(1) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(2) Is not primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care, as described in section 1861(j)(1)(A) of the Act;

(3) Provides 24-hour nursing service in accordance with section 1861(e)(5) of the Act; and

(4) Is licensed, or is approved as meeting the standards for licensing, by the State or local licensing agency.

Reasonable charges means customary charges insofar as they are reasonable.

§ 424.102 Situations that do not constitute an emergency.

Without additional evidence of a threat to life or health, the following situations do not in themselves indicate a need for emergency services:

(a) Lack of care at home.

(b) Lack of transportation to a participating hospital.

(c) Death of the patient in the hospital.

§ 424.103 Conditions for payment for emergency services.

Medicare pays for emergency services furnished to a beneficiary by a nonparticipating hospital or under arrangements made by such a hospital if the conditions of this section are met.

(a) *General requirements.* (1) The services are of the type that Medicare would pay for if they were furnished by a participating hospital.

(2) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with § 424.104.

(3) The need for emergency services arose while the beneficiary was not an inpatient in a hospital.

(4) In the case of inpatient hospital services, the services are furnished during a period in which the beneficiary could not be safely discharged or transferred to a participating hospital or other institution.

(5) The determination that the hospital was the most accessible hospital available and equipped to furnish the services is made in accordance with § 424.106.

(b) *Medical information requirements.* A physician (or, if appropriate, the hospital) submits medical information that—

(1) Describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital;

(2) Establishes that all the conditions in paragraph (a) of this section are met; and

(3) Indicates when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.104 Election to claim payment for emergency services furnished during a calendar year.

(a) *Terms of the election.* The hospital agrees to the following:

(1) To comply with the provisions of subpart C of part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(2) To comply with the provisions of subpart D of part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of a beneficiary.

(3) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(b) *Filing of election statement.* An election statement must be filed on a form designated by CMS, signed by an authorized official of the hospital, and either received by CMS, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If CMS accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which CMS determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to qualify.* If CMS has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, CMS will not accept another election statement from that hospital until CMS finds that—

(1) The reason for its failure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

§ 424.106 Criteria for determining whether the hospital was the most accessible.

(a) *Basic requirement.* (1) The hospital must be the most accessible one available and equipped to furnish the services.

(2) CMS determines accessibility based on the factors specified in paragraphs (b) and (c) of this section and the conditions set forth in paragraph (d) of this section.

(b) *Factors that are considered.* CMS considers the following factors in determining whether a nonparticipating hospital in a rural area meets the accessibility requirements:

(1) The relative distances of participating and nonparticipating hospitals in the area.

(2) The transportation facilities available to these hospitals.

(3) The quality of the roads to each hospital.

(4) The availability of beds at each hospital.

(5) Any other factors that bear on whether or not the services could be provided sooner in the nonparticipating hospitals than in a participating hospital in the general area.

In urban and suburban areas where both participating and nonparticipating hospitals are similarly available, CMS presumes that the services could have been provided in a participating hospital unless clear and convincing evidence shows that there was a medical or practical need to use the nonparticipating hospital.

(c) *Factors that are not considered.* CMS gives no consideration to the following factors in determining whether the nonparticipating hospital was the most accessible hospital:

(1) The personal preference of the beneficiary, the physician, or members of the family.

(2) The fact that the attending physician did not have staff privileges in a participating hospital which was available and the most accessible to the beneficiary.

(3) The location of previous medical records.

(d) *Conditions under which the accessibility requirement is met.* If a beneficiary must be taken to a hospital immediately for required diagnosis and treatment, the nonparticipating hospital meets the accessibility requirement if—

(1) It was the nearest hospital to the point where the emergency occurred, it was medically equipped to handle the type of emergency, and it was the most accessible, on the basis of the factors specified in paragraph (b) of this section; or

(2) There was a closer participating hospital equipped to handle the emergency, but the participating hospital did not have a bed available or would not accept the individual.

§ 424.108 Payment to a hospital.

(a) *Conditions for payment.* Medicare pays the hospital for emergency services if the hospital—

(1) Has in effect a statement of election to claim payment for all covered emergency services furnished during a calendar year, in accordance with § 424.104;

(2) Claims payment in accordance with § 424.32; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Subsequent claims.* If the hospital files subsequent claims because the initial claim did not include all the services furnished, those claims must include physicians' statements that—

(1) Contain sufficient information to clearly establish that, when the additional services were furnished, the emergency still existed; and

(2) Indicate when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.109 Payment to the beneficiary.

Medicare pays the beneficiary for emergency services if the following conditions are met:

(a) The hospital does not have in effect an election to claim payment.

(b) The beneficiary, or someone on his or her behalf, submits—

(1) A claim that meets the requirements of § 424.32;

(2) An itemized hospital bill; and

(3) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

§ 424.120 Scope.

This subpart sets forth the conditions for payment for services furnished in a foreign country.

§ 424.121 Scope of payments.

Subject to the conditions set forth in this subpart—

(a) Medicare Part A pays, in the amounts specified in § 413.74 of this chapter, for emergency and nonemergency inpatient hospital services furnished by a foreign hospital.

(b) Medicare Part B pays for certain physicians' services and ambulance services furnished in connection with covered inpatient care in a foreign hospital, as specified in § 424.124.

(c) All other services furnished outside the United States are excluded from Medicare coverage, as specified in § 411.9 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.122 Conditions for payment for emergency inpatient hospital services.

Medicare Part A pays for emergency inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) At the time of the emergency that required the inpatient hospital services, the beneficiary was—

(1) In the United States; or

(2) In Canada traveling between Alaska and another State without unreasonable delay and by the most direct route.

(b) The foreign hospital was closer to, or more accessible from, the site of the emergency than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The conditions for payment for emergency services set forth in § 424.103 are met.

(d) The hospital is a hospital as defined in § 424.101, and is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located.

(e) The determination of whether the hospital was more accessible is made in accordance with § 424.106.

§ 424.123 Conditions for payment for nonemergency inpatient services furnished by a hospital closer to the individual's residence.

Medicare Part A pays for inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) The beneficiary is a resident of the United States.

(b) The foreign hospital is closer or more accessible to the beneficiary's residence than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The foreign hospital is—

(1) A hospital as defined in § 424.101 and, it is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located; and

(2) Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or accredited or approved by a program of the country where it is located under standards the CMS finds to be essentially equivalent to those of the JCAHO.

(d) The services are covered services that Medicare would pay for if they

were furnished by a participating hospital.

[53 FR 6634, Mar. 2, 1988, as amended at 71 FR 48143, Aug. 18, 2006]

§ 424.124 Conditions for payment for physician services and ambulance services.

(a) *Basic rules.* Medicare Part B pays for physician and ambulance services if—

(1) They are furnished—

(i) To an individual who is entitled to Part B benefits; and

(ii) In connection with covered inpatient hospital services; and

(2) They meet the conditions set forth in paragraphs (b) and (c) of this section.

(b) *Physician services.* (1) The physician services are services covered under Medicare Part B and are furnished—

(i) In the hospital, during a period of covered inpatient services; or

(ii) Outside the hospital, on the day of admission and for the same condition that required inpatient admission; and

(2) The physician is legally authorized to practice in the country where he or she furnishes the services.

(c) *Ambulance services.* The ambulance services are—

(1) Necessary because the use of other means of transportation is contraindicated by the beneficiary's condition; and

(2) Furnished by an ambulance that meets the definition in § 410.41 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 64 FR 3649, Jan. 25, 1999]

§ 424.126 Payment to the hospital.

(a) *Conditions for payment.* Medicare pays the hospital if it—

(1) Has in effect an election that—

(i) Meets the requirements set forth in § 424.104; and

(ii) Reflects the hospital's intent to claim for all covered services furnished during a calendar year.

(2) Claims payment in accordance with §§ 424.32 and 413.74 of this chapter; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount of payment.* Payment is made (in accordance with § 413.74 of this chapter) on the basis of 100 percent of the hospital's customary charges, subject to the applicable deductible and coinsurance provisions set forth elsewhere in this chapter.

§ 424.127 Payment to the beneficiary.

(a) *Conditions for payment of inpatient hospital services.* Medicare pays the beneficiary if—

(1) The hospital does not have in effect an election to claim payment; and

(2) The beneficiary, or someone on his or her behalf, submits—

(i) A claim in accordance with § 424.32;

(ii) An itemized hospital bill; and

(iii) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount payable for inpatient hospital services.* The amount payable to the beneficiary is determined in accordance with § 424.109(b).

(c) *Conditions for payment for Part B services.* Medicare pays the beneficiary for physicians' services and ambulance services as specified in § 424.121, if an itemized bill for the services is submitted by the beneficiary or someone on his or her behalf and the conditions of § 424.126(a) (2) and (3) are met.

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subparts I–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *U.S. Government checks*—(1) *Responsibility.* The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of CMS.

(2) *Action by CMS.* CMS forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department

disbursing center responsible for issuing checks.

(3) *Action by the Treasury Department.* The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR parts 235, 240, and 245).

(b) *Intermediary and carrier benefit checks.* Checks issued by intermediaries and carriers are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Replacement procedures are carried out in accordance with § 424.352 under applicable State law (including any Federal banking laws or regulations that may affect the relevant State proceedings).

[58 FR 65129, Dec. 13, 1993]

§ 424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed or paid on forged endorsements.

(a) When an intermediary or carrier is notified by a payee that a check has been lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsement, the intermediary or carrier contacts the commercial bank on whose paper the check was drawn and determines whether the check has been negotiated.

(b) If the check has been negotiated—

(1) The intermediary or carrier provides the payee with a copy of the check and other pertinent information (such as a claim form, affidavit or questionnaire to be completed by the payee) required to pursue his or her claim in accordance with State law and commercial banking regulations.

(2) To pursue the claim, the payee must examine the check and certify (by completing the claim form, questionnaire or affidavit) that the endorsement is not the payee's.

(3) The claim form and other pertinent information is sent to the intermediary or carrier for review and processing of the claim.

(4) The intermediary or carrier reviews the payee's claim. If the intermediary or carrier determines that the claim appears to be valid, it forwards the claim and a copy of the check to the issuing bank. The intermediary or carrier takes further action to recover the proceeds of the check in accordance with the State law and regulations.

(5) Once the intermediary or carrier recovers the proceeds of the initial check, the intermediary or carrier issues a replacement check to the payee.

(6) If the bank of first deposit refuses to settle on the check for good cause, the payee must pursue the claim on his or her own and the intermediary or carrier will not reissue the check to the payee.

(c) If the check has not been negotiated—

(1) The intermediary or carrier arranges with the bank to stop payment on the check; and

(2) Except as provided in paragraph (d), the intermediary or carrier reissues the check to the payee.

(d) No check may be reissued under (c)(2) unless the claim for a replacement check is received by the intermediary or carrier no later than 1 year from the date of issuance of the original check, unless State law (including any applicable Federal banking laws or regulations that may affect the relevant State proceeding) provides a longer period which will control.

[58 FR 65130, Dec. 13, 1993]

Subparts N–O [Reserved]

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

SOURCE: 71 FR 20776, Apr. 21, 2006, unless otherwise noted.

§ 424.500 Scope.

The provisions of this subpart contain the requirements for enrollment, periodic resubmission and certification of enrollment information for revalidation, and timely reporting of updates and changes to enrollment information. These requirements apply to all providers and suppliers except for physicians and practitioners who have entered into a private contract with a beneficiary as described in part 405, subpart D of this chapter. Providers and suppliers must meet and maintain

these enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare covered services or supplies.

§ 424.502 Definitions.

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

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and be granted Medicare billing privileges.

Authorized official means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

Deactivate means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

Delegated official means an individual who is delegated by the ''Authorized Official,'' the authority to report changes and updates to the enrollment record. The delegated official must be an individual with ownership or control interest in, or be a W–2 managing employee of the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries.

Enroll/Enrollment means the process that Medicare uses to establish eligibility to submit claims for Medicare covered services and supplies. The process includes—

(1) Identification of a provider or supplier;

(2) Validation of the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries;

(3) Identification and confirmation of the provider or supplier's practice location(s) and owner(s); and

(4) Granting the provider or supplier Medicare billing privileges.

Enrollment application means a CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by OMB.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier.

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of the provider or supplier as defined in sections 1124 and 1124A(A) of the Act.

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information, or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier's billing privileges are terminated.

§ 424.505 Basic enrollment requirement.

To receive payment for covered Medicare items or services from either Medicare (in the case of an assigned claim) or a Medicare beneficiary (in the case of an unassigned claim), a provider or supplier must be enrolled in the Medicare program. Once enrolled, the provider or supplier receives billing privileges and is issued a valid billing number effective for the date a claim was submitted for an item that was

furnished or a service that was rendered. (See 45 CFR Part 162 for information on the National Provider Identifier and its use as the Medicare billing number.)

§ 424.510 Requirements for enrolling in the Medicare program.

(a) Providers and suppliers must submit enrollment information on the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process, including, if applicable, a State survey and certification or accreditation process, CMS enrolls the provider or supplier into the Medicare program. To be enrolled, a provider or supplier must meet enrollment requirements specified in paragraph (c) of this section.

(b) The effective dates for reimbursement are specified in § 489.13 of this chapter for providers and suppliers requiring State survey or certification or accreditation, § 424.5 and § 424.44 for non-surveyed or certified/accredited suppliers, and § 424.57 and section 1834(j)(1)(A) of the Act for DMEPOS suppliers.

(c) The effective date for reimbursement for providers and suppliers seeking accreditation from a CMS-approved accreditation organization as specified in § 489.13(d).

(d) Providers and suppliers must meet the following enrollment requirements:

(1) *Submittal of the enrollment application.* A provider or supplier must submit a complete enrollment application and supporting documentation to the designated Medicare fee-for-service contractor.

(2) *Content of the enrollment application.* Each submitted enrollment application must include the following:

(i) Complete, accurate, and truthful responses to all information requested within each section as applicable to the provider or supplier type.

(ii) Submission of all documentation required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to uniquely identify the provider or supplier. This documentation may include, but is not limited to, proof of the legal business name, practice location, social security number (SSN), tax identification number (TIN), National Provider Identifier (NPI), if issued, and owners of the business.

(iii) Submission of all documentation, including all applicable Federal and State licensure and regulatory requirements that apply to the specific provider or supplier type that relate to providing health care services, required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to establish the provider or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program.

(3) *Signature(s) required on the enrollment application.* The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in this chapter. This person must also have an ownership or control interest in the provider or supplier, as that term is defined in section 1124(a)(3) of the Act, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.

(i) *Requirements.* The signature requirements specified in paragraphs (d)(3)(i)(A) through (C) of this section outline who must sign the enrollment application for an enrolling provider or supplier. In the case of—

(A) An individual practitioner, the applying practitioner.

(B) A sole proprietorship, the applying sole proprietor.

(C) A corporation, partnership, group, limited liability company, or other organization (hereafter referred to collectively in this section as an organization), an authorized official, as defined in § 424.502. When an authorized official signs the certification statement on behalf of an organization, the signed statement is considered legally binding upon the organization.

(ii) *Delegation of authority*. The original enrollment application submitted for an organization's initial enrollment and all subsequent enrollment applications submitted for periodic revalidation of the organization's enrollment data (as required to maintain enrollment in the Medicare program) must be signed by an authorized official. Any updates or changes reported outside of the initial enrollment or periodic revalidation process may be signed by a delegated official(s) of the organization. The delegated official's signature binds the organization both legally and financially, as if the signature was that of the authorized official. Before the delegation of authority is established, the only acceptable signature on the enrollment application to report updates or changes to the enrollment information is that of the authorized official currently on file with Medicare. Once the delegation of authority is established, the only acceptable signatures on correspondence to report updates or changes to the enrollment information are those of the authorized official and the person(s) to whom this authority is delegated in accordance with the requirements described in this section. Individual practitioners and sole proprietors cannot delegate signature authority when submitting an enrollment application for any reason. All enrollment applications submitted by individual practitioners and sole proprietors must be signed by the enrolling or enrolled individual. Each delegation of authority to a delegated official must—

(A) Be assigned by the authorized official currently on file with CMS;

(B) Be submitted to CMS using the appropriate enrollment application or CMS established electronic enrollment process;

(C) Include the title and SSN of each person delegated authority to update or change the organization's enrollment information;

(D) Be an individual that has an ownership or control interest in the organization or is a W–2 managing employee as defined in section 1126(b) of the Act; and

(E) Be signed by the authorized official and the delegated official(s) of the organization.

(4) *Verification of information*. The information submitted by the provider or supplier on the applicable enrollment application must be such that CMS can validate it for accuracy at the time of submission.

(5) *Completion of any applicable State surveys, certifications, and provider agreements*. The providers or suppliers who are mandated under the provision in part 488 of this chapter to be surveyed or certified by the State survey and certification agency, and to also enter into and sign a provider agreement as outlined in part 489 of this chapter, must also meet those requirements as part of the process to obtain Medicare billing privileges.

(6) *Ability to furnish Medicare covered items or services*. The provider or supplier must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges.

(7) *Additional requirements*. Providers and suppliers must meet the provisions of § 424.520 regarding additional compliance and reporting requirements.

(8) *On-site review*. CMS reserves the right, when deemed necessary, to perform on-site inspections of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(i) *Medicare Part A providers*. CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) *Medicare Part B suppliers*. CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

§424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.

To maintain Medicare billing privileges, a provider or supplier (other than a DMEPOS supplier) must resubmit and recertify the accuracy of its enrollment information every 5 years. All providers and suppliers currently billing the Medicare program or initially enrolling in the Medicare program are required to complete the applicable enrollment application. The provider or supplier then enters a 5-year revalidation cycle once a completed enrollment application is submitted and validated. (Ambulance service providers must continue to resubmit enrollment information in accordance with §410.41(c)(2) of this chapter and DMEPOS suppliers must continue to renew enrollment in accordance with §424.57(e)). The requirements for the resubmission, recertification and reverification of enrollment information include the following:

(a) *Submission of the enrollment application and supporting documentation.* The provider or supplier must meet the submission, content, signature, verification, operational, inspection, and other requirements outlined in §424.510.

(1) CMS contacts each provider or supplier directly when it is time to revalidate their enrollment information.

(2) A provider or supplier must submit to CMS the applicable enrollment application with complete and accurate information and applicable supporting documentation within 60 calendar days of our notification to resubmit and certify to the accuracy of its enrollment information.

(b) *Completion of any applicable State surveys, certifications and provider agreements.* A new certification and a new provider agreement are not required for the purpose of resubmission and certification for revalidation of enrollment information. Providers and suppliers must continue to meet the requirements of parts 488 and 489 of this chapter, or any currently established supplier agreement, if applicable.

(c) *On-site inspections.* CMS reserves the right to perform on-site inspections of a provider or supplier to verify that the information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B suppliers.* CMS determines, upon review that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(d) *Off Cycle revalidations.* (1) CMS reserves the right to perform off cycle revalidations in addition to the regular 5-year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by CMS. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits.

(2) CMS reserve the right to adjust the routine 5-year revalidation schedule if we determine that revalidation should occur on a more frequent basis due to complaints or evidence we receive indicating noncompliance with the statute or regulations by specific provider or supplier types. The schedule may also be on a less frequent basis if we determine that the integrity of and compliance with the statute and regulations by specific provider or supplier types indicates that less frequent

validation is justified. If a change occurs, CMS notifies all affected providers and suppliers at least 90 days in advance of implementing the change.

(3) CMS revalidates enrollment information for ambulance service suppliers in accordance with § 410.41(c)(2) of this chapter (Requirements for ambulance suppliers), and DMEPOS suppliers renews enrollment in accordance with § 424.57(e) (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

§ 424.520 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

(a) *Certifying compliance.* CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:

(1) Compliance with title XVIII of the Act and applicable Medicare regulations.

(2) Compliance with Federal and State licensure, certification and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

(3) Not employing or contracting with individuals or entities—

(i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A (a)(6) of the Act; or

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.

(b) *Reporting requirements.* Following enrollment, a provider or supplier must report to CMS any changes to the information furnished on the enrollment application and furnish supporting documentation within 90 calendar days of the change, with the exception of DMEPOS suppliers which are required to report changes of information within 30 days as specified in § 424.57(c)(2), or a change of ownership or control of the provider or supplier that must also be reported within 30 calendar days. Failure to do so may result in the deactivation or revocation of the provider or supplier's Medicare billing privileges.

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider or supplier's enrollment application for the following reasons:

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 60 calendar days from the date of the contractor request for the missing information.

(2) The provider or supplier fails to furnish all required supporting documentation within 60 calendar days of submitting the enrollment application.

(b) *Extension of 60-day period.* CMS, at its discretion, may choose to extend the 60-day period if CMS determines that the provider or supplier is actively working with CMS to resolve any outstanding issues.

(c) *Resubmission after rejection.* To enroll in Medicare and obtain Medicare billing privileges after notification of a rejected enrollment application, the provider or supplier must complete and submit a new enrollment application and submit all supporting documentation for CMS review and approval.

(d) *Additional review.* Enrollment applications that are rejected are not afforded appeal rights.

§ 424.530 Denial of enrollment.

(a) *Reasons for denial.* CMS may deny a provider's or supplier's enrollment in the Medicare program for the following reasons:

(1) *Compliance.* The provider or supplier at any time is found not to be in compliance with the Medicare enrollment requirements described in this section or on the applicable enrollment application to the type of provider or supplier enrolling, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

(2) *Provider or supplier conduct.* A provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application, in accordance with section 1862(e)(1) of the Act, is—

(i) Excluded from the Medicare, Medicaid and any other Federal health care programs, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(3) *Felonies.* If within the 10 years preceding enrollment or revalidation of enrollment, the provider, supplier, or any owner of the provider or supplier, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. CMS considers the severity of the underlying offense.

(i) Offenses include—(A) Felony crimes against persons, such as murder, rape, or assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct).

(D) Any felonies outlined in section 1128 of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) *False or misleading information.* The provider or supplier has submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.)

(5) *On-site review.* Upon on-site review or other reliable evidence, we determine that the provider or supplier is not operational, or is not meeting Medicare enrollment requirements to furnish Medicare covered items or services. Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(b) *Resubmission after denial.* A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred if the denial:

(1) Was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

(2) Was appealed, the provider or supplier may reapply after notification that the determination was upheld.

(c) *Reversal of denial.* If the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare reimbursable services, the denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

(d) *Additional review.* When a provider or supplier is denied enrollment in Medicare, CMS automatically reviews

all other related Medicare enrollment files that the denied provider or supplier has an association with (for example, as an owner or managing employee) to determine if the denial warrants an adverse action of the associated Medicare provider or supplier.

(e) *Effective date of denial*. Denial becomes effective within 30 days of the initial denial notification.

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) *Reasons for revocation*. CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:

(1) *Noncompliance*. The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section or in the enrollment application applicable for its provider or supplier type and has not submitted a plan of corrective action as outlined in part 488 of this chapter. All providers and suppliers are granted an opportunity to correct the deficient compliance requirement prior to a final determination to revoke billing privileges.

(i) CMS may request additional documentation from the provider or supplier to determine compliance if adverse information is received or otherwise found concerning the provider or supplier.

(ii) Requested additional documentation must be submitted within 60 calendar days of request.

(2) *Provider or supplier conduct*. The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is—

(i) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(3) *Felonies*. The provider, supplier, or any owner of the provider or supplier, within the 10 years preceding enrollment or revalidation of enrollment, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Denials based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

(4) *False or misleading information*. The provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

(5) *On-site review*. CMS determines, upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients.

Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

(6) *Inadequate reverification information*. The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 60 calendar days of the provider or supplier's notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(7) *Misuse of billing number*. The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in § 424.80 or a change of ownership as outlined in § 489.18 of this chapter.

(b) *Effect of revocation on provider agreements*. When a provider's or supplier's billing privilege is revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

(c) *Re-enrollment after revocation*. If a provider or supplier seeks to re-establish enrollment in the Medicare program after notification that its billing privileges is revoked (either after the appeals process is exhausted or in place of the appeals process), the following conditions apply:

(1) The provider or supplier must re-enroll in the Medicare program through the completion and submission of a new applicable enrollment application and applicable documentation, as a new provider or supplier, for validation by CMS.

(2) Providers must be resurveyed and recertified by the State survey agency as a new provider and must establish a new provider agreement with CMS's Regional Office.

(d) *Reversal of revocation*. If the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, or an authorized or delegated official; or a medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

(e) *Additional review*. When a provider or supplier is revoked from the Medicare program, CMS automatically reviews all other related Medicare enrollment files that the revoked provider or supplier has an association with (for example, as an owner or managing employee) to determine if the revocation warrants an adverse action of the associated Medicare provider or supplier.

(f) *Effective date of revocation*. Revocation becomes effective within 30 days of the initial revocation notification.

§ 424.540 Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation*. CMS may deactivate a provider or supplier's Medicare billing privileges for the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in § 424.520(b) and § 424.550(b).

(b) *Reactivation of billing privileges*. (1) When deactivated for any reason other than nonsubmission of a claim, the provider or supplier must complete and

submit a new enrollment application to reactivate its Medicare billing privileges or, when deemed appropriate, at a minimum, recertify that the enrollment information currently on file with Medicare is correct.

(2) Providers and suppliers deactivated for nonsubmission of a claim are required to recertify that the enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim.

(3) Reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(c) *Effect of deactivation.* Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any conditions of participation.

§ 424.545 Provider and supplier appeal rights.

(a) A provider or supplier that is denied enrollment in the Medicare program or whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 405, subpart H, for suppliers, or part 498, subpart A for providers, of this chapter, which set forth the appeals process for providers and suppliers. When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement. Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

(b) A provider or supplier whose billing privileges are deactivated may file a rebuttal in accordance with § 405.374 of this chapter.

(c) The provider or supplier must be able to demonstrate that it meets the enrollment requirements and it must be able to make available any documents and records that support the provisions of this regulation and the Medicare enrollment application if requested by CMS or its agents.

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

(a) *General rule.* A provider or supplier is prohibited from selling its Medicare billing number or privileges to any individual or entity, or allowing another individual or entity to use its Medicare billing number.

(b) *Change of ownership.* In the case of a provider undergoing a change of ownership in accordance with part 489, subpart A of this chapter, the current owner and the prospective new owner must complete and submit enrollment applications before completion of the change of ownership. If the current owner fails to complete and submit an enrollment application to report the change, the current owner may be sanctioned or penalized, even after the date of ownership change, in accordance with § 424.520, § 424.540, and § 489.53 of this chapter. If the prospective new owner fails to submit a new enrollment application containing information concerning the new owner within 30 days of the change of ownership, CMS may deactivate the Medicare billing number. If an incomplete enrollment application is submitted, CMS may also deactivate the Medicare billing number based upon material omissions on the submitted enrollment application, or based on preliminary information received or determined by CMS that makes CMS question whether the new owner is ultimately granted a final transference of the provider agreement.

(c) *Suppliers not covered by part 489 of this chapter.* For those suppliers not covered by part 489 of this chapter, any change in the ownership or control of that supplier must be reported on the enrollment application within 30 days of the change as noted in § 424.540(a)(2). Generally, a change of ownership that

also changes the tax identification number requires the completion and submission of a new enrollment application from the new owner.

§ 424.555 Payment liability.

(a) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by suppliers of durable medical equipment, prosthetics, orthotics, and other supplies unless the supplier obtains (and renews, as set forth in section 1834(j) of the Act) Medicare billing privileges.

(b) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

(c) If any provider or supplier furnishes an otherwise Medicare covered item or service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier. The provider or supplier may also be criminally liable for pursuing payments that may not be made by reason of paragraph (b) of this section, in accordance with section 1128B(a)(3) of the Act.

PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS

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Subpart A—General Provisions

§ 426.100 Basis and scope.

(a) *Basis*. This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope*. This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

§ 426.110 Definitions.

For the purposes of this part, the following definitions apply:

Aggrieved party means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

Board means the Departmental Appeals Board.

Clinical and scientific experts mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

Deemed NCD means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no

national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

New evidence means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

Party means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

Proprietary data and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.65.

(2) The party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked proprietary is not considered proprietary.

Reasonableness standard means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Supplemental LCD/NCD record is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

Treating physician means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

§ 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

§ 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

Subpart B [Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

§ 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

§ 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set

forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

§ 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

§ 426. 325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;

(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M+C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

§ 426.330 Burden of proof.

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

§ 426.340 Procedures for review of new evidence.

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(2) Sets a reasonable timeframe—

(i) For LCDs, of not more than 90 days, by which the contractor completes the reconsideration; or

(ii) For NCDs, in compliance with the timeframes specified in section 1862(l) of the Act, by which CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) Does not meet—

(i) For LCDs, the 90-day reconsideration timeframe; or

(ii) For NCDs, the reconsideration timeframe specified by the Board, in compliance with section 1862(l) of the Act.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

[68 FR 63716, Nov. 7, 2003, as amended at 70 FR 70335, Nov. 21, 2005; 71 FR 9461, Feb. 24, 2006]

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp*.

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary

data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in any way with the ALJ on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the ALJ assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for the contractor to produce the LCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to the applicable contractor and CMS.

(3) Requires CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation.* If a review is pending regarding a particular LCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the ALJ consolidates the complaints and conducts a consolidated LCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same LCD or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the ALJ's decision.

(2) *Decision to consolidate complaints.* If an ALJ decides to consolidate complaints, the ALJ does the following:

(i) Provides notification that the LCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If an ALJ decides not to consolidate complaints, the ALJ conducts separate LCD reviews for each complaint.

[68 FR 63716, Nov. 7, 2003; 68 FR 65346, Nov. 19, 2003]

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340,

within such deadline as the ALJ may set.

§ 426.418 LCD record furnished to aggrieved party.

(a) *Elements of a contractor's LCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the contractor's LCD record consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD being challenged.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the LCD record not furnished to the aggrieved party.* The LCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

(a) Documents included in § 426.418(a).

(b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

(1) Retiring an LCD or LCD provision that is under review; or

(2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

(1) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has retired the LCD or revised the LCD to completely remove the provision in question, the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provision(s).

(2) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has revised the LCD provision in question but has not removed it altogether, the ALJ must continue the review based on the revised LCD. In this case, the contractor must send a copy of the supplemental record to the ALJ and all parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD.* An aggrieved party who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an LCD.*

To withdraw a complaint regarding an LCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the ALJ (*see* § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party*. If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints*. If the ALJ receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews*. If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid*. Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response*. The contractor has 30 days after receiving the aggrieved party's statement to submit a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation*. (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with § 426.432 and § 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps*. To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provison(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps*. The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard*. In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

§ 426.432 Discovery.

(a) *General rule*. If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order*. Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order*. The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available*. A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents*. For the purpose of this section, the term ''documents'' includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available*. Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data*. The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification*. The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena*. A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena*. A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena*. Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown*. The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted*. If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a pre-hearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (*See* § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (*See* § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

(a) A written decision, including a description of appeal rights.

(b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings*. An ALJ's decision must include one of the following:

(1) A determination that the provision of the LCD is valid under the reasonableness standard.

(2) A determination that the provision of the LCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.

(4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information*. An ALJ's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS or its contractors to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.

(f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record furnished to the public*. Except as provided in paragraph (b) of this section, the ALJ's LCD review record consists of any document or material that

the ALJ compiled or considered during the LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M+C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M+C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M+C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1) of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review*—(1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

(1) A statement upholding the part(s) of the ALJ decision named in the appeal.

(2) A statement reversing the part(s) of the ALJ decision named in the appeal.

(3) A statement modifying the part(s) of the ALJ decision named in the appeal.

(4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

(b) *Other information.* A Board decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the review of the ALJ decision.

(3) A summary of the ALJ's decision.

(4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.

(f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(7) The Board's decision.

(b) *Elements of the Board's LCD appeal record furnished to the court under seal.* The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M+C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M+C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

(1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last known address, the contractor, and CMS of the Board's remand decision; and

(2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

(1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) Email address, if applicable.

(2) *If the beneficiary has a representative,* the representative's indetifying information must include the following:

(i) Name.

(ii) Address.

(iii) Telephone number.

(iv) E-mail address (if any)

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

(i) Title of NCD being challenged.

(ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written

complaint with the Board if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on its own motion, concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceeding in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in this regulation.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an NCD review for failure to comply with a Board order or procedural request without good cause.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

(3) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

(7) Conduct an NCD review of any policy that is not an NCD, as defined in § 400.202 of this chapter.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his or her representative;

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae*.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

(14) Find invalid applicable Federal statutes, regulations, or rulings.

(15) Enter a decision specifying terms to be included in an NCD.

§ 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.510 Docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint*. The Board does the following upon receiving a complaint regarding an NCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular NCD; or

(ii) Related to a pending NCD review.

(3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint*. The Board determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint*. (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing

again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for condideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

(i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;

(ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;

(iii) Participation does not result in substantial delay; and

(iv) The petition for participation meets the criteria in § 426.513.

§ 426.513 Participation as *amicus curiae.*

(a) *Petition for participation.* Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

(1) The petitioner's interest in the hearing;

(2) Who will represent the petitioner; and

(3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation.* An *amicus curiae* is not a party to the hearing but may participate by—

(1) Submitting a written statement of position to the Board before the beginning of the hearing;

(2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in § 426.510(f)(3) and § 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

(1) Submitted with the initial complaint;

(2) Submitted with an amended complaint;

(3) Produced during discovery;

(4) Produced when the Board consults with scientific and clinical experts; and

(5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

(1) The NCD being challenged.

(2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (*see* § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

§ 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies

the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the NCD ends the review process.

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an NCD record has been supplemented, except that discovery and the taking of evidence is not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps*. The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

(1) Confine the NCD review to the provision(s) of the NCD raised in the aggrieved party's complaint.

(2) Conduct a hearing unless the matter can be decided on the written record.

(3) Close the NCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps*. The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard*. In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

§ 426.532 Discovery.

(a) *General rule*. If the Board orders discovery, the Board must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order*. Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The Board granting of a protective order*. The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Will unduly delay the proceeding.

(c) *Types of discovery available*. A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific NCD.

(d) *Types of documents*. For the purpose of this section, the term documents includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document.

(e) *Types of discovery not available*. Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information or proprietary data*. The Board must not under any circumstances order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification*. The Board notifies all parties in writing when the discovery period will be closed.

§ 426.535 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by witnesses or documents and state whether those facts could be established by evidence other than by the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

(2) Include the docket number and title of the NCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the Board a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.540 Evidence.

(a) Except as provided in this part, the Board is not bound by the Federal Rules of Evidence. However, the Board may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

(c) The Board may accept privileged information or proprietary data, but must maintain it under seal.

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

§ 426.544 Dismissals for cause.

(a) The Board may, at the request of any party, or on its own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the prehearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the Board without cause shown.

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (*See* § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (*See* § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

§ 426.545 Witness fees.

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.547 Issuance, notification, and posting of a Board's decision.

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's decision.

(a) *Findings.* The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information.* The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal,

the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

§ 426.555 Prohibited provisions of the Board's decision.

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

§ 426.557 Optional provisions of the Board's decision.

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

§ 426.560 Effect of the Board's decision.

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M+C organization, or other Medicare managed care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an M+C organization, or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M+C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief.* Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

§ 426.562 Notice of the Board's decision.

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.563 Future new or revised or reconsidered NCDs.

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as

additional evidence) than what the Board evaluated.

§ 426.565 Board's role in making an LCD or NCD review record available.

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

§ 426.566 Board decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

§ 426.587 Record for appeal of a Board NCD decision.

(a) *Elements of the Board's NCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered during an NCD review, including, but not limited to, the following:

(1) The NCD complaint.

(2) The NCD and NCD record.

(3) The supplemental NCD record, if applicable.

(4) Transcripts of record.

(5) Any other evidence relevant gathered under § 426.540.

(6) The Board's decision.

(b) *Documents excluded from the NCD review record furnished to the court.* The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.